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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): December 1, 2015**

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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 December 1, 2015, OncoGenex Pharmaceuticals, Inc. (the “Company”) announced that its Phase 3 AFFINITY trial is continuing based on the pre-planned interim futility analysis of the intent-to-treat population. In the final safety review, no new safety issues were identified by the Data Monitoring Committee. Separately, an analysis of a prospectively defined subpopulation of men in the AFFINITY trial who had multiple poor prognostic risk factors revealed that the combination of custirsen and cabazitaxel did not meet the rigorous criteria required to demonstrate an improvement in overall survival (hypothesized hazard ratio  $\leq 0.69$ , one-sided p value  $\leq 0.015$ ). Both the Data Monitoring Committee and the Company remain blinded to all analyses, and final results are expected in the second half of 2016, depending on timing of the event-driven final analysis.

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 December 1, 2015

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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: December 1, 2015

ONCOGENEX PHARMACEUTICALS, INC.

/s/ John Bencich

John Bencich  
Chief Financial Officer

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**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued by OncoGenex Pharmaceuticals, Inc. dated December 1, 2015

**OncoGenex Announces Phase 3 AFFINITY Trial with Custirsen Continues Following Interim Analyses***Final Results Expected in Second Half of 2016*

**BOTHELL Wash. and VANCOUVER, British Columbia, December 1, 2015**— Following an independent Data Monitoring Committee (DMC) meeting, OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) announced today that its Phase 3 AFFINITY trial is continuing based on the pre-planned interim futility analysis of the intent-to-treat (ITT) population. In the final safety review, no new safety issues were identified by the DMC. Both the DMC and OncoGenex remain blinded to all analyses and final results are expected in the second half of 2016, depending on timing of the event-driven final analysis.

AFFINITY is designed to evaluate whether the investigational treatment custirsen, when combined with cabazitaxel, improves survival in men with metastatic castrate-resistant prostate cancer (CRPC) whose disease has progressed following treatment with docetaxel. The final AFFINITY efficacy analysis is designed to show a survival benefit with 85 percent power based on a hypothesized hazard ratio of 0.75.

Separately, an analysis of a prospectively defined subpopulation of men in the AFFINITY trial who had multiple poor prognostic risk factors revealed that the combination of custirsen and cabazitaxel did not meet the rigorous criteria required to demonstrate an improvement in overall survival (hypothesized hazard ratio  $\leq 0.69$ , one-sided p value  $\leq 0.015$ ). This subpopulation was identified and evaluated based on a retrospective analysis of a previous Phase 3 trial of men with similar clinical features who experienced a reduced risk of death when custirsen was added to chemotherapy. In addition, OncoGenex pursued the evaluation of this subpopulation, independent of the ITT, in order to obtain an expedited approval for these patients with more aggressive disease.

“The overall survival endpoint of the entire AFFINITY trial remains clinically meaningful and its target hazard ratio of 0.75 is attainable with sufficient power to demonstrate a benefit from custirsen for men who are battling advanced prostate cancer,” said Scott Cormack, President and CEO of OncoGenex. “We designed the AFFINITY trial so that the final analysis of the ITT population could stand alone as a Phase 3 submission to regulatory agencies regardless of the outcome of the smaller subgroup.”

As part of the Phase 3 development program for custirsen, OncoGenex continues with its ENSPIRIT clinical trial in patients with non-small cell lung cancer (NSCLC). The trial is evaluating the ability of custirsen, in combination with docetaxel treatment as second-line chemotherapy, to extend survival in patients with NSCLC. Based on current enrollment projections, ENSPIRIT results could be available in the second half of 2016.

The company also expects several additional clinical trial milestones in 2016 with its other lead product candidate apatorsen, which include:

- Announcing results for the primary progression-free survival endpoint of the Phase 2 Spruce™ trial in advanced NSCLC
- Announcing results of the Phase 2 Borealis-2™ trial in patients with metastatic bladder cancer
- Completing enrollment in the Phase 2 Pacific™ trial in metastatic CRPC

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## Conference Call Details

OncoGenex will host a conference call at 4:30 p.m. Eastern Time today, Tuesday, December 1, 2015, 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.

## About the AFFINITY Trial

The Phase 3 AFFINITY trial is an international, randomized, open-label study designed to evaluate whether custirsen, when combined with cabazitaxel, has the potential to improve survival outcomes for metastatic CRPC patients whose disease has progressed following treatment with docetaxel. The two primary objectives of the study are overall survival in the ITT population and overall survival in men who had two or more pre-defined clinical prognostic features of metastatic CRPC.

Both groups 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 630 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](http://ClinicalTrials.gov) (NCT01578655).

## About prostate cancer

More than 220,000 new cases of prostate cancer are diagnosed each year and prostate cancer is the second leading cause of cancer-related deaths in the United States among men. Approximately 50% of patients with clinically localized prostate cancer are estimated to progress despite initial treatment.

Metastatic CRPC often spreads to the bone, making it difficult for some men to perform even the simplest daily activities, like standing up and walking around. Prostate cancer deaths are usually the result of metastatic CRPC, which has a median survival of less than two years.

## 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 men with metastatic CRPC and 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).

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**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 potential development of our product candidates and statements regarding our clinical trial plans and timelines. 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 our product candidates do not demonstrate the hypothesized or expected benefits, 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 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.

Spruce™, Borealis-2™ and Pacific™ are registered trademarks of OncoGenex Pharmaceuticals, Inc.

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