UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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 4, 2019

Otonomy, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-36591	26-2590070
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4796 Executive Drive
San Diego, CA 92121
(Address of principal executive offices, including zip code)

(619) 323-2200
(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 (see General Instruction 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 March 4, 2019, Otonomy, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2018. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated March 4, 2019

SIGNATURES

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.

OTONOMY, INC.

Date: March 4, 2019

By: /s/ Paul E. Cayer
Paul E. Cayer
Chief Financial and Business Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

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

- ***OTIVIDEX*ä *Phase 3 trial in Ménière's disease on track for results in first half 2020***
- ***OTO-313 Phase 1/2 trial in tinnitus expected to start in second quarter of 2019***
- ***OTO-413 Phase 1/2 trial in hearing loss expected to start in third quarter of 2019***
- ***$15 million term loan completed to extend cash runway into 2021***

Conference call and webcast today at 4:30 p.m. EST

SAN DIEGO, March 4, 2019 -- Otonomy, Inc. (NASDAQ: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today reported financial results for the fourth quarter and year ended December 31, 2018 and provided an update on its product pipeline and corporate activities. The company will host a conference call and webcast today at 4:30 p.m. EST to discuss recent highlights and financial results.

"Our accomplishments in 2018 have positioned the company for significant advancement in 2019 as we continue enrollment of our Phase 3 trial of OTIVIDEX in Ménière's disease, initiate Phase 1/2 clinical trials for OTO-313 in tinnitus and OTO-413 in hearing loss, and work towards delivering value-creating results for all three clinical trials in 2020," said David A. Weber, Ph.D., president and CEO of Otonomy. "We have also ensured that the necessary resources are in place to both complete these trials and continue to advance our exciting preclinical programs by carefully managing our expenses, establishing a co-promotion partnership for OTIPRIOÒ, and completing a debt financing that extends our cash runway into 2021. I look forward to sharing our plan and upcoming catalysts more broadly with investors during 2019."

Product Pipeline and Corporate Update

- **OTIVIDEX: Phase 3 trial in Ménière's disease enrolling patients with results expected in the first half of 2020.** Otonomy has completed one successful Phase 3 trial and is conducting this additional pivotal trial to support a submission for U.S. registration of OTIVIDEX in Ménière's disease. The company plans to enroll approximately 160 patients, with the design and conduct of this trial based on the successful AVERTS-2 trial. Results from the AVERTS-2 trial were presented at the American Academy of Otolaryngology - Head and Neck Surgery Foundation (AAO-HNSF) Annual Meeting in October 2018.
- **OTO-313: Phase 1/2 trial in tinnitus patients expected to start in the second quarter of 2019 with results in the first half of 2020.** OTO-313 is a sustained-exposure formulation of

the NMDA receptor antagonist gacyclidine. The Phase 1/2 clinical trial will include an initial safety cohort followed by an exploratory efficacy study that will enroll approximately 50 patients with unilateral tinnitus. An overview of the OTO-313 program was recently presented at the Association for Research in Otolaryngology (ARO) Annual Meeting.

- **OTO-413: Phase 1/2 trial in hearing loss patients expected to start in the third quarter of 2019 with results in the second half of 2020.** OTO-413 is a sustained-exposure formulation of brain-derived neurotrophic factor (BDNF) in development for the repair of cochlear synaptopathy, an underlying cause of hearing loss. The Phase 1/2 trial will enroll approximately 40 patients with speech-in-noise hearing loss. A presentation related to the OTO-413 program was recognized as a Neuroscience 2018 Hot Topic at the Society for Neuroscience (SfN) Annual Meeting in November 2018.

- **OTO-510: IND enabling activities to be initiated for cisplatin-induced hearing loss (CIHL) otoprotection program.** CIHL is an important unmet medical need with no approved therapies and approximately 500,000 patients, including 5,000 children undergoing chemotherapy with ototoxic platinum-based agents each year in the United States. OTO-510 is a sustained-exposure formulation of an undisclosed small molecule designed for intratympanic administration to provide otoprotection without tumor protection.

- **OTO-6XX: Development candidate selected for regenerative hearing loss program.** Otonomy has demonstrated regeneration of hair cells in a nonclinical proof-of-concept model using a class of small molecules formulated for sustained-exposure local delivery, and has selected a lead compound for development.

- **OTIPRIO: Co-promotion partnership with Mission Pharmacal in acute otitis externa (AOE) proceeding as planned.** Preparations are underway for Mission to launch OTIPRIO to high volume pediatric and primary care physician offices in advance of the peak summer season for treating AOE.

- **$15 million Term Loan Completed to Extend Cash Runway into 2021.** In December 2018, Otonomy completed a term loan financing with Oxford Finance LLC totaling $15 million. The loan provides for a 24-month interest-only repayment period, which can be extended upon successful results from the ongoing OTIVIDEX Phase 3 trial. There are no financial covenants or warrants associated with the loan.

Anticipated Upcoming Milestones

- In second quarter of 2019, initiate a Phase 1/2 clinical trial of OTO-313 in tinnitus patients.

