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 8, 2018

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 8, 2018, Otonomy, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2017. 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 8, 2018.

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 8, 2018

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 2017 Financial Results and Provides Corporate Update

Type C meeting completed with FDA for OTIVIDEX™ in Ménière's disease

Consistent with prior guidance, pivotal trial for OTIVIDEX to start mid-2018

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

SAN DIEGO, March 8, 2018 — Otonomy, Inc. (NASDAQ: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for otology, today reported financial results for the fourth quarter and year ended December 31, 2017 and provided an update on its corporate activities and product pipeline. The company will host a conference call and webcast today at 4:30 p.m. EST to discuss recent highlights and financial results.

Fourth Quarter 2017 and Subsequent Highlights

- **Announced Positive Results for the AVERTS-2 Phase 3 Trial of OTIVIDEX™ in Ménière's Disease and Completed a Type C Meeting with FDA:** In November 2017, Otonomy announced that the AVERTS-2 trial achieved its primary endpoint, count of definitive vertigo days (DVD) by Poisson Regression analysis in Month 3 (p value = 0.029), based on analysis of all 174 patients enrolled in the trial. Previously, the company announced that the AVERTS-1 trial missed the primary endpoint (p value = 0.62). Otonomy recently completed a Type C meeting with the U.S. Food and Drug Administration (FDA) that included a review of the AVERTS and other clinical trial results. Based on FDA feedback, and consistent with the company's prior guidance, we believe that one additional successful pivotal trial is sufficient to support the U.S. registration of OTIVIDEX in Ménière's disease. Otonomy expects to initiate this trial in mid-2018.
- **Obtained FDA Approval of OTIPRIO® for the Treatment of Acute Otitis Externa:** In March 2018, the FDA approved OTIPRIO (ciprofloxacin otic suspension) for the treatment of patients with acute otitis externa (AOE). Approval of the Supplemental New Drug Application (sNDA) significantly increases the potential market opportunity for OTIPRIO with approximately 4 million episodes of AOE occurring each year in the United States. In November 2017, the company announced the discontinuation of promotional support for OTIPRIO in order to significantly reduce operating expenses related to the product. OTIPRIO continues to be available for purchase by customers while Otonomy evaluates commercial partnering options for the product including divestiture.

- **Advancing Multiple Programs for Sensorineural Hearing Loss:** In January 2018, Otonomy announced the advancement of three distinct programs for hearing loss that address different pathologies and broad patient populations. OTO-413 is a sustained exposure formulation of brain-derived neurotrophic factor (BDNF) in development for the repair of cochlear synaptopathy and the treatment of speech-in-noise hearing difficulties. The company has initiated nonclinical studies and manufacturing for OTO-413 to support an Investigational New Drug (IND) application, with a Phase 1/2 clinical trial expected to begin in hearing loss patients in the first half of 2019. OTO-5XX is an otoprotectant in development for the prevention of cisplatin-induced hearing loss. OTO-6XX induces hair cell regeneration and is being developed for the treatment of severe hearing loss. The company expects to select a candidate for clinical development for both the OTO-5XX and OTO-6XX programs in the second half of 2018.
- **Developing OTO-313, an Improved Formulation of Gacyclidine, for the Treatment of Tinnitus:** Gacyclidine is a potent and selective N-Methyl-D-Aspartate (NMDA) receptor antagonist, a molecular class with potential for treating tinnitus based on both nonclinical and clinical studies. A Phase 1 clinical safety trial has been successfully completed using OTO-311, a poloxamer-based formulation of gacyclidine, with no safety concerns observed. Otonomy has shifted development to OTO-313, an alternative formulation of gacyclidine that has improved properties compared to OTO-311. The company expects to initiate a Phase 1/2 clinical trial for OTO-313 in tinnitus patients in the first half of 2019.
- **Presented Data for Hearing Loss and Tinnitus Programs at International Otology Research Conference:** In February 2018, company scientists and research collaborators delivered multiple data presentations at the Association for Research in Otolaryngology (ARO) Annual MidWinter Meeting. These presentations included data supporting the therapeutic potential of OTO-413 for the repair of cochlear synaptopathy. In addition, David A. Weber, Ph.D., president and CEO of Otonomy, delivered an invited presentation during the conference's Presidential Symposium.

"The fourth quarter of 2017 was a transformational period for Otonomy as we repositioned the company to focus on advancing our broad pipeline of development programs including OTIVIDEX for Ménière's disease, OTO-313 for tinnitus, and multiple programs for hearing loss," said Dr. Weber. "Furthermore, our recent positive regulatory updates position us for a very productive year ahead. Approval of OTIPRIO for AOE is an important accomplishment that will support our ongoing commercial partnering discussions, and the recent FDA feedback on OTIVIDEX provides clarity on our path forward for registration in Ménière's disease."

Anticipated Upcoming Milestones

- Initiate Phase 3 clinical trial for OTIVIDEX in Ménière's disease in mid-2018.
- Complete commercial partnership or divestiture of OTIPRIO in mid-2018.
- In second half of 2018, select a candidate for clinical development for both OTO-5XX and OTO-6XX hearing loss programs.

