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):

May 6, 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. ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	OTIC	The NASDAQ Stock Market LLC (The NASDAQ Global Select Market)

Item 2.02 Results of Operations and Financial Condition.

On May 6, 2019, Otonomy, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2019. 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 May 6, 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: May 6, 2019

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

Otonomy Reports First Quarter 2019 Financial Results and Provides Corporate Update

- ***OTO-313 Phase 1/2 trial in tinnitus initiated; results expected in first half of 2020***
- ***OTIPRIOÒ co-promotion agreement completed with Glenmark Therapeutics***
- ***OTIVIDEXä Phase 3 trial in Ménière's disease on track for results in first half of 2020***
- ***OTO-413 Phase 1/2 trial in hearing loss expected to start in third quarter of 2019; results expected in second half of 2020***
- ***Current capital funds operations into 2021***

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

SAN DIEGO, May 6, 2019 -- Otonomy, Inc. (NASDAQ: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today reported financial results for the quarter ended March 31, 2019 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. EDT to discuss recent highlights and financial results, and provide an overview of the OTO-313 program.

"This quarterly update highlights the continued execution of our business strategy including the plan to report clinical results from three trials in 2020 -- the Phase 3 trial of OTIVIDEX in Ménière's disease, the Phase 1/2 clinical trial of OTO-313 in tinnitus and Phase 1/2 trial of OTO-413 in hearing loss," said David A. Weber, Ph.D., president and CEO of Otonomy. "In addition, our partnership with Glenmark complements the existing co-promotion arrangement with Mission Pharmacal and ensures that we have broad promotional support for OTIPRIO in the peak swimmer's ear season this summer. We expect that these efforts will contribute to our already strong balance sheet that will fund the company's operations through the three clinical trial results next year and into 2021."

Product Pipeline and Corporate Update

- **Initiated Patient Enrollment for Phase 1/2 Clinical Trial of OTO-313 in Tinnitus with Results Expected in the First Half of 2020:** In April, Otonomy initiated enrollment of the first patients in a Phase 1/2 clinical trial for OTO-313, a sustained-exposure formulation of the NMDA receptor antagonist gacyclidine, in tinnitus patients. The randomized, double-blind, placebo-controlled trial

includes an initial safety cohort, which has completed enrollment, followed by an exploratory efficacy study that is initiating enrollment of approximately 50 patients with tinnitus.

- **Completed OTIPRIO Co-Promotion Agreement with Glenmark Therapeutics Inc., USA ("Glenmark"):** In May, Otonomy announced the signing of a co-promotion agreement that provides Glenmark with an exclusive right to promote OTIPRIO for acute otitis externa (AOE) to ear, nose and throat (ENT) physicians in the United States. Otonomy will receive an annual co-promotion fee and reimbursement of a proportion of product support expenses, and retain a share of adjusted gross profits from the sale of OTIPRIO to Glenmark's accounts.

- **Enrollment in OTIVIDEX Phase 3 Clinical Trial in Ménière's Disease is Ongoing 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 in the United States and Europe.

- **Conducting IND-Enabling Activities to Support Initiation of a Phase 1/2 trial for OTO-413 in Hearing Loss Patients in the Third Quarter of 2019:** 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. Otonomy is conducting nonclinical testing and manufacturing activities to support an Investigational New Drug Application Filing (IND) with the U.S. Food and Drug Administration (FDA). The Phase 1/2 trial will enroll approximately 40 patients with speech-in-noise hearing loss. Results are expected in the second half of 2020.

Anticipated Upcoming Milestones

- 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.

First Quarter Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $86.9 million as of March 31, 2019, compared to $97.3 million as of December 31, 2018.

- **Operating Expenses:** GAAP operating expenses were $12.1 million for the first quarter of 2019, compared to $11.8 million for the first quarter of 2018. Non-GAAP operating expenses, which exclude stock-based compensation, were $10.6 million for the first quarter of 2019, compared to $9.1 million for the first quarter of 2018.

- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the first quarter of 2019 were $8.8 million, compared to $5.6 million for the first quarter of 2018. The

increase was primarily due to expenses related to the OTIVIDEX Phase 3 clinical trial and increased costs for nonclinical and manufacturing activities to support initiation of clinical trials for OTO-313 and OTO-413.

- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the first quarter of 2019 were $3.3 million, compared to $6.2 million for the first quarter of 2018. The decrease was primarily a result of reduced selling expenses due to the discontinuation of promotional support for OTIPRIO.

- **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. EDT/1:30 p.m. PDT 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: 8076448. 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. 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 results, patient recruitment and enrollment plans for, and design and conduct of, the Phase 1/2 clinical trial for OTO-313; expectations regarding IND-enabling activities to support, 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; the activity under, and potential benefits of, the co-promotion agreements between Otonomy and Mission and between Otonomy and Glenmark; 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 and/or the co-promotion agreement between Otonomy and Glenmark; 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on May 6, 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.

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

	As of March 31, 2019	As of December 31, 2018
	(unaudited)	
Cash and cash equivalents	$ 16,276	$ 33,633
Short-term investments	70,671	63,651
Right-of-use assets	16,421	—
Total assets	110,287	104,992
Long-term debt, net	14,822	14,764
Leases, net of current	16,359	—
Total liabilities	40,998	25,255
Accumulated deficit	(427,202)	(415,218)
Total stockholders' equity	69,289	79,737

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

	Three Months Ended March 31,	
	2019	2018
	(unaudited)	
Product sales, net	$ 192	$ 301
Costs and operating expenses:		
Cost of product sales	213	272
Research and development	8,795	5,650
Selling, general and administrative	3,278	6,157
Total costs and operating expenses	12,286	12,079
Loss from operations	(12,094)	(11,778)
Other income, net	110	354
Net loss	$ (11,984)	$ (11,424)
Net loss per share, basic and diluted	$ (0.39)	$ (0.37)
Weighted-average shares used to compute net loss per share, basic and diluted	30,685,412	30,568,531

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

	Three Months Ended March 31,	
	2019	**2018**
	(unaudited)	
GAAP operating expenses		
Research and development	$ 8,795	$ 5,650
Selling, general and administrative	3,278	6,157
Total GAAP operating expenses	12,073	11,807
Non-GAAP adjustments		
R&D stock-based compensation expense	(659)	(637)
SG&A stock-based compensation expense	(834)	(2,072)
Total non-GAAP adjustments	(1,493)	(2,709)
Non-GAAP operating expenses	$ 10,580	$ 9,098

Otonomy, Inc.
Reconciliation of 2018 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