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): April 8, 2019

AUDENTES THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware		
(State or other jurisdiction of incorporation)		
001-37833		**46-1606174**
(Commission File Number)		**(IRS Employer Identification No.)**
600 California Street, 17th Floor **San Francisco, California**		**94108**
(Address of principal executive offices)		**(Zip Code)**

(415) 818-1001
(Registrant's telephone number, including area code)

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:

☐ Written communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communication 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 Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 8.01 Other Events.

On April 8, 2019, Audentes Therapeutics, Inc. issued a press release announcing the expansion of its scientific platform and pipeline to advance vectorized antisense treatments for the treatment of Duchenne muscular dystrophy and myotonic dystrophy type 1. The press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press release titled "Audentes Therapeutics Announces Expansion of AAV Technology Platform and Pipeline with New Development Programs for Duchenne Muscular Dystrophy and Myotonic Dystrophy".

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 hereunto duly authorized.

AUDENTES THERAPEUTICS, INC.

By: /s/ Tom Soloway
Tom Soloway
Chief Financial Officer

Date: April 8, 2019

Exhibit 99.1

AUDENTES

Audentes Therapeutics Announces Expansion of AAV Technology Platform and Pipeline with New Development Programs for Duchenne Muscular Dystrophy and Myotonic Dystrophy

- Platform expansion combines the delivery power of AAV with the precision tools of antisense oligonucleotides to develop best-in-class treatments for Duchenne muscular dystrophy (DMD) and myotonic dystrophy type 1 (DM1)

- Exclusive license agreement with the Research Institute at Nationwide Children's Hospital to develop first product candidate, AT702, for an initial cohort of boys with DMD; expect to commence a Phase 1/2 study in Q4 2019

- Collaboration with Nationwide Children's to evaluate vectorized RNA knockdown and vectorized exon skipping for DM1; IND planned in 2020

- Pipeline & platform expansion gives Audentes potential to treat up to 80% of DMD and 100% of DM1 patients over time

- New programs powered by large scale, internal cGMP manufacturing capacity and vector engineering expertise

Conference call and webcast Monday, April 8, 2019 at 8:30 am ET
Webcast may be accessed via the Investor and Media page of the Audentes website
Call may be accessed by dialing (833) 659-8620 (U.S.) or (409) 767-9247 (international) and using conference ID# 8879216

SAN FRANCISCO, Apr. 8, 2019 / PRNewswire/ -- Audentes Therapeutics, Inc. (Nasdaq: BOLD), a leading AAV-based genetic medicines company focused on developing and commercializing innovative products for serious rare neuromuscular diseases, today announced it has expanded its scientific platform and pipeline to advance vectorized antisense treatments for the treatment of Duchenne muscular dystrophy (DMD) and myotonic dystrophy type 1 (DM1). This approach combines the delivery power of AAV with the precision tools of antisense oligonucleotides, or ASOs, to develop potential best-in-class therapeutic candidates for these devastating neuromuscular diseases. To accelerate these promising new programs, Audentes has entered into a licensing agreement and will collaborate with Nationwide Children's Hospital, utilizing the expertise of Kevin M. Flanigan, M.D. and Nicolas S. Wein, Ph.D., two recognized leaders in the field of genetic medicines for neuromuscular diseases.

"Today's announcement represents a significant step forward in expanding our scientific platform and deepening our pipeline of product candidates for neuromuscular diseases with high unmet medical need," stated Matthew R. Patterson, Chairman and Chief Executive Officer. "We see tremendous potential in combining AAV with validated oligonucleotide-based approaches to treat diseases that are not amenable to traditional AAV-based gene replacement. We believe this approach, combined with our in-house large-scale cGMP manufacturing capability, can deliver best-in-class therapies for the treatment of Duchenne muscular dystrophy and myotonic dystrophy."

"We are excited to be collaborating with Audentes to advance these novel, highly differentiated approaches for DMD and DM1," stated Dr. Flanigan, Director of Nationwide Children's Center for Gene Therapy.

Vectorized exon skipping uses an AAV vector to deliver an antisense sequence designed to induce cells to skip over faulty or misaligned sections of genetic code, leading to the expression of a more complete, functional protein. For the treatment of DMD, this approach has the potential to provide significant advantages over microdystrophin gene replacement strategies that produce a substantially truncated protein, which may limit the degree and durability of disease correction, as well as existing ASO therapies, whose efficacy is limited by poor biodistribution to muscle tissue.

Audentes and Nationwide Children's are collaborating to develop AT702, an AAV-antisense candidate designed to induce exon 2 skipping for DMD with duplications of exon 2 and mutations in exons 1-5 of the dystrophin gene. In preclinical studies of mice with exon 2 duplications, AT702 demonstrated robust proof-of-concept with dose-dependent increases in production of wild type or near-wild type length dystrophin protein and improvements in muscle function. Audentes is currently conducting additional preclinical work and expects to commence a Phase 1/2 study at Nationwide Children's in the fourth quarter of 2019.

