# 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): March 8, 2012

# **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.)

1522 217th Place S.E. Bothell, Washington 98021 (Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (425) 487-9500

 $$\mathbf{N}/\mathbf{A}$$  (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 (see General Instruction A.2. below):

□ 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 2.02 Results of Operations and Financial Condition.

On March 8, 2012, OncoGenex Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2011. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

#### Item 7.01 Regulation FD Disclosure.

On March 8, 2012, the Company and Teva Pharmaceutical Industries Ltd. ("Teva") issued a joint press release titled "Teva and OncoGenex Announce Updates to Custirsen Development Program in Advanced Prostate Cancer." A copy of the press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

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

(d) Exhibits

99.2

Exhibit No. Description

99.1 Press release of OncoGenex Pharmaceuticals, Inc. dated March 8, 2012

Press release of OncoGenex Pharmaceuticals, Inc. and Teva Pharmaceutical Industries Ltd. dated March 8, 2012

The information in Item 2.02 and Item 7.01 of this Form 8-K and Exhibit 99.1 and Exhibit 99.2 attached hereto is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it 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 filing.

# 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: March 8, 2012

/s/ Cameron Lawrence

Cameron Lawrence Principal Accounting Officer

	EXHIBIT INDEX
Exhibit No.	Description
99.1	Press release of OncoGenex Pharmaceuticals, Inc. dated March 8, 2012
99.2	Press release of OncoGenex Pharmaceuticals, Inc. and Teva Pharmaceutical Industries Ltd. dated March 8, 2012

## OncoGenex Pharmaceuticals, Inc. Reports Financial Results for Fourth Quarter and Year End 2011 and Provides Update on Clinical Development Program

#### Conference call to be held on Thursday, March 8, 2012 at 4:30 p.m. Eastern Time

BOTHELL, WA., and VANCOUVER, British Columbia, March 8, 2012 – OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) today announced its fourth guarter and year end 2011 financial results and provided an update on the clinical development programs for its product candidates, custirsen and OGX-427.

"We have had an exciting start to 2012, as our development programs for our two lead assets continue to gain momentum, specifically in advanced prostate cancer, " said Scott Cormack, President and CEO of OncoGenex Pharmaceuticals. "The abiraterone data announcement today is excellent news for patients and for our company, as the development plans for both of our agents are now well aligned to a more defined landscape and are therefore positioned to improve upon existing treatments across the treatment continuum."

#### **Custirsen Clinical Development Updates:**

- Along with development partner, Teva Pharmaceutical Industries Ltd., OncoGenex announced plans to initiate a new Phase 3 study to evaluate the ability of custirsen to improve survival for patients with prostate cancer when combined with recently approved, second-line chemotherapy, Jevtana<sup>®</sup> (cabazitaxel). The new study will be conducted in lieu of the Prostate Cancer Saturn Study, which aimed to assess durable pain palliation as a primary endpoint. The study is expected to begin in the second-half of 2012.
- The SYNERGY Phase 3 study, evaluating a survival benefit in first-line chemotherapy castrate-resistant prostate cancer (CRPC), continues to
  accrue patients and is expected to complete enrollment later this year. The companies updated the enrollment target for SYNERGY from 800
  patients to 1000 patients which is expected to enhance the potential for SYNERGY to be reviewed by regulatory agencies independent of additional
  Phase 3 studies. Importantly, even with the trial size increasing by 25%, OncoGenex and Teva plan to complete enrollment later this year as
  originally disclosed.
- OncoGenex continues to work with Teva to finalize clinical development plans for custirsen in non-small cell lung cancer and expects to initiate this program in the second-half of 2012.

