

# ONCOGENEX PHARMACEUTICALS, INC.

## **FORM 8-K** (Current report filing)

Filed 08/16/16 for the Period Ending 08/16/16

Address	19820 NORTH CREEK PARKWAY SUITE 201 BOTHELL, WA 98011
Telephone	425-686-1500
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Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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

**Date of Report (Date of earliest event reported): August 16, 2016**

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**ONCOGENEX PHARMACEUTICALS, INC.**  
(Exact name of registrant as specified in its charter)

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**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.)

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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))
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**Item 8.01 Other Events.**

On August 16, 2016, OncoGenex Pharmaceuticals, Inc. (Company) announced results from the final analysis of AFFINITY, the Phase 3 trial of custirsen in men with metastatic castrate-resistant prostate cancer (CRPC) whose disease has progressed after treatment with docetaxel. The trial did not meet the primary endpoint of demonstrating a statistically significant improvement in overall survival for patients treated with custirsen in combination with cabazitaxel/prednisone compared to cabazitaxel/prednisone alone. The median overall survival for the custirsen arm was 14.2 months versus 13.4 months for the control arm with a hazard ratio of 0.946. Safety data were consistent with those observed in previous trials of custirsen in CRPC.

As a result of these data and previous custirsen findings, the Company plans to initiate discussions with the U.S. Food and Drug Administration (FDA) to evaluate options related to an early analysis of the Phase 3 ENSPIRIT trial investigating custirsen in combination with docetaxel as second-line chemotherapy in patients with non-small cell lung cancer. In the Company's proposal to the FDA, the trial's hypothesized hazard ratio of 0.75 and the p-value for the final survival analysis will remain the same, with a minimal reduction in power and a small change in the critical hazard ratio from 0.84 to 0.83. The ENSPIRIT trial is over 90% enrolled and more than 80% of the events have occurred. The Company believes this is sufficient to assess the potential effect of custirsen in non-small cell lung cancer.

The Company has also engaged MTS Health Partners, LP as its advisor to assist with the exploration of strategic alternatives.

A copy of the Company's press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued by OncoGenex Pharmaceuticals, Inc. dated August 16, 2016

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**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.

Date: August 16, 2016

ONCOGENEX PHARMACEUTICALS, INC.

/s/ John Bencich

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John Bencich  
Chief Financial Officer

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**EXHIBIT INDEX**

Exhibit Number

Description

99.1 Press Release issued by OncoGenex Pharmaceuticals, Inc. dated August 16, 2016

**OncoGenex Announces Results from the Phase 3 AFFINITY Trial of Custirsen in Men with Metastatic Castrate-Resistant Prostate Cancer**

*Conference Call on Tuesday, August 16, 2016 at 7:30 a.m. EDT*

**BOTHELL Wash. And VANCOUVER, British Columbia, August 16, 2016** –OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) announced today results from the final analysis of AFFINITY, the Phase 3 trial of custirsen in men with metastatic castrate-resistant prostate cancer (CRPC) whose disease has progressed after treatment with docetaxel. The trial did not meet the primary endpoint of demonstrating a statistically significant improvement in overall survival for patients treated with custirsen in combination with cabazitaxel/prednisone compared to cabazitaxel/prednisone alone.

The adverse events were consistent with those observed in previous trials of custirsen in metastatic CRPC. The final data will be submitted as a late-breaking abstract to the European Society for Medical Oncology (ESMO) Annual Congress 2016.

“We are obviously disappointed that custirsen was unable to demonstrate a survival benefit in prostate cancer. We would like to thank the patients who participated in the AFFINITY trial and their caregivers, as well as the investigators and their teams for their commitment to improving cancer care for patients who are in desperate need of new treatment options,” said Scott Cormack, President and CEO of OncoGenex.

As a result of these data and previous custirsen findings, OncoGenex plans to initiate discussions with the U.S. Food and Drug Administration (FDA) to evaluate options related to an early analysis of the Phase 3 ENSPIRIT trial investigating custirsen in combination with docetaxel as second-line chemotherapy in patients with non-small cell lung cancer (NSCLC).

“Given that the ENSPIRIT trial has nearly completed enrollment and we believe there are likely a sufficient number of events to determine the effect of custirsen in NSCLC, we are eager to expedite the final data analysis, which would allow us to conserve resources and fully understand the value of the asset as we evaluate our alternatives to maximize shareholder value,” said Cormack.

OncoGenex has engaged MTS Health Partners, LP as its advisor to assist with the exploration of strategic alternatives.

**Conference Call Details**

OncoGenex will host a conference call at 7:30 a.m. Eastern Time today, Tuesday, August 16, 2016, to discuss today’s news. A live event will be available on the Investor Relations section of the OncoGenex website at [www.OncoGenex.com](http://www.OncoGenex.com). Alternatively, visitors may access the live conference call by dialing (877) 606-1416 (U.S. & Canada) or (707) 287-9313 (International). A webcast replay will be available approximately two hours after the call and will be archived on [www.OncoGenex.com](http://www.OncoGenex.com) for 90 days.

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### **About the AFFINITY Trial**

The Phase 3 AFFINITY trial was an international, randomized, open-label study designed to evaluate whether custirsen, when combined with cabazitaxel, could improve survival outcomes for patients with metastatic CRPC whose disease has progressed after treatment with docetaxel.

Patients received cabazitaxel in combination with weekly custirsen or cabazitaxel alone, and treatment continued until disease progression, unacceptable toxicity or completion of 10 cycles. The AFFINITY trial enrolled 634 men with metastatic CRPC at 95 sites throughout North America, Europe, Russia and Australia. For more information on the AFFINITY trial, please visit [ClinicalTrials.gov \(NCT01578655\)](https://clinicaltrials.gov/ct2/show/study/NCT01578655).

### **About 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. The trial is investigating 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. ENSPIRIT is expected to enroll patients at approximately 50 sites globally. For more information on the ENSPIRIT trial, please visit [ClinicalTrials.gov \(NCT01630733\)](https://clinicaltrials.gov/ct2/show/study/NCT01630733).

### **About Custirsen**

Custirsen is a highly specific clusterin inhibitor designed to improve survival in patients with advanced cancer by disabling a fundamental cellular repair mechanism used by tumor cells. Custirsen binds to clusterin mRNA to block the production of clusterin protein and has enhanced the tumor cell destructive effects of multiple anti-cancer therapies across a variety of tumor models. By inhibiting clusterin, custirsen is designed to alter tumor dynamics by slowing tumor growth and inhibiting tumor resistance to partner treatments, so that the benefits of therapy, including survival, may be extended.

### **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 patients with advanced, unresectable NSCLC. Apatorsen is in Phase 2 clinical development and OGX-225 is currently in pre-clinical development. More information is available at [www.OncoGenex.com](http://www.OncoGenex.com) and at the company's Twitter account: [https://twitter.com/OncoGenex\\_IR](https://twitter.com/OncoGenex_IR).

### **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 the potential benefits and development of our product candidates, potential modifications to clinical development plans and business strategies. 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 risks and uncertainties include, among others, the risk that our product candidates do not demonstrate the hypothesized or expected benefits, the risk that our proposed modifications to clinical development activities are not agreed on by the FDA or do not result in the intended benefits, the risk that we cannot achieve our business strategies, the risk that new developments in the rapidly evolving cancer therapy landscape require changes in our clinical trial

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plans or limit the potential benefits of our product 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.