# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 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): December 19, 2009

# **ONCOGENEX PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware

033-80623 (Commission File Number) 95-4343413 (IRS Employer Identification No.)

(State or other jurisdiction of incorporation)

1522 217th Place S.E. Bothell, Washington 98021

(Address of Principal Executive Offices) (Zip Code)

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

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 1.01. Entry into a Material Definitive Agreement.

On December 20, 2009, OncoGenex Pharmaceuticals, Inc., through its wholly-owned subsidiary, OncoGenex Technologies Inc. (the "Company"), entered into a Collaboration and License Agreement (the "Collaboration Agreement") with Teva Pharmaceutical Industries Ltd. ("Teva") for the development and global commercialization of OGX-011 (and related compounds), a pharmaceutical compound designed to inhibit the production of clusterin, a protein associated with cancer treatment resistance. Under the Collaboration Agreement, Teva will pay the Company up-front payments in the aggregate amount of \$50 million, will pay up to \$370 million upon the achievement of developmental and commercial milestones and will pay royalties at percentage rates ranging from the mid-teens to mid-twenties on net sales. The Company is required to contribute \$30 million in direct and indirect costs towards the clinical development plan. On the same date, OncoGenex Pharmaceuticals, Inc. (the "Registrant") and Teva also entered into a stock purchase agreement (the "Stock Purchase Agreement") pursuant to which Teva will make an additional \$10 million equity investment in the Registrant at a 20% premium to a thirty-day average closing price.

In connection with the Collaboration Agreement and pursuant to the terms of agreements between the Company and Isis Pharmaceuticals, Inc. ("Isis") relating to OGX-011, the Company will pay Isis \$10 million. The Company will also pay approximately \$517,000 to the University of British Columbia ("UBC") pursuant to the terms of their license agreement relating to OGX-011 dated November 2001, as amended (the "UBC License Agreement"). The Teva up-front payment and equity investment, net of the Isis and UBC payments and prior to expenses, are anticipated to result in proceeds to the Registrant and its subsidiary of approximately \$49.5 million.

#### Agreements with Teva

Pursuant to the Collaboration Agreement, the Company and Teva agreed to collaborate in the development and global commercialization of OGX-011 (and possibly related compounds targeting Clusterin). Teva will receive the exclusive worldwide right and license to develop and commercialize products containing OGX-011 and related compounds (the "Licensed Products"). The Company has an option to co-promote any Licensed Product in the United States and Canada.

Under the Collaboration Agreement, Teva will pay the Company up-front payments in the aggregate amount of \$50 million. The Company is also eligible to receive up to an aggregate of \$370 million in additional payments from Teva upon reaching certain regulatory and sales milestones specified in the Collaboration Agreement. Pursuant to the terms of the third-party agreements, the Company anticipates that it would be required to pay third-parties 31% of any milestone payments that are not based on a percentage of net sales of the Licensed Product.

Teva will pay the Company tiered royalties on sales of the Licensed Product. The percentage rates of such royalties will range from the mid-teens to the mid-twenties, depending on aggregate annual net sales of the Licensed Product. In addition to the ongoing royalties, Teva will pay the Company additional one-time sales threshold royalties if certain aggregate net sales are achieved. Pursuant to the terms of third-party agreements, the Company anticipates it will pay royalties to third-parties of 4.88% to 8.00% of net sales, unless the Company's royalties are adjusted for competition from generic compounds, in which case royalties to third-parties will also be subject to adjustment on a country-by-country basis. Certain third-party royalties are tiered based on the royalty rate received by the Company. Minimum royalty rates payable by the Company assume certain third-party royalties are not paid at the time that the Licensed Product is marketed due to the expiration of patents held by such third-parties. Maximum royalty rates assume all third-party royalty rates currently in effect at the time the Licensed Product is marketed.

Teva and the Company have developed a clinical development plan (the "CDP") under which three Phase III clinical trials will be initiated:

- a Phase III clinical trial of the Licensed Product for second-line castrate resistant prostate cancer, expected to initiate in 2010. The Company will have primary responsibility for the oversight of this trial;
  - a Phase III clinical trial of the Licensed Product for first-line castrate resistant prostate cancer, expected to initiate in 2010; and

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a Phase III clinical trial of the Licensed Product for first-line non-small cell lung cancer, expected to initiate by early 2011.

Teva will be responsible for conducting any other studies and development work necessary to obtain required regulatory approvals. The Company may assume some of these activities if assigned by the Joint Steering Committee. Teva will be responsible for all such costs. The Joint Steering Committee will oversee the development and regulatory approval of any Licensed Product.

