

ONCOGENEX PHARMACEUTICALS, INC.

FORM 8-K (Current report filing)

Filed 01/06/17 for the Period Ending 01/06/17

Address	19820 NORTH CREEK PARKWAY SUITE 201 BOTHELL, WA 98011
Telephone	425-686-1500
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**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): January 6, 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:

- 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.

Attached hereto as Exhibit 99.1 is an investor presentation that Achieve Life Science, Inc. (“Achieve”) plans to present during the J.P. Morgan Healthcare Conference.

Item 9.01 Financial Statements and Exhibits.

Reference is made to the Exhibit Index included with this Current Report on Form 8-K.

Important Additional Information about the Proposed Merger

This communication is being made in respect of the proposed merger involving OncoGenex Pharmaceuticals, Inc. (“OncoGenex”) and Achieve. OncoGenex intends to file a registration statement on Form S-4 with the SEC, which will contain a joint proxy statement/prospectus and other relevant materials, and plans to file with the Securities and Exchange Commission (“SEC”) other documents regarding the proposed transaction. The final joint proxy statement/prospectus will be sent to the stockholders of OncoGenex and Achieve. The joint proxy statement/prospectus will contain information about OncoGenex, Achieve, the proposed merger and related matters. ***Stockholders are urged to read the joint proxy statement/prospectus (including any amendments or supplements) and other documents filed with the SEC carefully in their entirety when they become available, as they will contain important information that stockholders should consider before making a decision about the merger and related matters.*** In addition to receiving the joint proxy statement/prospectus and proxy card by mail, stockholders will also be able to obtain the joint proxy statement/prospectus, 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 joint proxy statement/prospectus that OncoGenex intends to 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 joint proxy statement/prospectus when it becomes available.

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: January 6, 2017

/s/ John Bencich

John Bencich
Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Achieve Life Science, Inc. Investor Presentation



Achieve Life Science, Inc.

January 2017



Forward Looking Statements

This presentation contains forward-looking statements, including, but not limited to, statements regarding the terms, timing, conditions to and anticipated completion of the proposed merger; the expected ownership of the combined company and the composition of the combined company's board of directors and management team; the anticipated distribution to OncoGenex Pharmaceuticals, Inc. (OncoGenex) stockholders of contingent value rights (CVRs) and the terms, timing and value of such CVRs; the timing of planned clinical development activities of cytisine; the projected path toward potential regulatory approval; the safety, efficacy and commercial potential of cytisine; plans, objectives, expectations and intentions with respect to future operations. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Achieve Life Science, Inc. (Achieve) and/or OncoGenex 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 Achieve or OncoGenex 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 success of the combined businesses; operating costs and business disruption during the pendency of and following the proposed merger; general business and economic conditions; the need for and ability to obtain additional financing; the ability to source sufficient amounts of cytisine to meet commercial demand; and the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates that are safe and effective for use as human therapeutics. Achieve 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.



Important Additional Information About the Merger

This communication is being made in respect of the proposed merger involving OncoGenex Pharmaceuticals, Inc. and Achieve Life Science, Inc. OncoGenex will file with the Securities and Exchange Commission, or SEC, a current report on Form 8-K, which will include the merger agreement and related documents. In addition, OncoGenex intends to file a registration statement on Form S-4 with the SEC, which will contain a joint proxy statement/prospectus and other relevant materials, and plans to file with the SEC other documents regarding the proposed transaction. The final joint proxy statement/prospectus will be sent to the stockholders of OncoGenex and Achieve. The joint proxy statement/prospectus will contain information about OncoGenex, Achieve, the proposed merger and related matters. **STOCKHOLDERS ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS) AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE, AS THEY WILL CONTAIN IMPORTANT INFORMATION THAT STOCKHOLDERS SHOULD CONSIDER BEFORE MAKING A DECISION ABOUT THE MERGER AND RELATED MATTERS.** In addition to receiving the joint proxy statement/prospectus and proxy card by mail, stockholders will also be able to obtain the joint proxy statement/prospectus, 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.