Separate from the Nationwide Children's collaboration, Audentes is also conducting preclinical work to advance AT751 and AT753, additional vectorized exon skipping candidates, to treat DMD patients with genotypes amenable to exon 51 and exon 53 skipping. Both AT751 and AT753 utilize the same vector construct backbone as AT702, enabling a potentially accelerated path into clinical development. With these initial programs, Audentes is targeting more than 25% of patients with DMD, and has plans to leverage its vectorized exon skipping platform to develop further product candidates to address up to 80% of DMD patients over time.

In addition, Audentes and Nationwide Children's are evaluating vectorized RNA knockdown and vectorized exon skipping for myotonic dystrophy type 1 (DM1). Both approaches are designed to prevent the accumulation of toxic dystrophia myotonica-protein kinase (DMPK) RNA in affected cells, thereby restoring normal cellular function. RNA knockdown and exon skipping have both been clinically validated in studies with ASOs. As with DMD, combining these approaches with AAV delivery is expected to overcome the biodistribution limitations of ASO-based therapies. Preclinical studies are underway, and Audentes expects an IND for the selected product candidate, AT466, to be filed in 2020.

Audentes plans to leverage its proprietary AAV gene therapy technology platform, consisting of end-to-end internal expertise from vector construct engineering to state-of the-art large-scale cGMP manufacturing, to rapidly advance these programs from discovery through clinical development. Internal process and analytical development, fill-finish, and QC testing capabilities complete the company's fully-integrated approach to production and release of product candidates for clinical and commercial use. The current 1,000-liter scale manufacturing operation provides enough capacity for global commercialization of the company's lead program AT132, as well as continued clinical development of pipeline programs, and the facility is designed for expansion to include an additional 8,000 liters of production capacity.

Conference Call

At 8:30 a.m. Eastern Time today, April 8, 2019, Audentes management will host a conference call and simultaneous webcast to discuss the expansion of its AAV technology platform and new development programs for DMD and DM1. To access a live webcast of the conference call and the slides used during today's presentation, please visit the Investor and Media page of the Audentes website at www.audentestx.com. Alternatively, please call (833) 659-8620 (U.S.) or (409) 767-9247 (international) and dial the conference ID#

8879216 to access the call. A replay of the webcast and slides will be available on the Audentes website for approximately 30 days.

About Duchenne Muscular Dystrophy
Duchenne muscular dystrophy (DMD) is the most common type of muscular dystrophy in children, affecting approximately 1 in 3,500 to 5,000 male births, with more than 300,000 patients living with the disease worldwide. DMD is caused by mutations in the dystrophin gene, which encodes the protein dystrophin, a structural protein involved in maintaining muscle cell integrity. Patients with DMD typically develop muscle weakness in the early years of life and become wheelchair-bound in their early teens. As the disease progresses, patients typically develop respiratory, orthopedic, and cardiac complications. Cardiomyopathy and breathing difficulties usually begin by the age of 20, and few individuals with DMD live beyond their thirties. There is no cure for DMD, and for most patients, there are no satisfactory symptomatic or disease-modifying treatments.

About Myotonic Dystrophy Type 1
Myotonic dystrophy type 1 (DM1), is a rare, neuromuscular disease that affects multiple organ systems, and is characterized primarily by myotonia and progressive muscle wasting and weakness. DM1 has several forms which range in age of presentation and severity, including congenital, infantile, juvenile, and adult (classic). There are more than 100,000 patients living with DM1 across the United States, Europe, and Japan. The disease is inherited in an autosomal dominant pattern and is caused by a mutation called a CTG trinucleotide repeat in the dystrophia myotonica-protein kinase (DMPK) gene. Patients with DM1 experience reduced quality of life and shortened life expectancy. There are no disease modifying therapies approved for DM1.

About Audentes Therapeutics, Inc.
Audentes Therapeutics (Nasdaq: BOLD) is a leading AAV-based genetic medicines company focused on developing and commercializing innovative products for serious rare neuromuscular diseases. We are leveraging our AAV gene therapy technology platform and proprietary manufacturing expertise to develop programs across three modalities: gene replacement, vectorized exon skipping, and vectorized RNA knockdown. Our product candidates are showing promising therapeutic profiles in clinical and preclinical studies across a range of neuromuscular diseases. Audentes is a focused, experienced and passionate team driven by the goal of improving the lives of patients.

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

About Nationwide Children's Hospital
Named to the Top 10 Honor Roll on *U.S. News & World Report's* 2018-19 list of "Best Children's Hospitals," Nationwide Children's Hospital is one of America's largest not-for-profit freestanding pediatric health care systems providing wellness, preventive, diagnostic, treatment and rehabilitative care for infants, children and adolescents, as well as adult patients with congenital disease. Nationwide Children's has a staff of more than 13,000 providing state-of-the-art pediatric care during more than 1.4 million patient visits annually. As home to the Department of Pediatrics of The Ohio State University College of Medicine, Nationwide Children's physicians train the next generation of pediatricians and pediatric specialists. The Research Institute at Nationwide Children's Hospital is one of the top 10 National Institutes of Health-funded freestanding pediatric research facilities. More information is available at NationwideChildrens.org.

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, the timing and nature of research and development activities, the nature of the results of data, the timing of regulatory filings, the

expected market size of DMD and DM1 and potential penetration into those markets, anticipated manufacturing activities and the expected benefits of the company's product candidates and technology platform. 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 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.

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