- In third quarter of 2019, initiate a Phase 1/2 clinical trial of OTO-413 in hearing loss patients.

- In first half of 2020, complete OTO-313 Phase 1/2 clinical trial.

- In first half of 2020, complete Phase 3 trial for OTIVIDEX in Ménière’s disease.

- In second half of 2020, complete OTO-413 Phase 1/2 clinical trial.

Fourth Quarter and Full Year 2018 Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $97.3 million as of December 31, 2018, compared to $120.0 million as of December 31, 2017. The cash balance for 2018 includes proceeds from a $15.0 million term loan provided by Oxford Finance LLC that was completed in December 2018.

- **Operating Expenses:** GAAP operating expenses were $13.2 million for the fourth quarter of 2018, compared to $17.5 million for the fourth quarter of 2017. For the full year 2018, GAAP operating expenses were $51.9 million compared to $89.5 million for 2017. Non-GAAP operating expenses, which exclude stock-based compensation and rent abatement expense, were $10.8 million for the fourth quarter of 2018, compared to $14.3 million for the fourth quarter of 2017. For the full year 2018, non-GAAP operating expenses were $39.5 million compared to $73.8 million for 2017.

- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the fourth quarter of 2018 were $9.7 million, compared to $6.0 million for the fourth quarter of 2017. The increase was primarily due to increased costs for nonclinical and manufacturing activities to support initiation of clinical trials for OTO-313 and OTO-413. For the full year 2018, GAAP R&D expenses were $31.8 million compared to $42.7 million for 2017.

- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the fourth quarter of 2018 were $3.6 million, compared to $11.5 million for the fourth quarter of 2017. The decrease was primarily a result of reduced selling expenses due to the discontinuation of promotional support for OTIPRIO. For the full year 2018, GAAP SG&A expenses were $20.0 million compared to $46.8 million for 2017.

- **Operating Expense Guidance:**
  - **2019:** Otonomy expects that GAAP operating expenses will be in the range of $55-$60 million, and that non-GAAP operating expenses will be in the range of $45-$50 million.
  - **2020:** Otonomy expects that operating expenses will be lower than 2019 as multiple clinical trials are completed.

- **Cash Runway:** Otonomy expects that its current cash, cash equivalents, and short term investments will be sufficient to fund the company through completion of the OTIVIDEX Phase 3 trial, OTO-313 Phase 1/2 trial, and OTO-413 Phase 1/2 trial in 2020, and will support company operations into 2021.

Webcast and Conference Call

Otonomy management will host a webcast and conference call regarding this announcement at 4:30 p.m. EST/1:30 p.m. PST today. The live call may be accessed by dialing (877) 305-6769 for domestic callers and (678) 562-4239 for international callers with conference ID code number:

9989017. A live webcast of the call will be available online in the investor relations section of Otonomy's website at www.otonomy.com and will be archived there for 30 days.

Non-GAAP Operating Expenses

In this press release, Otonomy's operating expenses are provided in accordance with generally accepted accounting principles (GAAP) in the United States and also on a non-GAAP basis. Non-GAAP operating expenses exclude stock-based compensation and rent abatement expense. Non-GAAP operating expenses are provided as a complement to operating expenses provided in accordance with GAAP because management believes non-GAAP operating expenses help indicate underlying trends in the company's business, are important in comparing current results with prior period results and provide additional information regarding the company's financial position. Management also uses non-GAAP operating expenses to establish budgets and operational goals that are communicated internally and externally and to manage the company's business and to evaluate its performance. The attached financial information includes a reconciliation of the GAAP operating expenses to non-GAAP operating expenses and a reconciliation of GAAP operating expense guidance to non-GAAP operating expense guidance.

About Otonomy
Otonomy is a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology. The company pioneered the application of drug delivery technology to the ear in order to develop products that achieve sustained drug exposure from a single local administration. This approach is covered by a broad patent estate and is being utilized to develop a pipeline of products addressing important unmet medical needs including Ménière's disease, hearing loss, and tinnitus. For additional information please visit www.otonomy.com.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements generally relate to future events or the future financial or operating performance of Otonomy. Forward-looking statements in this press release include, but are not limited to, timing of results, patient recruitment and enrollment plans for, and design and conduct of, the Phase 3 clinical trial for OTIVIDEX; timing of initiation and results, patient recruitment and enrollment plans for, and design and conduct of, the Phase 1/2 clinical trial for OTO-313; timing of initiation and results, patient recruitment and enrollment plans for, and design and conduct of, the Phase 1/2 clinical trial for OTO-413; expectations regarding IND enabling activities for OTO-510; expectations regarding OTO-6XX development; the activity and timing of launch under, and potential benefits of, the co-promotion agreement between Otonomy and Mission; the benefits of the loan provided by Oxford Finance LLC and the potential extension of the interest-only period; expectations regarding the timing and nature of upcoming milestones; expectations regarding operating expenses for 2019 and 2020; expectations that current capital is sufficient to fund the company through completion of the OTIVIDEX Phase 3 trial, OTO-313 Phase 1/2 trial, and OTO 413 Phase 1/2 trial, and will support company operations into 2021; and statements by Otonomy's president and CEO. Otonomy's expectations regarding these matters may not materialize, and actual results in future