#### OGX-427 Clinical Development Updates:

- Preliminary data on OGX-427 for the treatment of prostate and bladder cancer were presented earlier this month at the ASCO 2012 Genitourinary Cancers Symposium.
- A Phase 1 trial evaluating OGX-427 in patients with superficial or muscle-invasive bladder cancer demonstrated a trend towards decreased levels
  of Hsp27 and increased tumor cell death rates after intravesical treatment with OGX-427. Of the 15 patients treated with OGX-427, 33% had
  pathological complete responses in post-surgical tissue following 4 doses of OGX-427 administered intravesically over an 8 day period. A
  randomized Phase 2 clinical trial of OGX-427 in combination with gemcitabine/cisplatin in patients with metastatic bladder cancer is currently
  enrolling patients.
- In chemotherapy-naive patients with metastatic CRPC, preliminary randomized Phase 2 study results showed that patients in the OGX-427 treatment arm had a higher number of patients without disease progression at 12 weeks, and greater declines in prostate-specific antigen (PSA)

and circulating tumor cells (CTC) compared to the control arm. OncoGenex announced plans to initiate a randomized Phase 2 clinical trial evaluating OGX-427 in combination with Zytiga® (abiraterone) in patients with CRPC, supported in part by investigator grant funding.

#### **Financial Results**

- Revenue for the fourth quarter and year ended December 31, 2011 decreased to \$1.2 million and \$5.5 million, respectively, compared with \$2.3 million and \$13.6 million in the fourth quarter and year ended December 31, 2010. The decrease in 2011 as compared to 2010 was due to lower reimbursement revenue earned through our strategic collaboration with Teva resulting from manufacturing costs now being paid directly by Teva and lower clinical trial costs associated with the SATURN trial.
- At December 31, 2011, \$18.3 million of the \$30 million advanced reimbursement received from Teva in December 2009 was included in our Balance Sheet as Current Deferred Collaboration Revenue. This advanced reimbursement balance will continue to be reduced as we incur direct and indirect custirsen development costs. As a consequence of initiating the new CRPC survival trial later this year, we currently expect that all remaining Current Deferred Collaboration Revenue will be recognized as Collaboration Revenue by the fourth quarter of 2012. Once the remaining amount of the advanced reimbursement from Teva has been drawn to zero, all of our costs associated with the clinical programs under our collaboration will be reimbursed by Teva quarterly.
- Total operating expenses for the fourth quarter and year ended December 31, 2011 were \$9.2 million and \$27.8 million, respectively, compared with \$4.2 million and \$28.4 million in the fourth quarter and year ended 2010. The decrease in operating expenses in 2011 as compared with 2010 was due to a \$4.0 million non-cash restructuring expense recorded in 2010 which resulted from the revision of our sublease income assumptions used to estimate the excess lease facility liability associated with our office space located in Bothell, Washington, offset by higher OGX-427 manufacturing and clinical trial costs, and higher employee expenses.
- Net loss for the fourth quarter and year ended December 31, 2011 increased to \$9.6 million, or \$0.98 per diluted common share, and \$14.7 million, or \$1.51 per diluted common share, respectively, compared to net loss in the fourth quarter of 2010 of \$2.8 million, or \$0.31 per diluted common share, and a net loss of \$12.6 million, or \$1.79 per diluted common share, in the year ended 2010. The increase in net loss was primarily due to lower revenue recognized in 2011 in connection with the Collaboration Agreement with Teva, and higher expenses associated with our OGX-427 clinical trials.
- We had \$64.9 million in cash, cash equivalents and short-term investments as of December 31, 2011, compared to \$85.1 million as of December 31, 2010.

#### 2012 Outlook and Financial Guidance

- We expect 2012 operating cash requirements of between \$40 million and \$45 million, and expect to end 2012 with cash, cash equivalents, investments, and receivables from Teva of between \$20 million and \$25 million. This increase from the \$20.2 million in cash used in 2011 reflects the higher anticipated cash burn associated with the new Phase 3 study to evaluate an overall survival benefit for custirsen when combined with Jevtana<sup>®</sup>.
- Based on our current forecast, and excluding any proceeds from potential new partnerships or financings we expect that our existing capital resources, including cash, cash equivalents, short term investments and amounts receivable, will support our operations into 2014. As at March 8, 2012, we had 9,750,119 shares outstanding.