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About the Merger

- Achieve Life Science, Inc. and OncoGenex Pharmaceuticals, Inc. signed definitive merger agreement January 5, 2017
- Upon completion of the merger, Achieve shareholders are expected to own \approx 75% and OGXI shareholders are expected to own \approx 25% of the combined company
- OGXI shareholders are expected to receive contingent value rights for 80% of defined consideration received related to apatorsen
- Board composition to be 4 designates of Achieve and 3 designates of OGXI
- Merger expected to be completed in mid-2017 subject to OGXI shareholder approval



Post-Merger Management Team

Rick Stewart
Chairman & CEO

Chairman & CEO of Ricanto
CEO of Brabant Pharma (acquired by Zogenix)
Chairman & CEO of Huxley Pharma (acquired by BioMarin)
CEO of Amarin Corp
Founder & CBO of SkyePharma (acquired by Vectura)

John Bencich, MBA, CPA
CFO

CFO of OncoGenex
CFO of Integrated Diagnostics
CFO of Allozyne
CFO of Trubion Pharmaceuticals (acquired by Emergent)

Cindy Jacobs, PhD, MD
CMO

CMO of OncoGenex
CMO of Corixa (acquired by GSK)
VP Clinical Development, CellPro

Anthony Clarke, PhD
CSO

CSO of Ricanto
CSO of Brabant Pharma (acquired by Zogenix)
CSO of Huxley Pharma (acquired by BioMarin)
CSO of Amarin Corp

Overview: Achieve Life Science, Inc.

- Achieve is a privately-held, specialty pharma company focused on the development of cytisine for smoking cessation
 - In-licensed WW rights to cytisine from Sopharma (excluding Central and Eastern Europe)
- Cytisine is approved in Central and Eastern Europe for smoking cessation and sold through Sopharma
 - In-market exposure estimated in over 20 million patients
 - An extensive EMA-compliant PSUR/clinical safety database of 8.5 million patients
- Safety and efficacy are further supported by two Phase 3 clinical studies in over 2,000 patients published in NEJM

Expected Near-Term Milestones

- Complete FDA-required IND enabling non-clinical studies in 1H 2017
- File IND in 2H 2017
- Initiate FDA-required Phase 1 Fed/Fasted and Repeat Dose PK studies in 2H 2017 to support future NDA filing
- Initiate Phase 3 trial in 1H 2018
- File MAA in Europe potentially in 1H 2018
 - Meetings with German, Dutch and Swedish regulators in 1H 2017
 - Seeking agreement on MAA package and timing

Market Opportunity

- Smoking cessation is one of the most important public health issues globally
 - Smoking is the #1 cause of preventable deaths worldwide
 - Tobacco consumption is responsible for cancers, cardiovascular, pulmonary and GI diseases
 - More than 480,000 U.S. deaths annually from smoking-related disease
 - Smoking-related healthcare costs in the U.S. are ≈ \$170 billion annually
 - Medicaid expenditures attributable to smoking-related diseases total nearly \$22 billion annually, representing 11% of all expenditures
- Global smoking cessation market expected to reach \$4.4 billion by 2023
 - 44+ million smokers in U.S. alone (≈ 15% of the U.S. population)
 - According to the Centers for Disease Control and Prevention (CDC), nearly 70% of current smokers have expressed a desire to quit, 40% attempted to quit in the past year, but only 6.2% succeeded

