
**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 9, 2017

Audentes Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37833
(Commission File Number)

46-1606174
(IRS Employer
Identification No.)

600 California Street, 17th Floor
San Francisco, California
(Address of Principal Executive Offices)

94108
(Zip Code)

Registrant's Telephone Number, Including Area Code: (415) 818-1001

Not Applicable
(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))
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Item 2.02 Results of Operations and Financial Condition.

On March 9, 2017, the Company reported its financial results for the quarter and year ended December 31, 2016. A copy of the press release issued by the Company is furnished as Exhibit 99.1 to this report.

The information furnished with Item 2.02 of this report, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Exchange Act or under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press release dated March 9, 2017.

SIGNATURE

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 thereunto duly authorized.

Company Name

Date: March 9, 2017

By: /s/ Thomas Soloway

Thomas Soloway
Chief Financial Officer

Exhibit Index

Exhibit Number	Description
99.1	Press release dated March 9, 2017.

Audentes Therapeutics Reports Fourth Quarter and Full Year 2016 Financial Results and Provides Corporate Update

- IND for AT132 to treat X-Linked Myotubular Myopathy (XLMTM) submitted
- IND for AT342 to treat Crigler-Najjar Syndrome active
- Large scale, internal cGMP manufacturing established to support advancement of pipeline programs
- Preliminary clinical data from Phase 1/2 studies of AT342 and AT132 anticipated in the fourth quarter of 2017

San Francisco, Calif., March 9, 2017 / PRNewswire/ -- Audentes Therapeutics, Inc. (Nasdaq: BOLD), a biotechnology company focused on developing and commercializing gene therapy products for patients living with serious, life-threatening rare diseases, today reported its financial results for the fourth quarter and full year ended December 31, 2016, and provided an update on the company's recent achievements and anticipated upcoming milestones.

"2016 was a year of significant progress and accomplishment for Audentes," stated Matthew R. Patterson, President and Chief Executive Officer. "During the year we established large-scale cGMP manufacturing at our internal, state-of-the-art facility, submitted an IND for our Crigler Najjar program, initiated a clinical assessment study in patients with XLMTM and raised over \$75 million in a successful initial public offering. From this foundation, we plan to rapidly advance our pipeline of innovative gene therapy products into the clinic."

Mr. Patterson continued, "We remain focused on our mission to bring transformational products to patients living with serious, life-threatening rare diseases. To that end, 2017 promises to be an exciting year. We remain on track to obtain preliminary clinical data from the Phase 1/2 studies in our XLMTM and Crigler-Najjar programs by year end, and continue to make important progress in the development of our Pompe and CPVT programs."

Recent Achievements

- **AT132 for X-Linked Myotubular Myopathy:**
 - Investigational New Drug (IND) submitted to the U.S. Food and Drug Administration (FDA) in first quarter of 2017
 - As of March 1, 2017, enrolled 14 of the up to 16 patients anticipated in INCEPTUS, a prospective clinical assessment and phase 1/2 run-in study to characterize disease presentation in subjects aged three years or younger living with XLMTM. INCEPTUS is designed to serve as a longitudinal baseline and within-patient control, as well as facilitate operational aspects for subjects who enroll in ASPIRO, the phase 1/2 study of AT132
 - Initiated large-scale cGMP manufacturing at our internal state-of-the-art facility to supply the ASPIRO phase 1/2 study
 - **AT342 for Crigler-Najjar Syndrome:**
 - IND submitted and cleared by the FDA
 - Commenced enrollment in LUSTRO, a prospective clinical assessment and phase 1/2 run-in
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study to characterize the disease course, natural history, bilirubin variability and phototherapy usage of Crigler-Najjar subjects. LUSTRO is designed to serve as a longitudinal baseline and within-patient control, as well as facilitate operational aspects for subjects who enroll in VALENS, the phase 1/2 study of AT342

- Received Orphan Drug Designation from both the FDA and the European Medicines Agency (EMA)
- **Large-scale cGMP production initiated at state-of-the-art manufacturing facility:**
 - Plant designed and commissioned as a multi-product facility intended to support commercial licensure by both the FDA and EMA
 - Plan to initiate clinical trials of AT132 and AT342 this year with internally manufactured drug product

Upcoming Events

- **AT132 for X-Linked Myotubular Myopathy:**
 - Commence enrollment in ASPIRO, a phase 1/2 multicenter, multinational, open-label study in 12 XLMTM subjects less than five years of age
 - Report initial data from RECENSUS, a historical chart review, in mid-2017
 - Report initial data from INCEPTUS, the phase 1/2 run-in study, in mid-2017
 - Manufacture cGMP product at internal facility to supply ASPIRO
 - Report preliminary clinical data from ASPIRO in the fourth quarter of 2017
- **AT342 for Crigler-Najjar Syndrome:**
 - Commence enrollment in VALENS, the phase 1/2 multicenter, multinational, open-label study in approximately 12 subjects greater than one year of age
 - Report initial data from LUSTRO, the phase 1/2 run-in study in mid-2017
 - Manufacture cGMP product at internal facility to supply VALENS
 - Report preliminary clinical data from VALENS by the end of 2017
- **AT307 for CASQ2-CPVT:**
 - Complete IND enabling preclinical studies
 - File IND in the second half of 2017
- **AT982 for Pompe Disease:**
 - Investigator Sponsored IND for proof-of-concept study of AT982 to treat Pompe disease has been submitted to the FDA
 - Conduct additional preclinical studies in support of an IND filing to evaluate systemic administration of AT982 in Pompe disease
 - Report preliminary data from an investigator-sponsored proof-of-concept study evaluating intramuscular injection of AT982 in adult subjects with Pompe disease in the second half of 2017