#### Condensed Statements of Operations

(in thousands except share and per share amounts)

		Three Months Ended December 31,			Year Ended December 31,			
		2011 2010 (unaudited) (unaudited)					2010	
Collaboration revenue	\$	1,236	\$	2,334	\$	5,496	\$	13,616
Operating expenses								
Research and development	\$	7,477	\$	2,301	\$ 2	1,553	\$	18,483
General and administrative		1,731		1,948	(	5,230		5,840
Restructuring expense		_				_		4,038
								,
Total operating expenses		9,208		4,249	2	7,783		28,361
Other income (expense)		(1,596)		(885)		7,614		(839)
Loss (income) for the period before taxes		9,568		2,800	14	4,673		15,584
Income tax expense (recovery)		—				—		(3,000)
		0 500		0.000		4 070		40 504
Net loss (income)		9,568		2,800	14	4,673		12,584
Basic and diluted loss (income) per common shares		0.98	\$	0.31	\$	1.51	\$	1.79
Weighted average number of common shares	9	,748,639	8,9	914,287	9,729	9,340	7	,030,903

# Condensed Balance Sheets (in thousands)

	Dec	December 31, 2011		cember 31, 2010
Assets:			-	
Cash, cash equivalents and short term investments	\$	64,927	\$	85,107
Amounts receivable		812		1,224
Prepaid and other current assets		1,587		2,987
Property, equipment and other assets		689		600
Total assets	\$	68,015	\$	89,918
Liabilities and stockholders' equity:				
Accounts payable and accrued liabilities	\$	3,217	\$	893
Deferred Collaboration Revenue		18,271		10,000
Current portion of long term obligations		1,417		1,314
Warrant liability		7,881		15,269
Long term liabilities		6,339		18,317
Stockholders' equity	\$	30,890	\$	44,125
Total liabilities and stockholders' equity	\$	68,015	\$	89,918

#### **Conference Call Details**

OncoGenex will host a conference call at 4:30 p.m. Eastern Time today, Thursday, March 8, 2012, to provide a business update and discuss the fourth quarter and year ended 2011 results. A live event will be available on the Investor Relations section of the OncoGenex Web site at <u>www.oncogenex.com</u>. Alternatively, you may access the live conference call by dialing 877 -606-1416 (U.S. & Canada) or 707 -287-9313 (International). A replay of the webcast will be available approximately two hours after the call and will be archived for 90 days.

### 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 diverse 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 Industries Ltd. (NASDAQ: TEVA) have entered a global collaboration and license agreement to develop and commercialize OncoGenex' lead drug candidate, custirsen. Custirsen is currently in Phase 3 clinical development as a treatment in men with metastatic castrate-resistant prostate cancer. The companies plan to begin Phase 3 development of custirsen in first-line treatment of advanced, unresectable non-small cell lung cancer. OGX-427 is in Phase 2 clinical development; CSP-9222 and OGX-225 are currently in pre-clinical development. More information is available at www.OncoGenex.com.

#### **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 concerning our anticipated product development activities, such as expected clinical trial initiation 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 subject to risks and uncertainties, including, among others, the risk that final trial results will not demonstrate the same or any potential benefit as observed in preliminary trial results, the risk that subsequent studies may not confirm earlier trial results, the risk of delays in our expected clinical trials, the 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. 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.

Zytiga® is a registered trademark of the Johnson & Johnson Corporation

JEVTANA® is a registered trademark of sanofi-aventis

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SOURCE: OncoGenex Pharmaceuticals, Inc.

#### Teva and OncoGenex Announce Updates to Custirsen Development Program in Advanced Prostate Cancer

#### Second Phase 3 Trial Evaluating Survival Benefit of Custirsen Planned to Initiate in 2012

Jerusalem, Israel, Bothell, WA and Vancouver, British Columbia, March 8, 2012 – Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) and OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) announced today an update on their development program for custirsen, a product candidate being evaluated in Phase 3 studies for castrate-resistant prostate cancer (CRPC).

In a revised agreement between the two companies, the clinical trial program will now include the initiation of a Phase 3 study to evaluate if custirsen has the potential to improve survival rates for prostate cancer patients when combined with the recently-approved, second-line chemotherapy drug Jevtana<sup>®</sup> (cabazitaxel).

