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): November 5, 2018

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 November 6, 2018, Audentes Therapeutics, Inc. (the "***Company***") reported its financial results for the quarter and nine months ended September 30, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 5, 2018, Kush Parmar, M.D., Ph.D. notified the Company of his decision to resign from the Board effective as of the same date. The resignation was not due to any disagreement with the Company.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	**Description**
99.1	Press release dated November 6, 2018.

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: November 6, 2018

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

AUDENTES

Exhibit 99.1

Audentes Therapeutics Reports Third Quarter 2018 Financial Results and Provides Corporate Update

- *Completed Cohort 2 enrollment in ASPIRO, the Phase 1/2 clinical study of AT132 for the treatment of X-linked Myotubular Myopathy*

- *Plan interactions with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) in Q4 2018 to discuss development plans and the potential registration pathway for AT132*

San Francisco, Calif., Nov. 6, 2018 / 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 third quarter ended September 30, 2018 and provided an update on the company's recent achievements and upcoming milestones.

"In the third quarter, we continued to see exciting progress in the clinical development of AT132," stated Matthew R. Patterson, Chairman and Chief Executive Officer. "We recently presented new ASPIRO data at the 23rd International Annual Congress of the World Muscle Society demonstrating significant and durable improvements in neuromuscular and respiratory function in all treated patients. We are particularly pleased that three of our Cohort 1 patients have achieved ventilator independence, an unprecedented result for children with congenital myopathies that have been ventilated since birth. In addition, we have recently completed enrollment of the Cohort 2 dose of $3x10^{14}$ vg/kg, including three treated patients and one untreated control patient. We look forward to engaging with the FDA and EMA in the coming weeks to discuss development plans and the potential registration pathway for AT132, and to advance our goal of making this important treatment available to patients living with XLMTM as rapidly as possible."

Mr. Patterson continued, "Additionally, our recent follow-on financing positions Audentes to deliver on many important milestones, including the initiation of our commercial planning activities for AT132, progression of our Pompe program toward IND, and expansion of our pipeline of innovative AAV-based product candidates targeting neuromuscular diseases with significant unmet medical need."

Recent Achievements & Upcoming Key Events

- AT132 for XLMTM:
  - Presented additional positive interim data from ASPIRO during an oral presentation at the 23rd International Annual Congress of the World Muscle Society (WMS)
  - The ASPIRO WMS data set included safety and efficacy results ranging from 4 to 48 weeks for eight patients enrolled in ASPIRO, including the seven patients enrolled in Cohort 1 ($1x10^{14}$ vg/kg; six treated and one untreated control) and the sentinel patient in Cohort 2 ($3x10^{14}$ vg/kg), as well as week 24 muscle biopsy data for the first four treated patients. All treated patients showed meaningful improvements in neuromuscular and respiratory function. Three patients achieved ventilator independence, and all other patients showed significant reductions in ventilator dependence. Additionally, the growing body of week 24 muscle biopsy data continued to show robust tissue transduction, protein expression, and histological improvement with AT132 treatment at the initial $1x10^{14}$ vg/kg dose.

- Completed enrollment of Cohort 2 of ASPIRO, including three patients treated at a dose of $3x10^{14}$ vg/kg and one enrolled as the Cohort 2 untreated control
- Awarded Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA
- Plan to engage with FDA and EMA in Q4 2018 to discuss development plans and the potential registration pathway for AT132 in both the United States and Europe
- Next program update planned in Q1 2019

- AT982 for Pompe Disease:
  - Completed analysis of nonclinical studies and determined mechanism of the dose-dependent safety signal observed in the NHP toxicology study
  - Additional IND-enabling studies underway in the Pompe mouse model
  - Plan to file IND in 2019

- AT342 for Crigler-Najjar Syndrome:
  - Enrollment in VALENS Phase 1/2 study ongoing
  - Next program update planned in Q1 2019

- Pipeline expansion:
  - Continuing to advance our research initiative focused on the design and development of a novel AAV-based therapeutic targeting a large neuromuscular disease with significant unmet medical need