periods are subject to risks and uncertainties. Actual results may differ materially from those indicated by these forward-looking statements as a result of these risks and uncertainties, including but not limited to: Otonomy's limited operating history and its expectation that it will incur significant losses for the foreseeable future; Otonomy's ability to accurately forecast financial results; Otonomy's ability to obtain additional financing; Otonomy's dependence on the regulatory success and advancement of its product candidates; the uncertainties inherent in the clinical drug development process, including, without limitation, Otonomy's ability to adequately demonstrate the safety and efficacy of its product candidates, the nonclinical and clinical results for its product candidates, which may not support further development, and challenges related to patient enrollment in clinical trials; Otonomy's ability to obtain regulatory approval for its product candidates; the risks of the occurrence of any event, change or other circumstance that could give rise to the termination of the co-promotion agreement between Otonomy and Mission; the risks of the occurrence of any event, change or other circumstance that could impact Otonomy's ability to repay or comply with the terms of the loan provided by Oxford Finance LLC; side effects or adverse events associated with Otonomy's product candidates; Otonomy's ability to successfully commercialize its product candidates, if approved; competition in the biopharmaceutical industry; Otonomy's dependence on third parties to conduct nonclinical studies and clinical trials; Otonomy's dependence on third parties for the manufacture of its product candidates; Otonomy's dependence on a small number of suppliers for raw materials; Otonomy's ability to protect its intellectual property related to its product candidates in the United States and throughout the world; expectations regarding potential market size, opportunity and growth; Otonomy's ability to manage operating expenses; implementation of Otonomy's business model and strategic plans for its business, products and technology; and other risks. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in Otonomy's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 4, 2019, and Otonomy's future reports to be filed with the SEC. The forward-looking statements in this press release are based on information available to Otonomy as of the date hereof. Otonomy disclaims any obligation to update any forward-looking statements, except as required by law.

Contacts:

Media Inquiries
Spectrum Science
Leticia Diaz
Vice President
202.587.2517
ldiaz@spectrumscience.com

Investor Inquiries
Westwicke Partners
Robert H. Uhl
Managing Director
858.356.5932
robert.uhl@westwicke.com

###

Otonomy, Inc.
Condensed Balance Sheet Data
(in thousands)

	As of December 31, 2018	As of December 31, 2017
Cash and cash equivalents	$ 33,633	$ 18,456
Short-term investments	63,651	101,548
Total assets	104,992	128,364
Long-term debt, net	14,764	-
Total liabilities	25,255	11,085
Accumulated deficit	(415,218)	(364,850)
Total stockholders' equity	79,737	117,279

Otonomy, Inc.
Condensed Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended December 31,		Years Ended December 31,	
	2018	2017	2018	2017
	(unaudited)			
Product sales, net	$ 208	$ 270	$ 745	$ 1,236
Costs and operating expenses:				
Cost of product sales	271	1,948	946	3,098
Research and development	9,669	6,041	31,844	42,701
Selling, general and administrative	3,580	11,451	20,008	46,838
Total costs and operating expenses	13,520	19,440	52,798	92,637
Loss from operations	(13,312)	(19,170)	(52,053)	(91,401)
Other income, net	467	337	1,685	1,271
Net loss	$ (12,845)	$ (18,833)	$ (50,368)	$ (90,130)
Net loss per share, basic and diluted	$ (0.42)	$ (0.62)	$ (1.65)	$ (2.97)
Weighted-average shares used to compute net loss per share, basic and diluted	30,646,951	30,375,053	30,610,244	30,304,158

Otonomy, Inc.
Reconciliation of GAAP to Non-GAAP Operating Expenses
(in thousands)

	Three Months Ended December 31,		Years Ended December 31,	
	2018	2017	2018	2017
	(unaudited)			
GAAP operating expenses				
Research and development	$ 9,669	$ 6,041	$ 31,844	$ 42,701
Selling, general and administrative	3,580	11,451	20,008	46,838
Total GAAP operating expenses	13,249	17,492	51,852	89,539
Non-GAAP adjustments				
R&D stock-based compensation expense	(1,075)	(597)	(4,447)	(3,763)
SG&A stock-based compensation expense	(1,375)	(2,592)	(7,955)	(9,878)
Rent abatement	-	-	-	(2,084)
Total non-GAAP adjustments	(2,450)	(3,189)	(12,402)	(15,725)
Non-GAAP operating expenses	$ 10,799	$ 14,303	$ 39,450	$ 73,814

Otonomy, Inc.
Reconciliation of 2019 GAAP to Non-GAAP Operating Expense Guidance
(in millions)

GAAP operating expenses	$55 - $60
Non-GAAP adjustments	
Stock-based compensation expense	$10
Non-GAAP operating expenses	$45 - $50