Funding responsibilities for the CDP will be allocated as follows:

- the Company will be required to spend \$30 million in direct and indirect development costs, such contribution to be funded by the upfront payment provided by Teva as an advanced reimbursement for development expenses of the Company (the "Company Development Expenses") and
- Teva will fund all other expenses under the CDP.

In addition to the development costs noted above, Teva is also responsible for all costs relating to product commercialization including costs incurred in relation to the Company's co-promotion option, except for start-up costs in advance of commercialization.

The Collaboration Agreement will remain in effect, on a country-by-country basis, until the expiration of the obligation of Teva to pay royalties on sales of the Licensed Product in such country (or earlier termination under its terms). Commencing after the completion of all three Phase III clinical trials set forth in the CDP, or upon early termination due to a material adverse change in the Company's patent rights related to OGX-011 or safety issues or "futility" as defined in the Collaboration Agreement, Teva may terminate the Collaboration Agreement in its sole discretion upon three months' notice if notice is given prior to regulatory approval of a Licensed Product and upon six months' notice if notice is given after such regulatory approval. If Teva terminates the Collaboration for any reasons other than an adverse change in OGX-011 patent rights, safety issues or "futility" determination as previously described, it will remain responsible for paying for any remaining costs of all three Phase III clinical trials, except for Company Development Expenses. Either party may terminate the Collaboration Agreement is terminated other than for an uncured material breach by Teva, the Company will pay Teva a royalty on sales of Licensed Products. The percentage rates of such royalties (which are in the single digits) depend if termination occurs prior to the first regulatory approval in the United States or a primary European Market or after one of these approvals. These royalties would expire on a country-by-country basis on the earlier of ten years after the first commercial sale of a Licensed Products regulator or certain thresholds related to generic competition.

In the event of a change of control of the Company:

within 90 days of the change of control, Teva may terminate the joint steering committee in its sole discretion, terminate theo-promotion option in its sole discretion if not then exercised by the Company or if exercised but not yet executed by the Company, or terminate the co-promotion option if in its commercially reasonable opinion co-promotion with the Company's successor would be materially detrimental to Teva's interests.

Pursuant to the terms of the Stock Purchase Agreement, Teva will also make a \$10 million equity investment in the Registrant through its purchase of 267,531 shares of the Registrant's common stock (the "Shares") at a price of \$37.38 per Share.

#### Amendment to Isis and UBC License Agreements

To facilitate the execution and performance of the Collaboration Agreement, the Company and Isis agreed to amend the Isis License Agreement and the Company and UBC agreed to amend the UBC License Agreement, in each case, effective December 19 and December 20, 2009, respectively.

The amendment to the Isis License Agreement provides, among other things, that if the Company is the subject of a change of control with a third party, where the surviving company immediately following such change of control has the right to develop and sell the product, then (i) a milestone payment of \$20 million will be due and payable to Isis 21 days following the first commercial sale of the product in the United States; and (ii) unless such surviving entity had previously sublicensed the product and a royalty rate payable to Isis by the Company has been established, the applicable royalty rate payable to Isis will thereafter be the maximum amount payable under the Isis License Agreement. Any non-royalty milestone amounts previously paid will be credited toward the \$20 million milestone if not already paid. As a result of the \$10 million milestone payment of change of control discussed above is a maximum of \$10 million. As the Company has now licensed the product to Teva and established a royalty rate payable to Isis, no royalty rate adjustments would apply if Teva acquires the Company and is the surviving company.

The amendments to the UBC License Agreement are deemed not material to the Company.

#### **Other Disclosures; Forward-Looking Statements**

The foregoing summary does not purport to be a complete description of the terms of the Collaboration Agreement, the Stock Purchase Agreement or the amendments to the Isis License Agreement and the UBC License Agreement, and is qualified in its entirety by reference to such agreements, copies of which are expected to be filed as an exhibits to the Registrant's Annual Report on Form 10-K for the year ending December 31, 2009. Portions of such agreements may be omitted in accordance with a request for confidential treatment that the Registrant expects to submit to the Securities and Exchange Commission. A copy of the press release announcing the transactions with Teva is attached hereto as Exhibit 99.1 and is hereby incorporated by this reference.

This report includes forward-looking statements regarding the development, activity, therapeutic potential and safety of OGX-011 in the treatment of cancer. Any statement describing the Registrant's or the Company's goals, expectations, financial or other projections, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such products. The Registrant's forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Although the Registrant's forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by the Registrant. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning the Registrant's programs are described in additional detail in its annual report on Form 10-K for the year ended December 31, 2008, which is on file with the SEC.

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

Exhibit No.	Description
99.1	Press Release dated December 21, 2009.

