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): February 27, 2019

Audentes Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37833**	**46-1606174**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
600 California Street, 17th Floor San Francisco, California		**94108**
(Address of Principal Executive Offices)		**(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))

Indicate by check mark whether the registrant is an emerging growth company 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 February 27, 2019, Audentes Therapeutics, Inc. (the "***Company***") reported its financial results for the quarter and year ended December 31, 2018. 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 February 27, 2019.

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: February 27, 2019

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

Exhibit 99.1

AUDENTES

Audentes Therapeutics Reports Fourth Quarter 2018 and Full Year Financial Results and Provides Corporate Update

On track to select optimal dose of AT132 for the treatment of XLMTM in the second quarter of 2019, and gain final agreement on BLA and MAA submission pathways in the third quarter of 2019

On track to submit an Investigational New Drug (IND) application for AT845 for Pompe Disease in the third quarter of 2019

Strong balance sheet with December 31, 2018 cash, cash equivalents, marketable securities, and restricted cash of $418.1 million, expected to fund operations into 2021

SAN FRANCISCO, February 27, 2019 / PRNewswire/ -- Audentes Therapeutics, Inc. (Nasdaq: BOLD), a biotechnology company focused on developing and commercializing innovative 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, 2018 and provided an update on the company's recent achievements and anticipated upcoming milestones.

"2018 was a transformative year marked by significant progress in advancing our mission to bring innovative gene therapy products to patients living with severe, life-threatening rare diseases," stated Matthew R. Patterson, Chairman and Chief Executive Officer. "Importantly, we established a compelling clinical profile for AT132, our product candidate being developed to treat XLMTM, and are in ongoing discussions with the FDA and EMA to facilitate agreement on license application pathways for AT132."

Mr. Patterson continued, "We enter 2019 with over two years of cash runway, a position of strength that will ensure our research and development efforts continue to advance across our promising portfolio. To that end, we remain highly encouraged by preclinical work in our Pompe disease program and continue to guide to a third quarter IND submission for AT845. We are also continuing to advance our new product candidate, AT720, a novel AAV-based therapeutic being developed to treat a large neuromuscular disease with significant unmet medical need, and plan to disclose the therapeutic target and provide a program overview in the second quarter of 2019."

Recent Achievements & Upcoming Key Events

AT132 for X-Linked Myotubular Myopathy (XLMTM):

- Completed productive initial interactions with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) to discuss potential BLA and MAA submission pathways for AT132 under the Regenerative Medicine Advanced Therapy (RMAT) and Priority Medicines (PRIME) designations, respectively.
- Proceeding with previously announced plan to enroll an additional 3-5 patients in Cohort 2 ($3x10^{14}$ vector genomes per kilogram) of ASPIRO, the Phase 1/2 study of AT132.

- On track to select optimal dose of AT132 in the second quarter of 2019. Optimal dose selection will be determined after an evaluation of the six-month biopsy results from the first three patients dosed in Cohort 2 of ASPIRO.
- Subsequent to the determination of the optimal dose, Audentes plans to provide an updated data package to FDA and EMA to facilitate final agreement on license application pathways in the third quarter of 2019.
- Continuing process and facility validation efforts based on preliminary FDA feedback on our chemistry, manufacturing, and controls (CMC) plans, to support AT132 registration efforts.
- Since program inception, AT132 clinical material has been manufactured utilizing the same process, facility, and scale intended to supply the commercial market.
- Next clinical data presentation planned at the 2019 Annual Meeting of the American Society of Gene and Cell Therapy (ASGCT) in Washington, D.C. from April 29th to May 2nd.

AT845 for Pompe Disease:

- Encouraged by continued progress in preclinical studies.
- On track to file IND in the third quarter of 2019.

AT342 for Crigler-Najjar Syndrome:

- VALENS Phase 1/2 study ongoing.
- Next program update planned in the second quarter of 2019.

Pipeline Expansion:

- Advancing our new product candidate, AT720, a novel AAV-based therapeutic being developed to treat a large neuromuscular disease with significant unmet medical need.
- On track to disclose the therapeutic target and provide a program overview in the second quarter of 2019.

Manufacturing:

- State-of-the-art, internal, large-scale cGMP manufacturing facility provides sufficient capacity for AT132 global commercialization as well as continued clinical development of pipeline programs.
- Currently operating in mammalian, serum-free suspension culture production process at 1,000-liter scale with the ability to add up to an additional 5,000 liters of capacity.
- Internal analytical development, fill-finish, and QC testing capabilities provide a fully-integrated platform to design, manufacture, fill, and release our product candidates for clinical and eventually, commercial use.