The new trial, which aims to enroll approximately 630 men and is expected to begin later this year, will be conducted in lieu of the Prostate Cancer Saturn Study, a trial designed with a primary endpoint of measuring a durable pain palliation benefit for custirsen in second-line treatment of CRPC. The shift in focus to evaluate overall survival in second-line prostate cancer is a result of numerous, recently-approved agents that are redefining the standard of care in this patient setting.

"The amendments made to the Phase 3 program reflect the rapidly-evolving CRPC landscape and our commitment to ensure custirsen data are aligned with requirements to demonstrate improvements in survival across the treatment continuum," said Lesley Russell, Senior Vice President, Head of R&D for Global Branded Products at Teva Pharmaceuticals. "Developing custirsen for patients suffering from advanced prostate cancer remains a top priority within the Teva Oncology product-line and we believe this new trial is a reflection of that commitment."

Custirsen's other Phase 3 study, SYNERGY, evaluating a survival benefit in the first-line CRPC setting, continues to accrue patients and is expected to complete enrollment later this year. The companies are increasing the enrollment from 800 to 1000 patients to optimize the potential to be submitted to regulatory agencies independent of additional Phase 3 studies. The increase in enrollment is not expected to alter timelines for completion of the study.

Additional details on the updates to the custirsen development program will be discussed during the OncoGenex Quarterly Earnings Call to be held this afternoon, March 8, at 4:30pm EST. To join the call, dial (877) 606-1416 (U.S. & Canada) or (707) 287-9313 (International).

#### About Custirsen

Custirsen is the only compound currently in development designed to inhibit the production of clusterin, a protein commonly over-produced in cancer cells, and one cause of treatment resistance. In Phase 2 trials of patients with metastatic CRPC, custirsen combined with docetaxel showed a 6.9 month improvement in overall survival over docetaxel alone. Additionally, 50 percent of patients experienced durable pain palliation for a duration of 12 weeks or longer. Custirsen has received Fast Track designation from the U.S. Food and Drug Administration (FDA).

#### About Teva

Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) is a leading global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic drugs as well as innovative and specialty pharmaceuticals and active pharmaceutical ingredients. Headquartered in Israel, Teva is the world's largest generic drug maker, with a global product portfolio of more than 1,300 molecules and a direct presence in about 60 countries. Teva's branded businesses focus on CNS, oncology, pain, respiratory and women's health therapeutic areas as well as biologics. Teva currently employs approximately 46,000 people around the world and reached \$18.3 billion in net revenues in 2011.

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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: our ability to develop and commercialize additional pharmaceutical products, competition from the introduction of competing generic equivalents and the impact of increased governmental pricing pressures, the effects of competition on revenues of our innovative products, especially Copaxone® (including competition from innovative orally-administered alternatives, as well as from potential generic equivalents), potential liability for revenues of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic version of Protonix®, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products, the extent to which any manufacturing or guality control problems damage our reputation for high guality production and require costly remediation, our ability to identify, consummate and successfully integrate acquisitions (including the acquisition of Cephalon), our ability to achieve expected results through our innovative R&D efforts, dependence on the effectiveness of our patents and other protections for innovative products, intense competition in our specialty pharmaceutical businesses, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, our potential exposure to product liability claims to the extent not covered by insurance, any failures to comply with the complex Medicare and Medicaid reporting and payment obligations, our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement, adverse effects of political or economical instability, major hostilities or acts of terrorism on our significant worldwide operations, increased government scrutiny in both the U.S. and Europe of our agreements with brand companies, interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, the impact of continuing consolidation of our distributors and customers, the difficulty of complying with U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority requirements, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, the termination or expiration of governmental programs or tax benefits, any failure to retain key personnel or to attract additional executive and managerial talent, environmental risks and other factors that are discussed in our Annual Report on Form 20F for the year ended December 31, 2011 and in our other filings with the U.S. Securities and Exchange Commission.

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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 subject to risks and uncertainties, including, among others, the risk that final trial results will not demonstrate the same or any potential benefit as observed in preliminary trial results, the risk that subsequent studies may not confirm earlier trial results, 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 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 Quarterly Report on Form 10-Q for third quarter ended September 30, 2011. 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.

JEVTANA® is a registered trademark of sanofi-aventis

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