### SIGNATURES

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

> ONCOGENEX PHARMACEUTICALS, INC. (Registrant)

Date: December 21, 2009

By: /s/ Stephen Anderson Name: Stephen Anderson Title: Chief Financial Officer and Secretary



Teva Contacts: Elana Holzman Teva Pharmaceutical Industries Ltd. 972 (3) 926-7554 Kevin Mannix Teva North America (215) 591-8912

For Immediate Release



#### **OncoGenex Contacts:**

Scott Cormack President & CEO (604) 736-3678 Jason Spark, Porter Novelli Media and Investor Relations for OncoGenex (619) 849-6005

#### Teva Expands Innovative Pipeline with License Agreement to Develop and Commercialize OncoGenex' Late Stage Innovative Treatment for Multiple Oncology Indications

— Phase III trials of OGX-011 in first- and second-line advanced prostate cancer and non-small cell lung cancer, expected to begin in 2010 and early 2011 —

- Significantly strengthens Teva's oncology offerings with novel therapeutic designed to target resistance to cancer treatments -

JERUSALEM, ISRAEL, BOTHELL, WA and VANCOUVER, CANADA, December 21, 2009 — Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) announced today that they have entered into a global license and collaboration agreement to develop and commercialize OGX-011, as well as an agreement to purchase shares in OncoGenex. OGX-011 is a Phase III cancer therapy designed to inhibit cancer treatment resistance. OGX-011 is expected to be used as adjunct therapy to enhance the effectiveness of chemotherapy and has shown promising results when added to currently available chemotherapies in several tumor types addressing a significant unmet medical need.

The agreement will further enhance Teva's oncology offerings and strengthen its global branded product pipeline with a promising product candidate entering three Phase III trials involving large patient populations. Teva and OncoGenex will collaborate on a global Phase III clinical program, with two Phase III clinical trials expected to be initiated in 2010: a Phase III Study for Second-line Chemotherapy in Men with Metastatic Castrate Resistant Prostate Cancer (CRPC) and a Phase III Study in First-Line Chemotherapy for Metastatic CRPC. An additional Phase III Study in First-Line Treatment of Advanced, Unresectable Non-Small Cell Lung Cancer (NSCLC) is intended to be initiated by early 2011.

Under the terms of the collaboration and share purchase agreements, Teva will provide OncoGenex with a \$60 million initial cash payment, which includes a \$10 million equity investment in OncoGenex common stock at a price of \$37.38 per share, upfront payment of \$20 million and prepayment of \$30 million for OncoGenex's contribution to the development costs of OGX-011. OncoGenex will be eligible to receive up to \$370 million in additional cash payments upon achievement of various milestones, including regulatory milestones and sales targets. In addition, OncoGenex will receive tiered royalties on sales of the product with the royalty percentage ranging from the mid-teens to the mid-twenties, depending upon the amount of net sales. Teva is responsible for all commercialization and development expenses. OncoGenex retains an option to co-promote OGX-011 in the U.S. and Canada.

"We see OGX-011 as a key component of our branded oncology medicines franchise, expanding our pipeline of existing oncology therapeutics and broadening the future available therapies made by Teva for oncology patients and care providers," said **Moshe Manor**, **Teva's Group VP**, **Global Branded Products**. "OGX-011 is supported by compelling data demonstrating the drug's ability to benefit patients on top of several currently available chemotherapies in a number of oncology indications. In addition to prostate cancer, we are particularly enthusiastic about the therapeutic activity seen in the Phase II clinical trial in lung cancer."

"Together with Teva, we have forged a strong path moving forward for the development of OGX-011 that commits significant cash investment to a broadened Phase III clinical development plan that includes first- and second-line castrate resistant prostate cancer as well as non-small cell lung cancer," said **Scott Cormack, President and CEO of OncoGenex**. "The agreement provides us with capital resources for the development of OGX-011 through completion of the Phase III clinical trials and into product commercialization. We're creating a solid foundation to maximize the broad potential of OGX-011 and bring this important treatment option to cancer patients."

#### OncoGenex to Host Investor Conference Call Monday, December 21, 2009 at 8:30 a.m. ET

OncoGenex management will host a conference call at 8:30 a.m. Eastern Time Monday, December 21, 2009. A live webcast will be available through the Events and Presentations Web page found in the Investor Relations section of the OncoGenex Web site at <u>www.ir.oncogenex.com</u>. Alternatively, you may access the live conference call by dialing 888-747-4649 (U.S. & Canada) or 913-312-1507 (International). A webcast replay will be available approximately two hours after the call and will be archived at the same Web location for 90 days.

#### About Prostate Cancer

The National Cancer Institute estimates that in 2009, approximately 192,280 new cases of prostate cancer will be diagnosed in the U.S. As the most frequently diagnosed cancer among men, one in six men will be diagnosed with prostate cancer during their lifetime. It is estimated that in 2009 in the U.S., 27,360 deaths will result due to the disease.