Corporate:

- Expanded our leadership team with the addition of Eric Mosbrooker, Senior Vice President and Chief Commercial Officer, to lead the development and execution of our global commercial strategy.

Fourth Quarter and Full Year 2018 Financial Results

- **Cash Position:** At December 31, 2018, Audentes had cash, cash equivalents, marketable securities and restricted cash of $418.1 million. In 2018, we strengthened the balance sheet with two follow-on financings, resulting in aggregate net proceeds of approximately $380 million after the deduction of

underwriting discounts, commissions, and offering expenses. Our current cash, cash equivalents, and marketable securities are expected to fund operations into 2021.

- **Research and Development Expenses**: Research and development expenses were $28.2 million for the fourth quarter of 2018 and $104.4 million for the year ended December 31, 2018, compared to $21.7 million and $75.9 million, respectively, for the same periods in 2017. The increase in research and development expenses was primarily attributable to increases in our research and development headcount and related personnel and facilities costs as we continued to make investments in our internal research and development and manufacturing capabilities.

- **General and Administrative Expenses:** General and administrative expenses were $9.4 million for the fourth quarter of 2018 and $30.0 million for the year ended December 31, 2018, compared to $5.2 million and $17.3 million, respectively, for the same periods in 2017. The increase in general and administrative expenses was primarily attributable to increases in our general and administrative headcount and related personnel and facilities costs, increases in consulting, professional services and audit fees, and costs related to on-going regulatory compliance activities as a public company.

- **Net Loss:** Net loss was $35.6 million for the fourth quarter of 2018 and $128.8 million for the year ended December 31, 2018, compared to $24.4 million and $90.2 million, respectively, for the same periods in 2017.

Conference Call
At 4:30 p.m. Eastern Time today, Audentes management will host a conference call and a simultaneous webcast to discuss its fourth quarter and full year 2018 financial results and provide a corporate update. To access a live webcast of the conference call, please visit the Events & Presentations page within the Investors + Media section 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# 1196899 to access the call.

A replay of the webcast will be available on the Audentes website for approximately 30 days.

About Audentes Therapeutics, Inc.
Audentes Therapeutics (Nasdaq: BOLD) is a biotechnology company focused on developing and commercializing innovative gene therapy products for patients living with serious, life-threatening rare diseases. We are currently conducting Phase 1/2 clinical studies of our lead product candidates AT132 for the treatment of X-Linked Myotubular Myopathy (XLMTM) and AT342 for the treatment of Crigler-Najjar Syndrome. We have two additional product candidates in development, including AT845 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: anticipated clinical milestones, the timing and nature of clinical development activities, the timing of the release of data from ongoing clinical trials, the timing of regulatory interactions and the nature of potential agreements reached with regulatory

authorities, the timing of regulatory filings, the expected benefits of the company's product candidates and the use and adequacy of cash reserves. 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 commercialize its product candidates, the timing and results of preclinical and clinical trials, fund development activities and achieve development goals, establish and scale-up manufacturing processes that comply with regulatory requirements, 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

Amounts in thousands except share and per share data

Operating Results

	Three months ended December 31,		Year ended December 31,	
	2018	2017	2018	2017
	Unaudited			
Operating expenses:				
Research and development	$ 28,213	$ 21,671	$ 104,370	$ 75,902
General and administrative	9,385	5,210	30,002	17,275
Total operating expenses	37,598	26,881	134,372	93,177
Loss from operations	(37,598)	(26,881)	(134,372)	(93,177)
Interest income, net	2,368	284	6,030	767
Other expense, net	(362)	(24)	(479)	(74)
Loss before income taxes	(35,592)	(26,621)	(128,821)	(92,484)
Income tax benefit	-	2,246	-	2,246
Net loss	$ (35,592)	$ (24,375)	$ (128,821)	$ (90,238)
Net loss per share, basic and diluted	$ (0.84)	$ (0.82)	$ (3.40)	$ (3.40)
Shares used in computing net loss per share, basic and diluted	42,400,890	29,847,934	37,839,855	26,578,162

Selected Balance Sheet Data

	December 31, 2018	December 31, 2017
Cash, cash equivalents, marketable securities and restricted cash	$ 418,055	$ 137,299
Total assets	$ 472,555	$ 178,662
Total liabilities	$ 29,801	$ 22,064
Total stockholders' equity	$ 442,754	$ 156,598

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