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):

November 5, 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 November 5, 2018, Otonomy, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 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 November 5, 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: November 5, 2018

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

Otonomy Reports Third Quarter 2018 Financial Results and Provides Corporate Update

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

Conference call will include review of OTO-413 program selected as "Hot Topic" at Society for Neuroscience Annual Meeting

SAN DIEGO, November 5, 2018 -- Otonomy, Inc. (NASDAQ: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for otology, today reported financial results for the quarter ended September 30, 2018 and provided an update on its corporate activities and product pipeline including a review of the OTO-413 program recently selected as a "Hot Topic" at the Society for Neuroscience Annual Meeting.

Third Quarter 2018 and Subsequent Highlights

- **Announced Multiple Presentations at Society for Neuroscience Annual Meeting and Selection of OTO-413 Presentation as "Hot Topic":** Otonomy recently announced multiple presentations related to the company's programs in hearing loss and tinnitus at the Society for Neuroscience Annual Meeting being held from November 3-7 in San Diego. This includes two presentations demonstrating the therapeutic potential of OTO-413, a sustained-exposure formulation of brain-derived neurotrophic factor (BDNF), for the repair of cochlear synaptopathy, and a single presentation related to OTO-313, a sustained-exposure formulation of gacyclidine in development for tinnitus. One of the OTO-413 presentations was selected as a Neuroscience 2018 Hot Topic. Otonomy expects to initiate a Phase 1/2 clinical trial for OTO-413 in patients with speech-in-noise hearing difficulty and a Phase 1/2 clinical trial for OTO-313 in tinnitus patients in the first half of 2019.
- **Attended a Patient-Focused Drug Development (PFDD) Workshop on Chemotherapy-Induced Hearing Loss (CIHL) in Pediatric Oncology:** In September 2018, Otonomy attended and helped sponsor a PFDD workshop on pediatric CIHL organized by patient advocates that included participation from members of the Oncology Center of Excellence at the U.S. Food and Drug Administration (FDA). Presentations by patients and parents highlighted the significant negative impact of CIHL on the lives of children and the need for a therapeutic that provides otoprotection without tumor protection. Otonomy expects to select a clinical candidate for its OTO-5XX CIHL otoprotection program by end of 2018 to address this important unmet medical need.

- **Initiated Phase 3 Trial for OTIVIDEXä in Ménière's Disease:** In July 2018, Otonomy announced initiation of the additional Phase 3 trial required to support submission for U.S. registration of OTIVIDEX in Ménière's disease. The design and conduct of this pivotal trial, which will enroll approximately 160 patients, is based on the successful AVERTS-2 Phase 3 trial. Otonomy expects top-line results in the first half of 2020.

- **Presented Results from OTIVIDEX AVERTS-2 Trial at International Otolaryngology Conference:** In September 2018, Mr. John Phillips, FRCS (ORL-HNS), Consultant Otolaryngologist at Norfolk & Norwich University Hospitals in the United Kingdom, presented positive results from the AVERTS-2 Phase 3 trial of OTIVIDEX in Ménière's disease at the annual meeting of the American Academy of Otolaryngology - Head and Neck Surgery Foundation. 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.

- **Completed Co-Promotion Partnership for OTIPRIOÒ in Acute Otitis Externa:** In August 2018, Otonomy announced the signing of a co-promotion agreement with Mission Pharmacal, a well-established privately held pharmaceutical company, that provides Mission with an exclusive right to promote OTIPRIO for acute otitis externa (AOE) in pediatrician and primary care physician offices as well as urgent care clinics in the United States. This agreement is expected to generate positive cashflow for Otonomy, which retains all commercial rights for other OTIPRIO indications and customer segments.

- **Obtained Favorable Ruling in Patent Interference Case:** Although not involving issued patents covering OTIPRIO or the company's product candidates, Otonomy filed a request for interference in April 2015 against a U.S. patent application controlled by Auris Medical Holding in order to broadly protect the company's technology in the field of sustained-exposure otic drug delivery. Otonomy appealed an initial ruling by the Patent Trial and Appeal Board, and in August 2018, the Federal Circuit Court issued a final ruling in Otonomy's favor.