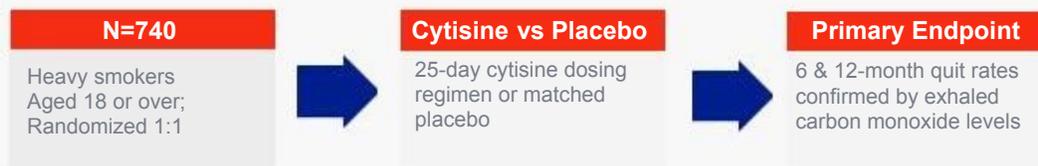
Cytisine: Product Overview

Well Characterized MOA	Strong Ex-U.S. Clinical and Safety Profile	Defined U.S. Regulatory Pathway	Market Experience and Product Opportunity
<ul style="list-style-type: none"> • Cytisine is a plant-based alkyloid found in members of the leguminosae family • Partial agonist that binds with high affinity to the $\alpha_4\beta_2$ nicotinic acetylcholine receptor • $\alpha_4\beta_2$ nicotinic receptor is well-characterized in addiction, interrupts nicotine craving 	<ul style="list-style-type: none"> • Two Phase III trials; 2,050 patients, both published in <i>NEJM</i> • \approx 10,000 patients in clinical trials to-date • Excellent safety profile • \approx 8.5 million patients in European PSUR Safety database 	<ul style="list-style-type: none"> • IND enabling studies nearing completion • IND expected to be filed in 2H 2017 • Phase I fed/fasted & repeat dose PK study • Phase 3 trial expected to be initiated in 1H 2018 	<ul style="list-style-type: none"> • Oral product approved for smoking cessation in Central and Eastern Europe • \approx 20 million patients treated • Cost-effective • Demonstrated superiority to nicotine replacement in large, randomized trial • Similar efficacy to varenicline, with potentially less side effects



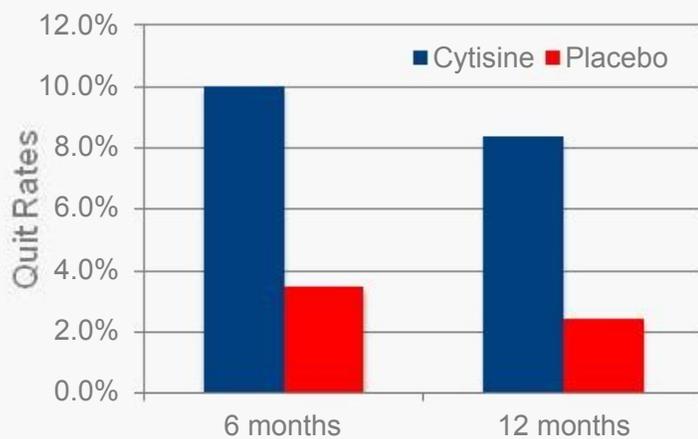
Clinical Overview

Phase 3 Trial – TASC (Cytisine vs. Placebo)



- Double-blind, randomized, placebo-controlled; minimal behavioral support
- Conducted in Poland with funding support from Medical Research Council, Cancer Research UK, Wellcome Foundation, University College London and others
- Cytisine 3.4 times more likely to result in smoking cessation after 12 months (p=0.001)
 - Higher than previous studies have shown for varenicline (2.3) and NRT (1.3)
- Overall adverse events between cytisine and placebo were similar with higher GI events in cytisine group
- No Serious Adverse Events related to therapy

TASC Phase 3 Trial Results

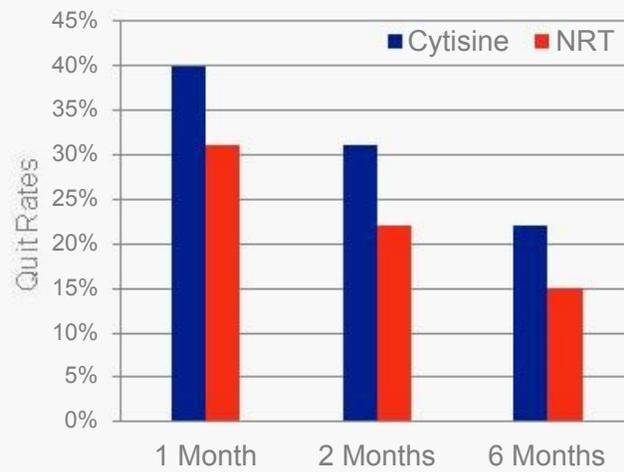


Phase 3 Trial – CASCAID (Cytisine vs. NRT)



- Randomized, open-label, active-controlled, non-inferiority study design with moderate behavioral support
- Cytisine compared to nicotine replacement therapy (NRT)
- Conducted by University of Auckland and funded by Health Research Council, New Zealand
- Cytisine 1.43 times more likely than NRT to result in smoking cessation after 6 months (p=0.002)
 - Not only non-inferior to NRT, but deemed to be superior by investigators
- No overall difference in adverse effects between cytisine and NRT
- No Serious Adverse Effects related to therapy

