# 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): July 13, 2015

# **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.)

19820 North Creek Parkway Bothell, Washington (Address of Principal Executive Offices)

98011 (Zip Code)

Registrant's telephone number, including area code: (425) 686-1500

N/A (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 8.01 Other Events.

On July 13, 2015, OncoGenex Pharmaceuticals, Inc. (the "Company") announced its Phase 3 ENSPIRIT trial evaluating custirsen in the treatment of advanced or metastatic non-small cell lung cancer is continuing as planned per the recommendation of an Independent Data Monitoring Committee. This decision was based upon completion of the second and final planned interim futility analysis.

A copy of the Company's press release is filed as Exhibit 99.1 to this Current Report on Form8-K.

#### Item 9.01 Financial Statements and Exhibits.

Description

(d) Exhibits

Exhibit	

99.1 Press Release issued by OncoGenex Pharmaceuticals, Inc. dated July 13, 2015

## 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: July 13, 2015

/s/ John Bencich John Bencich Chief Financial Officer Description Press Release issued by OncoGenex Pharmaceuticals, Inc. dated July 13, 2015

4

#### OncoGenex Announces Custirsen Phase 3 "ENSPIRIT" Trial Continues Following Completion of Final Futility Survival Analysis

#### Rigorous Criteria Met, Trial in NSCLC Patients Proceeds as Planned

BOTHELL, Wash. and VANCOUVER, British Columbia, July 13, 2015 /CNW/ — OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) announced today that its Phase 3 ENSPIRIT trial evaluating custirsen in the treatment of advanced or metastatic non-small cell lung cancer (NSCLC) is continuing as planned per the recommendation of an Independent Data Monitoring Committee (IDMC). This decision was based upon completion of the second and final planned interim futility analysis.

"Passing this important milestone strengthens our belief in custirsen and its potential to provide clinical benefit in this patient population with advanced disease and limited treatment options," said Scott Cormack, President and CEO of OncoGenex. "While the ENSPIRIT results remain blinded, this news is particularly exciting following the protocol amendment, which set a high bar for continuing the trial."

Two interim analyses were originally planned to evaluate whether to stop the trial for futility. OncoGenex filed an amendment with the U.S. Food and Drug Administration amending the statistical design and analysis plan that included a more rigorous and expedient evaluation of the potential survival benefit associated with custirsen in NSCLC. Based on current enrollment, initial ENSPIRIT results could be available in the second half of 2016.

"While advancements have been made for NSCLC patients with specific mutations and biomarkers, treatment resistance continues to be a challenge and combination chemotherapy remains the therapeutic backbone for the majority of patients with lung cancer," said Cindy Jacobs, PhD, MD, Chief Medical Officer and Executive Vice President of OncoGenex. "As we continue to gain a better understanding of the patients most likely to benefit from custirsen, we look forward to the results of our two Phase 3 trials in the lung and prostate cancer settings."

Recent findings from a retrospective analysis of data from the Phase 3 SYNERGY trial showed a benefit with custirsen therapy when added to first-line docetaxel chemotherapy in men with metastatic castrate-resistant prostate cancer (CRPC) who had a poor prognosis. The analysis showed that over 40 percent of men in the trial had at least 2 of the 5 common risk factors for poor prognosis. In these men, the analysis found a 27 percent lower risk of death when custirsen was used in combination with first-line docetaxel compared to docetaxel alone. Subject to finalizing the pending protocol amendment, timing for the final analysis of the poor prognosis subpopulation in the Phase 3 AFFINITY trial is projected to occur by the end of 2015, while the final analysis for the intent-to-treat population is projected to occur in the second half of 2016.

#### About the Phase 3 ENSPIRIT Trial

The Phase 3 ENSPIRIT trial is an international, randomized, open-label trial designed to evaluate custirsen for the treatment of advanced or metastatic NSCLC in 700 patients who have progressed after initial chemotherapy treatment, with a hypothesized hazard ratio (HR) of 0.75 and a critical HR of 0.84. The trial will investigate if combining custirsen with docetaxel, a standard second-line NSCLC chemotherapy, has the potential to improve survival outcomes compared to docetaxel alone in these patients. The trial is expected to enroll patients at approximately 50 sites globally. OncoGenex has filed an amendment with the FDA and regulatory agencies in all countries where it is the sponsor. The

company will file in two remaining countries as it becomes the sponsor. For more information on the ENSPIRIT trial, please visit <a href="http://clinicaltrials.gov/ct2/show/NCT01630733">http://clinicaltrials.gov/ct2/show/NCT01630733</a>.

#### About Custirsen

Custirsen is an experimental drug that is designed to block the production of the protein clusterin, which may play a fundamental role in cancer cell survival and treatment resistance. Clusterin is upregulated in tumor cells in response to treatment interventions such as chemotherapy, hormone ablation and radiation therapy and has been found to be overexpressed in a number of cancers, including prostate, lung, breast and bladder. Increased clusterin production has been linked to faster rates of cancer progression, treatment resistance and shorter survival duration. By inhibiting clusterin, custirsen is designed to alter tumor dynamics, slowing tumor growth and resistance to partner treatments, so that the benefits of therapy, including survival, may be extended.

Custirsen has Fast Track designation by the U.S. Food and Drug Administration for NSCLC and metastatic CRPC.

#### 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. Custirsen is currently in Phase 3 clinical development as a treatment in men with metastatic castrate-resistant prostate cancer and in patients with advanced, unresectable non-small cell lung cancer. Apatorsen is in Phase 2 clinical development and OGX-225 is currently in pre-clinical development. More information is available at <a href="https://twitter.com/OncoGenex\_IR">www.OncoGenex\_com</a> and at the company's Twitter account: <a href="https://twitter.com/OncoGenex\_IR">https://twitter.com/OncoGenex\_IR</a>.

#### **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 regarding timing for clinical trial milestones and statements regarding the potential benefits and potential development of our product candidates. 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 bability to risks and uncertainties, including, among others, 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 we are unable to raise on acceptable terms the capital needed to complete our clinical trials, the risk that our product candidates do not demonstrate the hypothesized or expected benefits 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.