#### About NSCLC Cancer

The National Cancer Institute estimates that in 2009, approximately 219,440 new cases of lung cancer will be diagnosed in the U.S. Non-small cell lung cancer accounts for approximately 85% of all lung cancer cases. With 159,390 deaths estimated for 2009 in the U.S., lung cancer remains responsible for the most cancer-related deaths in both men and women, representing 28% of all cancer-related deaths.

#### About OGX-011

OGX-011 is designed to inhibit the production of clusterin, a protein that is associated with cancer treatment resistance, and has completed Phase II clinical trials in prostate, lung and breast cancer. OGX-011 has received Fast Track designation from the FDA for the treatment of progressive metastatic prostate cancer in combination with docetaxel.

Clusterin is a protein that is over-produced in several types of cancer and in response to many cancer treatments, including hormone ablation therapy, chemotherapy and radiation therapy. Preclinical and other data suggest that clusterin promotes cell survival. Increased clusterin production has been linked to faster rates of cancer progression, treatment resistance and shorter survival duration. Since increased clusterin production is observed in many human cancers, including prostate, non-small cell lung, breast, ovarian, bladder, renal, pancreatic, anaplastic large cell lymphoma and colon cancers and melanoma, OGX-011 may have broad market potential to treat many cancer indications and disease stages.

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#### About Teva

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is the world's leading generic pharmaceutical company and is among the top 20 pharmaceutical companies in the world. The Company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients, as well as animal health pharmaceutical products. Over 80 percent of Teva's sales are in North America and Europe.

#### **About OncoGenex Pharmaceuticals**

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. OGX-011, the lead candidate that has completed five Phase II clinical trials in prostate, lung and breast cancers, is designed to inhibit the production of a specific protein associated with treatment resistance; OGX-427 is in Phase I clinical development; SN2310 has completed a Phase I clinical trial; and CSP-9222 and OGX-225 are currently in pre-clinical development.

OGX-011, OGX-427 and OGX-225 utilize second-generation antisense technology, licensed from Isis Pharmaceuticals (NASDAQ: ISIS), to target and inhibit production of specific proteins which OncoGenex believes are important in tumor progression and treatment resistance. OncoGenex and Isis partnered in the successful discovery of OGX-011, OGX-427 and OGX-225 and with respect to OGX-011, in its initial development. In 2008, OncoGenex and Isis amended their OGX-011 agreement to provide OncoGenex with sole rights to OGX-011 and sole responsibility for development and related costs and partnering decisions, subject to financial obligations to Isis. OncoGenex is also solely responsible for development and related costs and partnering decisions regarding OGX-427 and OGX-225. Key intellectual property related to OGX-011, OGX-011, OGX-427 and OGX-225 were discovered by the University of British Columbia and the Vancouver Prostate Centre, and were exclusively licensed to OncoGenex.

More information about OncoGenex is available atwww.oncogenex.com.

#### Teva's Safe Harbor Statement under the U.S. Private Securities Litigation Reform Act of 1995:

This release contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: results of the phase III clinical trials involving OGX-011, the potential efficacy or future market or marketability of OGX-011, our ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic equivalents, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products and regulatory changes that may prevent us from utilizing exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Neurontin®, Lotrel®, Protonix® and Eloxatin®, the current economic conditions, competition from brand-name companies that are under increased pressure to counter generic products, or competitors that seek to delay the introduction of generic products, the effects of competition on our innovative products, especially Copaxone® sales, dependence on the effectiveness of our patents and other protections for innovative products, the impact of consolidation of our distributors and customers, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, our ability to achieve expected results though our innovative R&D efforts, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the uncertainty surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, the regulatory environment and changes in the health policies and structures of various countries, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, our ability to successfully identify, consummate and integrate acquisitions, the potential exposure to product liability claims to the extent not covered by insurance, our exposure to fluctuations in currency, exchange and interest rates, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, our ability to enter into patent litigation

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settlements and the intensified scrutiny by the U.S. government, the termination or expiration of governmental programs and tax benefits, impairment of intangible assets and goodwill, environmental risks, and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").

#### **OncoGenex's 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 potential milestones, royalties and other payments that may be received by OncoGenex in the future, anticipated clinical and other product development activities and timing and costs of these activities, market potential for OGX-011 and success of activities to attain market approval and sales. 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. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Such forward-looking statements are subject to risks and uncertainties, including, among others, 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 2008. The Company undertakes no obligation to update the forward-looking statements or circumstances occurring after the date hereof, other than as may be required by applicable law.

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