"The selection of our OTO-413 presentation as a Hot Topic at the 2018 Society for Neuroscience Annual Meeting and the recent workshop on pediatric CIHL highlight the important unmet medical need addressed by our hearing loss programs," said David A. Weber, Ph.D., president and CEO of Otonomy. "When taken together with our OTIVIDEX Phase 3 program for Ménière's disease and OTO-313 program for tinnitus, we have the broadest product pipeline addressing the largest market opportunities in the untapped neurotology field. I look forward to further discussing our pipeline and upcoming milestones with investors in the coming months beginning with our review of the OTO-413 program on today's call."

Anticipated Upcoming Milestones

- By the end 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.

Third Quarter Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $92.6 million as of September 30, 2018, compared to $120.0 million as of December 31, 2017.

- **Operating Expenses:** GAAP operating expenses were $13.1 million for the third quarter of 2018, compared to $21.6 million for the third quarter of 2017. Non-GAAP operating expenses, which exclude stock-based compensation and rent abatement expense, were $10.1 million for the third quarter of 2018, compared to $17.4 million for the third quarter of 2017.

- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the third quarter of 2018 were $8.3 million, compared to $10.8 million for the third quarter of 2017. The decrease was primarily a result of decreased clinical trial activities for OTIVIDEX versus the prior year period.

- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the third quarter of 2018 were $4.7 million, compared to $10.5 million for the third quarter of 2017. The decrease was primarily a result of reduced selling expenses due to the discontinuation of promotional support for OTIPRIO.

- **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: 9792838. 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 potential benefits of the co-promotion agreement between Otonomy and Mission, timing of top-line results and patient recruitment and enrollment plans for the Phase 3 trial for OTIVIDEX, timing of a Phase 1/2 clinical trial for OTO-313, timing of a Phase 1/2 clinical trial for OTO-413, timing of candidate selection for OTO-5XX and OTO-6XX programs, 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; 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; 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 5, 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 September 30, 2018	As of December 31, 2017
	(unaudited)	
Cash and cash equivalents	$ 21,382	$ 18,456
Short-term investments	71,180	101,548
Total assets	100,215	128,364
Total liabilities	10,217	11,085
Accumulated deficit	(402,373)	(364,850)
Total stockholders' equity	89,998	117,279

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(unaudited)			
Product sales, net	$ 113	$ 282	$ 537	$ 966
Costs and operating expenses:				
Cost of product sales	162	290	675	1,150
Research and development	8,300	10,761	22,175	36,660
Selling, general and administrative	4,652	10,548	16,428	35,387
Total costs and operating expenses	13,114	21,599	39,278	73,197
Loss from operations	(13,001)	(21,317)	(38,741)	(72,231)
Interest income	455	319	1,218	934
Net loss	$ (12,546)	$ (20,998)	$ (37,523)	$ (71,297)
Net loss per share, basic and diluted	$ (0.41)	$ (0.69)	$ (1.23)	$ (2.35)
Weighted-average shares used to compute net loss per share, basic and diluted	30,630,125	30,314,155	30,597,874	30,280,267

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(unaudited)			
GAAP operating expenses				
Research and development	$ 8,300	$ 10,761	$ 22,175	$ 36,660
Selling, general and administrative	4,652	10,548	16,428	35,387
Total GAAP operating expenses	12,952	21,309	38,603	72,047
Non-GAAP adjustments				
R&D stock-based compensation expense	(1,037)	(823)	(3,372)	(3,167)
SG&A stock-based compensation expense	(1,770)	(2,424)	(6,580)	(7,285)
Rent abatement	-	(695)	-	(2,084)
Total non-GAAP adjustments	(2,807)	(3,942)	(9,952)	(12,536)
Non-GAAP operating expenses	$ 10,145	$ 17,367	$ 28,651	$ 59,511

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