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):
January 9, 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)**	**(I.R.S. 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 reports)

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 January 9, 2018, Otonomy, Inc. (the "Company") issued a press release announcing certain preliminary results for its fiscal 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 January 9, 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 hereunto duly authorized.

OTONOMY, INC.

Date: January 9, 2018

By: /s/ Eric Loumeau
Eric Loumeau
General Counsel and Chief Compliance Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

Otonomy Provides Corporate and Product Pipeline Update

SAN DIEGO, January 9, 2018 — Otonomy, Inc. (NASDAQ: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for diseases and disorders of the ear, today provided an update on its product pipeline and financial guidance.

- **OTIVIDEX™ demonstrated statistical significance for multiple efficacy endpoints in the AVERTS-2 trial of patients with Ménière's disease:** As previously announced, the AVERTS-2 Phase 3 trial achieved its primary efficacy endpoint, count of definitive vertigo days (DVD) by Poisson Regression analysis in Month 3, for all 174 patients enrolled in the trial (p value = 0.029). This endpoint and a number of additional efficacy endpoints were also statistically significant for the 111 patients who were enrolled in the AVERTS-2 trial through Month 3 at the time of study termination. These endpoints are shown below.

Analysis of Patients Enrolled through Month 3 (n = 111)	p value
Count of DVD by Poisson Regression Analysis	0.014
Mean Vertigo Severity Score	0.030
Change in Vertigo Frequency from Baseline	0.030
Numbers of Days Sick at Home or Bedridden	0.042

  The clinically significant treatment benefit demonstrated by OTIVIDEX versus placebo in AVERTS-2 was consistent with expectations from the Phase 2b trial. Based on completion of data review, the AVERTS-1 trial failed due to a significantly higher placebo response and was not attributable to a difference in patient demographics or baseline characteristics compared to AVERTS-2. A review of the AVERTS trials including consultation with outside experts suggests that the higher placebo response was primarily due to increased expectation bias in the U.S. trial. Otonomy has requested a Type C meeting with the U.S. Food and Drug Administration (FDA) and expects to meet during the first quarter of 2018 to review the AVERTS results and any remaining clinical requirements for registration of OTIVIDEX in Ménière's disease. The company expects that any remaining clinical development required for registration will be initiated in mid-2018.

- **Advancing three distinct programs for hearing loss that address different pathologies and broad patient populations:** Hearing loss is a large and growing unmet need with estimates by the World Health Organization that more than 360 million people worldwide

have disabling levels of loss. This leads to social isolation, lower quality of life, and higher rates of dementia and depression. Common causes include aging, noise, exposure to ototoxic drugs, and genetics, with increased noise exposure from use of recreational music devices accelerating the onset of hearing loss. The pathologies of hearing loss typically involve damage to hair cells and/or spiral ganglion neurons in the inner ear. As briefly described below, Otonomy is advancing three distinct hearing loss programs targeting different pathologies: repair of synaptopathy for treatment of hidden hearing loss (OTO-413), protection of hair cells from ototoxic drugs including cisplatin chemotherapy (OTO-5XX), and hair cell regeneration for treatment of severe hearing loss (OTO-6XX).