CASCAID Phase 3 Trial Results



Cochrane Database Review: Cytisine Efficacy Profile

Cytisine

- Pooled RR based on 2 published studies*
- n=937
- RR (CI_{95%}) at longest follow-up 3.98 (2.01-7.87)

Varenicline

- Pooled RR based on 27 published studies
- N=12,625
- RR (CI_{95%}) longest follow-up 2.24 (2.06-2.43)

Key findings

- No apparent difference in efficacy between cytisine and varenicline
- Cytisine has an Relative Risk ("RR") = 3.98; varenicline = 2.24
- Cytisine trials were conducted with minimal behavioral support, varenicline trials with behavioral support
- Behavioral support can increase patient response by 10%-15%
- Minimal behavioral support may have limited cytisine headline cessation rates

MOA Differences between Cytisine and Varenicline

Efficacy

- Cytisine and varenicline are partial agonists at the $\alpha_4\beta_2$ nicotinic acetylcholine receptor
- Activity at this receptor in the ventral tegmental area of the brain mediates therapeutic effect
- The two drugs have similar efficacy

Safety

- Varenicline interacts potently with a broader range of nicotinic receptors than cytisine
- Action at these additional receptors may be associated with additional side effects

Site	Receptor	Cytisine	Varenicline
Brain	$\alpha_4\beta_2$	✓	✓
	α_7	✗	✓
Periphery	$\alpha_3\beta_4$	✗	✓

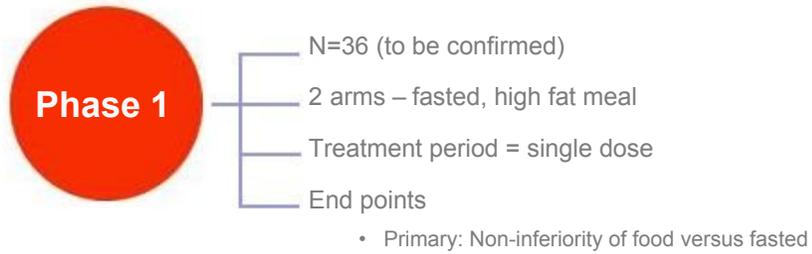


Clinical Development

Anticipated Path to U.S. and EU Regulatory Approval

- FDA directed U.S. regulatory pathway (meeting June 19, 2015)
 - File IND utilizing non-clinical data package (compliant with current guidelines)
 - Conduct fed/fasted and repeat dose PK studies
 - Conduct Phase III study in the U.S.
- Meet with EMA to agree on EU regulatory pathway
 - Meet with national regulators in Germany, Holland & Sweden
 - Determine whether existing MAA dossier is sufficient for MAA submission
 - Include new non-clinical data
 - Include data from TASC and CASCAID Phase 3 trials
 - Potential to file an MAA with EMA with additional datasets