- Manufacturing:
  - Continuing BLA preparation and validation efforts for our internal cGMP manufacturing facility, AT132 process and analytical methods
  - Since program inception, clinical material has been manufactured utilizing substantially the same process, scale, and facility intended to supply the commercial market
  - Current facility, scale and process yield provide sufficient capacity for the expected global commercial needs of XLMTM and Crigler-Najjar markets, and ongoing clinical supply for current and planned pipeline programs

Third Quarter 2018 Financial Results

- **Cash Position:** As of September 30, 2018, we had cash, cash equivalents, marketable securities and restricted cash of $285.5 million, which includes approximately $3.6 million of restricted cash and approximately $1.3 million of long-term investments. In October 2018, we further strengthened our balance sheet with the completion of a follow-on financing, issuing 5,980,000 shares of common stock (inclusive of 780,000 shares of common stock pursuant to the underwriters' option to purchase additional shares) at an offering price of $29.00 per share, resulting in net proceeds of approximately $162.8 million after the deduction of underwriting discounts, commissions and estimated offering expenses. Our current cash, cash equivalents, and marketable securities are expected to fund operations into 2021.

- **Research and Development Expense**: Research and development expense was $29.9 million for the third quarter of 2018 compared to $20.9 million for the same period in 2017, an increase of $9.0 million. The increase in research and development expense was primarily attributable to an increase in development costs related to our AT982 program, increased headcount and related facility costs, increased internal manufacturing costs and higher stock-based compensation expense. Research and development expense for the third quarter includes $2.6 million of non-cash stock-based compensation expense. For the nine months

ended September 30, 2018, research and development expense was $76.2 million compared to $54.2 million for the same period in 2017.

- **General and Administrative Expense:** General and administrative expense was $7.8 million for the third quarter of 2018 compared to $4.3 million for the same period in 2017, an increase of $3.5 million. The increase in general and administrative expense was primarily attributable to increases in headcount and related facility costs, professional service fees, stock-based compensation expense and compliance costs associated with operating as a public company. General and administrative expense for the third quarter includes $2.0 million of non-cash stock-based compensation expense. For the nine months ended September 30, 2018, general and administrative expense was $20.6 million compared to $12.1 million for the same period in 2017.
- **Net Loss:** Net loss was $36.3 million for the third quarter of 2018 compared to $25.0 million for the same period in 2017. For the nine months ended September 30, 2018, net loss was $93.2 million as compared to $65.9 million for the same period in 2017.

Conference Call
At 4:30 pm Eastern Time today after the market closes, Audentes management will host a conference call and a simultaneous webcast to discuss its third quarter 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 Investor + 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# 1473209 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 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: anticipated clinical milestones, potential pipeline expansion, the timing and nature of clinical development activities, the timing of the release of data from ongoing or upcoming clinical trials, the timing of regulatory filings, the expected safety profile of the company's product candidates, the expected benefits of the company's product candidates, the expected capacity of the company's internal manufacturing facility, 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, the company's ability to 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

Operating Results:
(amounts in thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
	Unaudited			
Operating expenses:				
Research and development	$ 29,918	$ 20,868	$ 76,157	$ 54,231
General and administrative	7,817	4,342	20,617	12,065
Total operating expenses	37,735	25,210	96,774	66,296
Loss from operations	(37,735)	(25,210)	(96,774)	(66,296)
Interest income, net	1,509	221	3,662	483
Other expense, net	(65)	(20)	(117)	(50)
Net loss	$ (36,291)	$ (25,009)	$ (93,229)	$ (65,863)
Net loss per share, basic and diluted	$ (0.97)	$ (0.88)	$ (2.57)	$ (2.59)
Shares used in computing net loss per share, basic and diluted	37,359,877	28,388,145	36,302,803	25,476,261

Selected Balance Sheet Information:
(amounts in thousands)

	September 30, 2018	December 31, 2017
	Unaudited	
Cash, cash equivalents, marketable securities and restricted cash	$ 285,542	$ 137,299
Total assets	$ 337,773	$ 178,662
Total liabilities	$ 27,218	$ 22,064
Total stockholders' equity	$ 310,555	$ 156,598

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