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): August 7, 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 August 7, 2018, Audentes Therapeutics, Inc. (the "***Company***") reported its financial results for the quarter and six months ended June 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 9.01 Financial Statements and Exhibits.

Exhibit Number	**Description**
99.1	Press release dated August 7, 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: August 7, 2018

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

Exhibit 99.1

Audentes Therapeutics Reports Second Quarter 2018 Financial Results and Provides Update on ASPIRO, the Phase 1/2 Clinical Trial of AT132 in Patients with X-Linked Myotubular Myopathy

- *Muscle biopsy data demonstrate highly efficient tissue transduction as indicated by vector copy number, robust myotubularin protein expression as assessed by western blot, and significant improvement in histology in first three treated patients at 24-week timepoint*

- *Efficacy analysis updated to include week 24 assessments for Patient 3, demonstrating significant improvements in neuromuscular and respiratory function and reduction in ventilator dependence*

- *No serious adverse events in any patient since the last data update provided at ASGCT in May 2018*

- *Proceeding with per protocol dose escalation from $1x10^{14}$ vector genomes per kilogram (vg/kg) to $3x10^{14}$ vg/kg*

San Francisco, Calif., August 7, 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 second quarter ended June 30, 2018 and provided an update on ASPIRO, the phase 1/2 clinical trial of AT132 in patients with X-Linked Myotubular Myopathy (XLMTM), including muscle biopsy results from the first three patients treated in the study and the week 24 efficacy analysis for Patient 3.

"We're very pleased with continued clinical progress in ASPIRO, and in particular the results of the muscle biopsy data from the first three ASPIRO patients, which show unprecedented levels of tissue transduction and protein expression from a systemically administered gene therapy for a neuromuscular disease," stated Dr. Suyash Prasad, Senior Vice President and Chief Medical Officer of Audentes. "The consistency of effect between the functional measures and histological improvement gives us further confidence in the emerging profile of AT132 as a therapy with the potential to bring transformative benefit to patients living with XLMTM. We look forward to continuing with the per protocol dose escalation and initiating enrollment of the second dose cohort at the $3x10^{14}$ vg/kg dose in the coming weeks."

"We anticipate building on the significant momentum of our XLMTM program with continued progress across our portfolio of product candidates, including advancing an exciting new research initiative directed toward a large neuromuscular disease with significant unmet medical need," stated Matthew R. Patterson, Chief Executive Officer of Audentes. "Coupled with further advancements in the commercial readiness of our manufacturing operations, we believe we are well-positioned as a leader in the AAV gene therapy field with significant near-term growth potential."

ASPIRO Update

Today's announcement includes incremental safety, efficacy and muscle biopsy data updates since the most recent data disclosure in an oral presentation held on May 16, 2018 at the American Society of Gene and Cell Therapy (ASGCT) Annual Meeting.

Safety
There have been no serious adverse events in any patient since the last update.

Efficacy
The ASGCT oral presentation included week-24 assessments for Patients 1, 2, and 4 (untreated control) as well as earlier assessments for Patients 5, 6, and 7 from the Cohort 1 expansion group. Today's update adds week 24 assessments for Patient 3 to the available data set, including:

- CHOP-INTEND score: increased from 34 at baseline to 48 at week 24 (41% increase)
- Maximal Inspiratory Pressure (MIP): increased from 26 cmH_20 at baseline to 70 cmH_20 at week 24 (170% increase)
- Ventilator support: decreased from continuous (24 hours/day) invasive ventilator support at baseline to night-time only (8 hours/day) ventilator support at week 24

Subsequent to the week 24 assessment, Patient 2 successfully achieved ventilator independence.

Muscle biopsy
Muscle biopsy samples at the 24-week timepoint show evidence of highly efficient tissue transduction as indicated by vector copy number, robust myotubularin protein expression as assessed by western blot, and significant improvement in histology as assessed by improved myofiber size, nuclei peripheralization and organelle localization.

	Vector Copy Per Diploid Genome		**MTM1 Protein Expression As a Percent of Normal**	
	Baseline	Week 24	Baseline	Week 24
Patient 1	BLOD	6.2	BLOD	~120%
Patient 2	BLOD	7.1	5%	~250%
Patient 3	BLOD	2.7	BLOD	~80%

BLOD = Below limit of detection

Based on these findings, the independent Data Monitoring Committee for ASPIRO recommended continuing with dose escalation per protocol, from $1x10^{14}$ vg/kg for Cohort 1 to $3x10^{14}$ vg/kg for Cohort 2. Patient screening is underway, and dosing is expected to commence in the coming weeks.