Planned Phase 1 Fed/Fasted Study

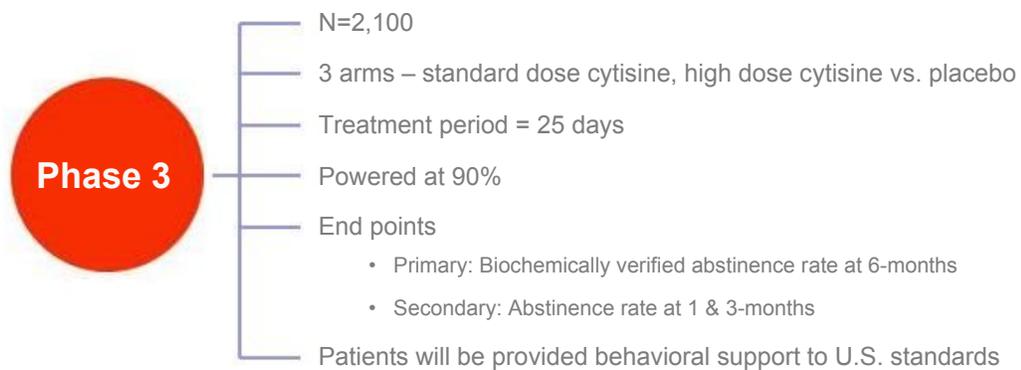


Planned Phase 1 Repeat-dose Pharmacokinetic Study



- N=12 (individuals from fed/fasted study)
- Conducted with fed/fasted study as a Part A/Part B design
- Standard dose cytosine, high dose cytosine vs. placebo
- Treatment period = 25 days
- End points
 - Full PK profile on first and final dose
 - Peak/trough PK profiles after each change (decrease) in dose

Planned Phase 3 Trial Design



Manufacturing & Supply Chain



Sopharma

API & solid dosage form manufacturer

- Exclusive supply agreement for 100% of the cytosine that is required by Achieve
- Supply FDA enabling clinical trials
- Production sufficient to meet global market

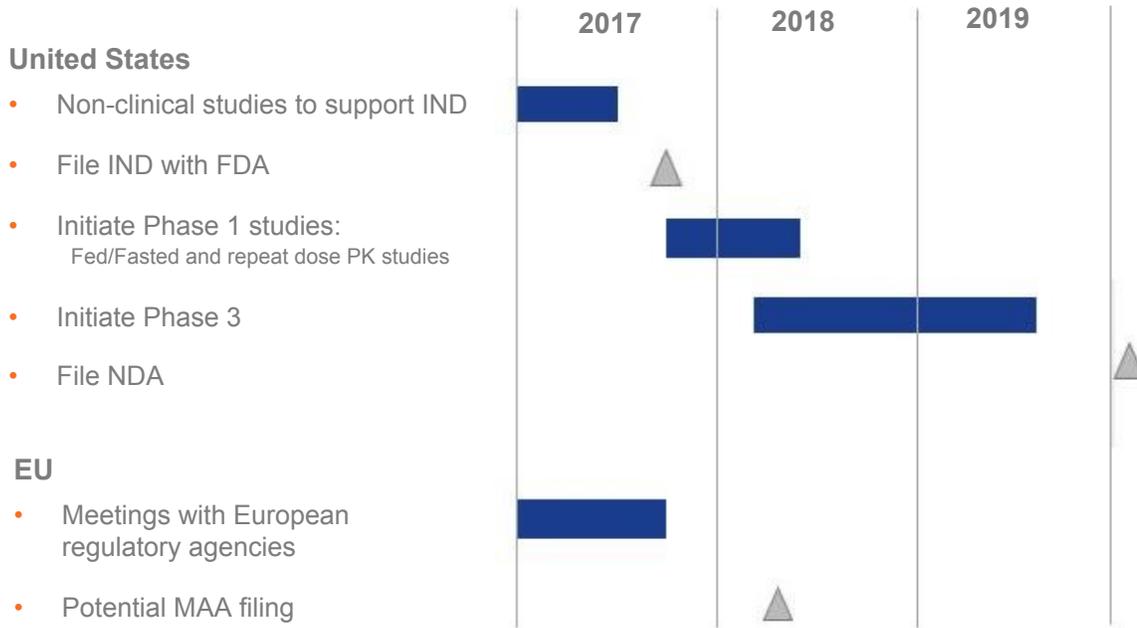
EU-GMP compliant pharmaceutical manufacturing

- Opened November 2013
- Capacity 4 billion tablets

Multiple Layers of Product Exclusivity

- Regulatory exclusivity
 - U.S.: 5 years under Hatch-Waxman
 - EU: 10 years under Article 8
- Exclusive Worldwide Supply of Cytisine from Sopharma (Bulgaria)
 - Derived from seeds of the tree Golden chain (*Cytisuslaburnum*)
 - Trees are currently only grown in orchards in Bulgaria controlled by Sopharma
 - Able to stockpile seeds for future demand
 - 5-7 years required for trees to mature
 - Currently not able to be chemically synthesized

Anticipated Path to Commercialization in U.S. and EU



Thank you