Fourth Quarter and Full Year 2016 Financial Results

- **Cash Position:** As of December 31, 2016, Audentes had cash, cash equivalents, and short-term investments of \$104.9 million. The current cash position is projected to fund operations into late 2018.
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- **R&D Expense:** Research and development expenses were \$16.6 million for the fourth quarter of 2016 and \$48.8 million for the year ended December 31, 2016, compared to \$7.9 million and \$20.2 million, respectively, for the same periods in 2015. The increase in research and development expenses was primarily attributable to an increase in personnel and facility related expenses due to increased headcount, increased internal manufacturing costs, an increase in preclinical study costs for our development programs and an increase in expenses related to our expanded internal research and development activities.
- **G&A Expense:** General and administrative expenses were \$3.2 million for the fourth quarter of 2016 and \$11.3 million for the year ended December 31, 2016, compared to \$2.1 million and \$6.5 million, respectively, for the same periods in 2015. The increase in general and administrative expenses was primarily attributable to increased personnel, consulting and facility related costs due to increased headcount and an increase in professional service fees, audit fees and insurance costs following completion of the initial public offering in July 2016.
- **Net Loss:** Net loss was \$19.7 million for the fourth quarter of 2016 and \$59.7 million for the year ended December 31, 2016, compared to \$10.0 million and \$26.5 million, respectively, for the same periods in 2015.

About Audentes Therapeutics, Inc.

Audentes Therapeutics (Nasdaq: BOLD) is a biotechnology company focused on developing and commercializing gene therapy products for patients living with serious, life-threatening rare diseases. We have four products in development, AT132 for the treatment of X-Linked Myotubular Myopathy (XLMTM), AT342 for the treatment of Crigler-Najjar Syndrome, AT982 for the treatment of Pompe disease, and AT307 for the treatment of the CASQ2 subtype of Catecholaminergic Polymorphic Ventricular Tachycardia (CASQ2-CPVT). We are a focused, experienced and passionate team committed to forging strong, global relationships with the patient, research and medical communities.

For more information regarding Audentes, please visit www.audentestx.com.

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: our ability to advance our pipeline of products, including our ability to initiate Phase 1/2 studies and report preliminary clinical data in our XLMTM and Crigler-Najjar programs on their expected timelines; our plans to report data from RECENSUS, INCEPTUS and LUSTRO; our ability to scale our manufacturing processes in compliance with regulatory requirements to supply drug product to advance our programs, including our ability to internally manufacture the clinical supply of product for our planned studies in XLMTM and Crigler-Najjar; our plans to complete IND enabling studies in our CPVT program, and the ability to establish manufacturing and file an IND for this program; our plans to develop our Pompe disease program, including the conduct of additional preclinical studies, manufacturing scale-up and our ability to report preliminary data from an intramuscular proof-of-concept study in accordance with expected timelines; and the adequacy of our current cash position to fund our planned operations into late 2018. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Although the company believes that the expectations reflected in such forward-looking statements are reasonable, the company cannot guarantee future events, results, actions, levels of activity, performance or achievements, and the timing and results of biotechnology development and potential regulatory approval is inherently uncertain. Forward-looking statements are subject to risks and uncertainties that may cause the company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the company's

ability to advance its product candidates, obtain regulatory approval of and ultimately commercial its product candidates, the timing and results of preclinical and clinical trials, the company's ability to fund development activities and achieve development goals, the company's ability to establish and scale-up manufacturing processes that comply with regulatory requirements, the company's ability to protect intellectual property and other risks and uncertainties described under the heading "Risk Factors" in documents the company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

Selected Financial Information

Operating Results:

(amounts in thousands except share and per share data)

	Three months ended December 31,		Year ended December 31,	
	2016	2015	2016	2015
	<i>Unaudited</i>			
Operating expenses:				
Research and development	\$ 16,599	\$ 7,900	\$ 48,770	\$ 20,235
General and administrative	3,233	2,132	11,276	6,491
Total operating expenses	19,832	10,032	60,046	26,726
Loss from operations	(19,832)	(10,032)	(60,046)	(26,726)
Interest income	167	67	472	245
Other income (expense), net	(11)	6	(94)	23
Net loss	\$ (19,676)	\$ (9,959)	\$ (59,668)	\$ (26,458)
Net loss per share, basic and diluted	\$ (0.91)	\$ (4.97)	\$ (5.59)	\$ (23.03)
Shares used in computing net loss per share, basic and diluted	21,726,223	2,004,860	10,673,559	1,148,827

Selected Balance Sheet Information:

(amounts in thousands)

	December 31,	
	2016	2015
Cash, cash equivalents and short-term investments	\$ 104,883	\$ 95,227
Total assets	\$ 142,057	\$ 117,469
Total liabilities	\$ 22,686	\$ 15,780
Total stockholders' equity	\$ 119,371	\$ 101,689

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