Recent Achievements & Upcoming Key Events

- AT132 for XLMTM:
  - Presented positive interim data from ASPIRO during an oral presentation at the ASGCT Annual Meeting in May 2018.
  - The ASPIRO data set now includes safety and efficacy results through week 24 for patients 1-4 of Cohort 1, and up to week 4 data for the Cohort 1 expansion patients (patients 5-7), as well as week 24 muscle biopsy data for patients 1-3. To date, all patients show clinically meaningful improvements in neuromuscular and respiratory function. Patients 1-3 show significant reductions in ventilator dependence, with Patient 1 achieving ventilator independence by week 24.
  - Awarded PRIME designation by the European Medicines Agency

- Next data update anticipated at the 23rd International Congress of the World Muscle Society, October 2–6, 2018

- AT342 for Crigler-Najjar Syndrome:
  - Presented initial proof of concept at a dose of $1.5x10^{12}$ vg/kg at the Annual Congress of the 51st Annual Meeting of the European Society for Paediatric Gastroenterology, Hepatology and Nutrition in May 2018
  - AT342 has been well-tolerated with no significant treatment-related safety signals
  - Dose escalating to $6x10^{12}$ vg/kg and plan to provide the next interim data update from VALENS in the fourth quarter of 2018

- AT982 for Pompe Disease:
  - Presented preclinical data from AT982 in a Pompe mouse model at the ASGCT Annual Meeting in May 2018
  - Conducting preclinical program in support of IND submission to evaluate AT982 in both infantile and late onset Pompe disease patients
  - Plan to submit the AT982 IND in 2019
  - Plan to initiate INQUIRO, a prospective natural history run-in study in both infantile and late onset Pompe disease patients in the first half of 2019

- AT307 for CASQ2-CPVT:
  - IND application is active
  - Received Fast Track designation from the FDA
  - Continuing patient identification activities to better characterize CASQ2-CPVT prevalence. Results from these efforts will inform clinical plans as they relate to the timing of a potential phase 1/2 clinical trial.

- Pipeline expansion:
  - Research initiative underway focused on the design and development of a novel AAV-based therapeutic targeting a large neuromuscular disease with significant unmet medical need

- Manufacturing:
  - Commenced 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 and scale provide sufficient capacity for the expected global commercial needs of XLMTM and Crigler-Najjar markets, and ongoing clinical supply for current pipeline programs.

Second Quarter 2018 Financial Results

- **Cash Position:** At June 30, 2018, Audentes had cash, cash equivalents, and short-term investments of $314.4 million. Current cash, cash equivalents and short-term investments are expected to fund operations into the second half of 2020.

- **Research and Development Expense**: Research and development expense was $26.3 million for the second quarter of 2018 compared to $18.8 million for the same period in 2017, an increase of $7.5 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 compensation expense. Research and development expense for the second quarter includes $2.3 million of non-cash stock-based compensation expense. For the six months ended June 30, 2018, research and development expense was $46.2 million compared to $33.4 million for the same period in 2017.

- **General and Administrative Expense:** General and administrative expense was $6.3 million for the second quarter of 2018 compared to $4.1 million for the same period in 2017, an increase of $2.2 million. The increase in general and administrative expense was primarily attributable to increases in headcount and related facility costs, professional service fees, stock compensation expense and public company regulatory compliance costs. General and administrative expense for the second quarter includes $1.8 million of non-cash stock-based compensation expense. For the six months ended June 30, 2018, general and administrative expense was $12.8 million compared to $7.7 million for the same period in 2017.
- **Net Loss:** Net loss was $31.4 million for the second quarter of 2018 compared to $22.7 million for the same period in 2017. For the six months ended June 30, 2018, net loss was $56.9 million as compared to $40.9 million for the same period in 2017.

Conference Call

At 8:00 a.m. Eastern Time today, Audentes management will host a conference call and a simultaneous webcast to discuss its second quarter 2018 financial results and provide an update on ASPIRO, the phase 1/2 clinical trial of AT132 in Patients with X-Linked Myotubular Myopathy. 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 1-833-659-8620 (U.S.) or 1-409-767-9247 (international) and dial the conference ID 2572579 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 trials 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 clinical trials, the timing of regulatory filings, 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 June 30,		Six months ended June 30,	
	2018	2017	2018	2017
	Unaudited			
Operating expenses:				
Research and development	$ 26,348	$ 18,776	$ 46,239	$ 33,363
General and administrative	6,281	4,065	12,800	7,723
Total operating expenses	32,629	22,841	59,039	41,086
Loss from operations	(32,629)	(22,841)	(59,039)	(41,086)
Interest income, net	1,294	115	2,153	262
Other expense, net	(32)	(13)	(52)	(30)
Net loss	$ (31,367)	$ (22,739)	$ (56,938)	$ (40,854)
Net loss per share, basic and diluted	$ (0.85)	$ (0.87)	$ (1.59)	$ (1.70)
Shares used in computing net loss per share, basic and diluted	36,935,940	26,212,614	35,765,506	23,996,187

Selected Balance Sheet Information:
(amounts in thousands)

	June 30, 2018	December 31, 2017
	Unaudited	
Cash, cash equivalents and short-term investments	$ 314,434	$ 133,605
Total assets	$ 366,051	$ 178,662
Total liabilities	$ 25,087	$ 22,064
Total stockholders' equity	$ 340,964	$ 156,598

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