

ONCOGENEX PHARMACEUTICALS, INC.

FORM 425

(Filing of certain prospectuses and communications in connection with business combination transactions)

Filed 05/15/17

Address	19820 NORTH CREEK PARKWAY SUITE 201 BOTHELL, WA 98011
Telephone	425-686-1500
CIK	0000949858
Symbol	OGXI
SIC Code	2835 - In Vitro and In Vivo Diagnostic Substances
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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): May 15, 2017

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 (see General Instructions 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 15, 2017, OncoGenex Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter of 2017. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of OncoGenex Pharmaceuticals, Inc. dated May 15, 2017

The information in Item 2.02 of this Form 8-K and Exhibit 99.1 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.

Date: May 15, 2017

ONCOGENEX PHARMACEUTICALS, INC.

/s/ John Bencich

John Bencich
Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of OncoGenex Pharmaceuticals, Inc. dated May 15, 2017

OncoGenex Pharmaceuticals, Inc. Reports Financial Results for First Quarter 2017

BOTHELL, WA, and VANCOUVER, British Columbia, May 15, 2017 – OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) today announced financial results for the first quarter ended March 31, 2017.

Recent Events

- In January 2017, Achieve Life Science, Inc. (Achieve) and OncoGenex announced they entered into a definitive merger agreement.
- In February 2017, OncoGenex announced that apatorsen results from two randomized Phase 2 clinical trials were presented at the American Society of Clinical Oncology (ASCO) 2017 Genitourinary Cancers Symposium, held February 16th - 18th in Orlando. Clinical data from trials in bladder and prostate cancers demonstrated apatorsen was well-tolerated and improved patient outcomes when administered in combination with standard-of-care treatments.
- In March 2017, Achieve announced a strategic collaboration with the National Center for Complementary and Integrative Health (NCCIH) at the National Institutes of Health (NIH) to conduct non-clinical studies in support of an overall clinical development plan for cytosine as a smoking cessation treatment. As part of the collaboration, Achieve is providing cytosine to the NIH to conduct a series of non-clinical studies required by the U.S. Food and Drug Administration (FDA) to support the submission of an Investigational New Drug (IND) application. The collaboration commenced in March 2015 and results of the studies are expected in the second-quarter of 2017.
- In March 2017, the Society for Research in Nicotine and Tobacco (SRNT) held a symposium on cytosine research at its annual conference held in Florence, Italy. The symposium was chaired by Professor Nancy Rigotti, MD, Massachusetts General Hospital/Harvard Medical School, with presentations from Associate Professor Natalie Walker, PhD, National Institute for Health Innovation, University of Auckland, on “Cytosine versus Varenicline for Smoking Cessation: Two Clinical Trials from the Australasian Cytosine Trialist Group,” and “The Challenge to Getting Cytosine Licensed For Use Worldwide: Policy Considerations.” Dr. Walker was the principal investigator of the 1,310 patient phase 3 CASCAID trial published in the New England Journal of Medicine in December, 2014 titled “Cytosine versus Nicotine for Smoking Cessation”.

Financial Results

As of March 31, 2017, the company’s cash, cash equivalents, and short-term investments were \$16.5 million compared with \$25.5 million as of December 31, 2016. Based on current expectations, OncoGenex believes that its cash, cash equivalents, and short-term investments will be sufficient to fund its currently planned operations for at least the next 12 months.

Revenue for the three months ended March 31, 2017 decreased to zero from \$2.9 million for three months ended March 31, 2016. Total operating expenses for the three months ended March 31, 2017 were \$3.3 million compared to \$7.4 million for the same period in 2016. Net loss for the three months ended March 31, 2017 was \$3.3 million compared to \$3.7 million for the same period in 2016.

As of May 15, 2017 OncoGenex had 30,087,485 shares outstanding.

About OncoGenex

OncoGenex is a biopharmaceutical company committed to the development and commercialization of new therapies that address treatment resistance in cancer patients. The company's product candidate, apatosen (OGX-427), is designed to inhibit production of Hsp27, disable cancer cells' defenses and overcome treatment resistance. Hsp27 is an intracellular protein that protects cancer cells by helping them survive, leading to resistance and more aggressive cancer phenotypes. Both the potential single-agent activity and synergistic activity of apatosen with cancer treatments may increase the overall benefit of existing therapies and augment the durability of treatment outcomes, which could lead to increased patient survival. More information is available at www.OncoGenex.com and at the company's Twitter account: https://twitter.com/OncoGenex_IR.

About Achieve and Cytisine

Achieve is developing cytisine as a smoking cessation aid. Cytisine is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is an established smoking cessation treatment that has been approved and marketed in Central and Eastern Europe for more than 15 years. It is estimated that over 20 million people have used cytisine to help combat nicotine addiction, including approximately 2,000 patients in Phase 3 clinical trials conducted in Europe and New Zealand. Achieve's focus is to address the global smoking health epidemic, which is currently the leading cause of preventable death and is responsible for nearly six million people losing their lives annually worldwide. Discussions have been held with FDA and a European regulatory agency to determine the clinical and regulatory pathway towards making cytisine widely available.