- **OTO-413 is a sustained exposure formulation of BDNF that has been advanced into IND-enabling activities for the treatment of hidden hearing loss:** OTO-413 is a proprietary formulation of brain-derived neurotropic factor (BDNF) which is a naturally occurring protein involved in neuron growth and repair. Nonclinical studies by Otonomy and other research groups have demonstrated that local administration of BDNF repairs ribbon synapses damaged due to noise trauma or exposure to ototoxic chemicals and restores hearing function. Otonomy has initiated nonclinical testing 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. The initial indication for OTO-413 will be patients with hidden hearing loss, a synaptopathy-related hearing loss characterized by speech-in-noise hearing difficulty. This condition affects nearly 3% of the U.S. population[1].
- **OTO-5XX is an otoprotectant in development for the prevention of cisplatin-induced hearing loss (CIHL):** A number of drug classes cause ototoxicity including platinum-based chemotherapeutic agents and aminoglycosides. Otonomy established feasibility of conducting clinical trials in patients undergoing cisplatin chemotherapy through a small Phase 2 trial with OTIVIDEX in pediatric patients. The company has identified a therapeutic target that offers a higher level of otoprotection than steroids based on nonclinical proof-of-concept studies, and is evaluating molecules in this class. Selection of a candidate for clinical development is expected to occur in the second half of 2018. The initial indication for OTO-5XX will be the prevention of CIHL, which is relevant for approximately 500,000 patients in the U.S. who are treated each year with platinum-based chemotherapies.
- **OTO-6XX induces hair cell regeneration and is being developed for the treatment of severe hearing loss:** Considerable interest and attention has been focused by otology researchers over the past several decades for ways to regenerate hair cells as an approach to treating severe hearing loss, which is estimated to affect 6.6 million people in the U.S.[2] This effort has included extensive research with non-mammalian species that are capable of hair cell regeneration in order to identify pathways for therapeutic intervention. Targeting one of these pathways, Otonomy has demonstrated regeneration of hair cells in a nonclinical proof-of-concept model using a class of small molecules. Selection of a candidate for clinical development is expected to occur 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.
- **OTIPRIO® divestiture discussions in process with multiple parties:** As announced in November 2017, Otonomy has discontinued commercial support of OTIPRIO (ciprofloxacin otic suspension) and is pursuing a sale of the asset. FDA review of the Supplemental New Drug Application (sNDA) for acute otitis externa is ongoing with a Prescription Drug User Fee Act (PDUFA) action date of March 2, 2018. OTIPRIO continues to be available for purchase by customers with net sales for the fourth quarter of 2017 totaling $0.3 million, comparable to net sales recorded for the prior quarter.
- **Financial guidance:** Recent actions taken to discontinue OTIPRIO commercial support and eliminate other non-essential positions have reduced ongoing operating costs significantly. Otonomy expects GAAP operating expenses for 2017 to total in the range of $95-$100 million with non-GAAP expenses totaling $73-$78 million. The company expects GAAP operating expenses for 2018 to total in the range of $52-$57 million with non-GAAP expenses to total $40-$45 million. Otonomy's cash balance including cash, cash equivalents, and short-term investments totaled $120 million at the end of 2017. This cash balance is expected to fund the completion of clinical development required for U.S. registration of OTIVIDEX in Ménière's disease, and support advancement of the other programs.

"We are excited to begin 2018 given our broad product pipeline targeting important unmet medical needs and large patient populations in otology, and our strong balance sheet to support its development," said David A. Weber, Ph.D., president and CEO of Otonomy. "Results of the successful AVERTS-2 trial clearly demonstrate that OTIVIDEX provides a significant clinical benefit for patients with Ménière's disease, and our advancement of multiple programs for hearing loss and continued development of gacyclidine for tinnitus together illustrate our commitment to developing innovative treatments for this emerging field."

1 Tremblay et al., Ear Hear (2015)
2 Goman and Lin, Am J Public Health (2016)

About Otonomy

Otonomy is a biopharmaceutical company dedicated to the development of innovative therapeutics for diseases and disorders of the ear. 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, plans to meet with the FDA regarding the clinical development requirements for OTIVIDEX™ and the timing of any such meeting, timing of any remaining OTIVIDEX clinical work required, timing of IND filing and Phase 1/2 clinical trial for OTO-413, timing of Phase 1/2 clinical trial for OTO-313, financial guidance for 2018, timing of candidate selection for OTO-5XX and OTO-6XX programs, ability to fund completion of OTIVIDEX clinical development, and the ability of Otonomy to complete a divestiture of OTIPRIO®, 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; 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 8, 2017, 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
Canale Communications
Heidi Chokeir, Ph.D.
Senior Vice President
619.849.5377
heidi@canalecomm.com

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

###