- In first half of 2019, initiate a Phase 1/2 clinical trial of OTO-313 in tinnitus patients.
- In first half of 2019, initiate a Phase 1/2 clinical trial of OTO-413 in hearing loss patients.

Fourth Quarter and Full Year 2017 Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $120.0 million as of December 31, 2017, compared to $196.4 million as of December 31, 2016.
- **Revenue:** Net sales of OTIPRIO totaled $0.3 million for the fourth quarter of 2017 and the fourth quarter of 2016. For the full year 2017, net sales totaled $1.2 million compared to $0.7 million for 2016. Despite the discontinuation of promotional support in the fourth quarter of 2017, OTIPRIO monthly shipments for the first two months of 2018 have continued at approximately the same monthly level as during the prior two quarters.
- **Operating Expenses:** GAAP operating expenses were $17.5 million for the fourth quarter of 2017, compared to $26.2 million for the fourth quarter of 2016. For the full year 2017, GAAP operating expenses were $89.5 million compared to $110.5 million for 2016. Non-GAAP operating expenses, which exclude stock-based compensation and rent abatement expense, were $14.3 million for the fourth quarter of 2017, compared to $22.7 million for the fourth quarter of 2016. For the full year 2017, non-GAAP operating expenses were $73.8 million compared to $97.7 million for 2016.
- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the fourth quarter of 2017 were $6.0 million, compared to $14.2 million for the fourth quarter of 2016. The decrease was primarily a result of decreased clinical trial activities for OTIPRIO and OTIVIDEX versus the prior year period. For the full year 2017, GAAP R&D expenses were $42.7 million compared to $60.7 million for 2016.
- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the fourth quarter of 2017 were $11.5 million, compared to $12.0 million for the fourth quarter of 2016. For the full year 2017, GAAP SG&A expenses were $46.8 million compared to $49.8 million for 2016.
- **Financial Guidance:** Otonomy reaffirms its expectations that GAAP operating expenses for 2018 will be in the range of $52-$57 million, and that non-GAAP operating expenses for 2018 will be in the range of $40-$45 million.

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: 1898244. 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 otology. 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, the market size for OTIPRIO in AOE, the company's expectations regarding its commercial partnering options for OTIPRIO, including divestiture and timing of any such transaction, timing of a Phase 3 trial for OTIVIDEX, timing of a Phase 1/2 clinical trial for OTO-413, timing of candidate selection for OTO-5XX and OTO-6XX programs, timing of Phase 1/2 clinical trial for OTO-313, financial guidance for 2018, 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 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; 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 8, 2018, 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.

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

	As of December 31, 2017	As of December 31, 2016
Cash and cash equivalents	$ 18,456	$ 24,156
Short-term investments	101,548	172,222
Total assets	128,364	208,596
Total liabilities	11,085	15,859
Accumulated deficit	(364,850)	(274,720)
Total stockholders' equity	117,279	192,737

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

	Three Months Ended December 31,		Years Ended December 31,	
	2017	2016	2017	2016
Product sales, net	$ 270	$ 273	$ 1,236	$ 683
Costs and operating expenses:				
Cost of product sales	1,948	909	3,098	1,664
Research and development	6,041	14,165	42,701	60,723
Selling, general and administrative	11,451	12,052	46,838	49,777
Total costs and operating expenses	19,440	27,126	92,637	112,164
Loss from operations	(19,170)	(26,853)	(91,401)	(111,481)
Other income	337	281	1,271	898
Net loss	$ (18,833)	$ (26,572)	$ (90,130)	$ (110,583)
Net loss per share, basic and diluted	$ (0.62)	$ (0.88)	$ (2.97)	$ (3.69)
Weighted-average shares used to compute net loss per share, basic and diluted	30,375,053	30,215,162	30,304,158	29,962,781

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

	Three Months Ended December 31,		Years Ended December 31,	
	2017	2016	2017	2016
GAAP operating expenses				
Research and development	$ 6,041	$14,165	$ 42,701	$ 60,723
Selling, general and administrative	11,451	12,052	46,838	49,777
Total GAAP operating expenses	17,492	26,217	89,539	110,500
Non-GAAP adjustments				
R&D stock-based compensation expense	(597)	(781)	(3,763)	(2,996)
SG&A stock-based compensation expense	(2,592)	(2,540)	(9,878)	(9,574)
Rent abatement	—	(232)	(2,084)	(232)
Total non-GAAP adjustments	(3,189)	(3,553)	(15,725)	(12,802)
Non-GAAP operating expenses	$14,303	$22,664	$ 73,814	$ 97,698

Otonomy, Inc.
Reconciliation of 2018 GAAP to Non-GAAP Operating Expense Guidance
(in millions)

GAAP operating expenses	$52 - $57
Non-GAAP adjustments	
Stock-based compensation expense	12
Non-GAAP operating expenses	$40 - $45