Important Additional Information about the Proposed Merger

This communication is being made in respect of the proposed merger involving OncoGenex Pharmaceuticals, Inc. and Achieve Life Science, Inc. OncoGenex has filed a registration statement on Form S-4 (File No. 333-216961) with the Securities and Exchange Commission (SEC), which contains a preliminary proxy statement/prospectus/information statement and other relevant materials, and plans to file with the SEC other documents regarding the proposed transaction. The final proxy statement/prospectus/information statement will be sent to the stockholders of OncoGenex and Achieve. The proxy statement/prospectus/information statement contains information about OncoGenex, Achieve, the proposed merger and related matters. STOCKHOLDERS ARE URGED TO READ THE PROXY STATEMENT/PROSPECTUS/INFORMATION STATEMENT (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS) AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY IN THEIR ENTIRETY AS THEY BECOME AVAILABLE, AS THEY CONTAIN IMPORTANT INFORMATION THAT STOCKHOLDERS SHOULD CONSIDER BEFORE MAKING A DECISION ABOUT THE MERGER AND RELATED MATTERS. In addition to receiving the final proxy statement/prospectus/information statement and proxy card by mail, stockholders will also be able to obtain the proxy statement/prospectus/information statement, as well as other filings containing information about OncoGenex, without charge, from the SEC's website (<http://www.sec.gov>) or, without charge, by directing a written request to: OncoGenex Pharmaceuticals, Inc., 19820 North Creek Parkway, Suite 201, Bothell, WA 98011, Attention: Investor Relations or to Achieve Life Science, Inc., 30 Sunnyside Avenue, Mill Valley, CA 94941, Attention: Rick Stewart.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities in connection with the proposed merger shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Participants in Solicitation

OncoGenex and its executive officers and directors may be deemed to be participants in the solicitation of proxies from OncoGenex's stockholders with respect to the matters relating to the proposed merger. Achieve and its officers and directors may also be deemed a participant in such solicitation. Information regarding OncoGenex's executive officers and directors is available in OncoGenex's proxy statement on Schedule 14A, filed with the SEC on April 21, 2016. Information regarding any interest that OncoGenex, Achieve or any of the executive officers or directors of OncoGenex or Achieve may have in the transaction with Achieve will be set forth in the final proxy statement/prospectus/information statement that OncoGenex will file with the SEC in connection with its stockholder vote on matters relating to the proposed merger. Stockholders will be able to obtain this information by reading the final proxy statement/prospectus/information statement when it becomes available.

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 proposed merger with Achieve Life Science; the development of apatorsen and cytosine; the potential benefits of apatorsen and cytosine; and the adequacy of cash reserves. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. OncoGenex and/or Achieve may not actually achieve the proposed merger, or any plans or product development goals in a timely manner, if at all, or otherwise carry out the intentions or meet the expectations or projections disclosed in these 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, including, among others, the failure of the OncoGenex or Achieve stockholders to approve the transaction; the failure of either party to meet the closing conditions of the transaction; delays in completing the transaction and the risk that the transaction may not be completed at all; the failure to realize the anticipated benefits from the transaction or delay in realization thereof; the success of the combined businesses; operating costs and business disruption during the pendency of and following the proposed merger; the risk that product candidates will not receive regulatory approval or be successfully commercialized; the risk that new developments in the rapidly evolving cancer therapy landscape require changes in business strategy or clinical development plans; the risk that product candidates may not demonstrate the hypothesized or expected benefits; general business and economic conditions; and the other factors described in our risk factors set forth in OncoGenex's filings with the Securities and Exchange Commission from time to time, including its Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. OncoGenex 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.

OncoGenex Contact:

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Consolidated Statements of Loss

(In thousands, except per share and share data)

(unaudited)

	Three months ended March 31,	
	2017	2016
Collaboration revenue	\$ —	\$ 2,940
Operating expenses:		
Research and development	912	4,642
General and administrative	2,532	2,299
Restructuring costs (recovery)	(98)	431
Litigation settlement loss	—	—
Total operating expenses	<u>3,346</u>	<u>7,372</u>
Loss from operations	(3,346)	(4,432)
Other income (expense)	77	725
Net loss	<u>\$ (3,269)</u>	<u>\$ (3,707)</u>
Basic and diluted net loss per share	<u>\$ (0.11)</u>	<u>\$ (0.12)</u>
Weighted average number of basic and diluted common shares	<u>30,076,160</u>	<u>29,827,824</u>

Consolidated Balance Sheets**(In thousands)**

	March 31, 2017 (unaudited)	December 31, 2016
Assets:		
Cash, cash equivalents, short term investments and restricted cash	\$ 16,722	\$ 25,735
Interest receivable	—	32
Amounts receivable	237	478
Prepaid expenses and other current assets	765	954
Property, equipment and other assets	179	271
Total assets	<u>\$ 17,903</u>	<u>\$ 27,470</u>
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 1,745	\$ 8,166
Current portion of long-term obligations	55	57
Warrant liability	180	232
Long term liabilities	32	49
Stockholders' equity	15,891	18,966
Total liabilities and stockholders' equity	<u>\$ 17,903</u>	<u>\$ 27,470</u>