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):

May 7, 2020

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))

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)

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 May 7, 2020, Otonomy, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2020. 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 7, 2020

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 7, 2020

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

FOR IMMEDIATE RELEASE

Otonomy Reports First Quarter 2020 Financial Results and Provides Corporate Update

Conference call to review status of clinical trials and timing to results to be held in June

SAN DIEGO, May 7, 2020 -- 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, 2020 and provided an update on its product pipeline and corporate activities. In lieu of a conference call today, the company plans to host a program update call in June to review the status and timeline to results for the three ongoing clinical trials including the Phase 3 trial of OTIVIDEX® in Ménière's disease.

"As we announced several weeks ago, we have taken steps to ensure the health and safety of our employees, patients, and study site healthcare professionals during the COVID-19 pandemic while also working diligently to mitigate the impact to our ongoing clinical trials," said David A. Weber, Ph.D., president and CEO of Otonomy. "Collection of patient-reported symptom data continues to be very good supporting the integrity of these trials. However, quarantine restrictions have slowed new patient enrollment in the OTIVIDEX trial and required us to pause enrollment in the OTO-413 trial, which has now resumed. Regarding the OTO-313 trial, we have enrolled a sufficient number of patients to inform our next steps in the program and have discontinued further enrollment. We look forward to reviewing the status of these trials as well as timing to results during a program update call in June."

Otonomy Business Updates

- **COVID-19 Pandemic: update provided in April 2020.** Otonomy has taken steps to protect the health and safety of its employees and community by generally adopting a work from home policy in line with directives from the State of California and guidance from the U.S. Centers for Disease Control and Prevention (CDC). On-site activities have been restricted to certain essential facility and laboratory support functions and social distancing policies have been implemented. We are also assessing our eligibility for programs under the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

- **OTIVIDEX Phase 3 clinical trial in Ménière's disease: patient compliance for reporting vertigo episodes is high and new patient enrollment is ongoing.** This trial is being

conducted at approximately 60 trial sites dispersed across different regions of the United States and multiple countries in Europe. We believe there is minimal impact of COVID-19 on the integrity of efficacy data being collected because patients report their vertigo episodes via a daily telephone diary and compliance continues to be high. Quarantine restrictions are impacting the rate of new patient enrollment, which is being managed on a country-by-country and site-by-site basis according to local conditions.

- **OTO-313 Phase 1/2 clinical trial in tinnitus: patient enrollment in exploratory efficacy cohort has been completed.** An initial safety cohort of this randomized, double-blind, placebo-controlled trial was successfully completed and a second cohort designed to evaluate the activity of OTO-313 across multiple exploratory efficacy endpoints including the Tinnitus Functional Index (TFI) questionnaire is ongoing. This second cohort has enrolled a total of 35 patients, which Otonomy believes is sufficient to inform next steps for the OTO-313 program. As a result, new patient enrollment has been discontinued and the company will initiate study completion activities following final patient visits. Timing to study results will be provided during the program review call in June.

- **OTO-413 Phase 1/2 clinical trial in hearing loss: new patient enrollment has resumed.** This is an ascending single dose safety and exploratory efficacy study being conducted at a limited number of trial sites in the United States. As previously announced, we have successfully completed several dose cohorts but temporarily paused new patient enrollment because site visits are required for extensive hearing assessments to evaluate both safety and exploratory efficacy. We have resumed new patient enrollment, which is being managed on a site-by-site basis.

- **GJB2 gene therapy program: preclinical data presented for novel and proprietary AAV capsids.** Otonomy and Applied Genetic Technologies Corporation (AGTC) are collaborating to co-develop and co-commercialize an AAV-based gene therapy to restore hearing in patients with hearing loss caused by a mutation in the gap junction beta 2 gene (GJB2) -- the most common cause of congenital hearing loss. Preclinical results presented at the Association for Research in Otolaryngology (ARO) meeting in January demonstrated that a gene of interest can be expressed in support cells of the cochlea, which are the relevant target cells for treating GJB2 deficiency, using novel and proprietary AAV capsids.

- **OTO-510: preclinical data presented for novel and proprietary class of otoprotectant agents.** Cisplatin is a potent chemotherapeutic agent that is widely used to treat a variety of cancers in adults and children, however it is commonly associated with severe adverse effects including cisplatin-induced hearing loss (CIHL). At ARO, Otonomy presented preclinical results demonstrating varying degrees of otoprotection against CIHL for several classes of therapeutic agents. In particular, a novel class of agents that potently binds to cisplatin demonstrated greater otoprotection than anti-oxidant and anti-apoptotic molecules, and increased potency relative to other cisplatin-binding molecules currently in development.

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

selected a lead compound for development. The OTO-6XX program is targeting hair cell regeneration for the treatment of severe hearing loss.

First Quarter Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $48.6 million as of March 31, 2020, compared to $60.7 million as of December 31, 2019.

- **Long-term Debt:** Otonomy obtained a $15 million term loan from Oxford Finance LLC in December 2018. The loan provides for a 24 month interest-only repayment period, followed by 35 months of amortization.

- **Operating Expenses:** GAAP operating expenses were $11.5 million for the first quarter of 2020, compared to $12.1 million for the first quarter of 2019. Non-GAAP operating expenses, which exclude stock-based compensation, were $10.1 million for the first quarter of 2020, compared to $10.6 million for the first quarter of 2019.

- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the first quarter of 2020 were $7.7 million, compared to $8.8 million for the first quarter of 2019. The decrease for the quarter was primarily due to reduced third-party development costs that were partially offset by increased compensation expense.

- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the first quarter of 2020 were $3.8 million, compared to $3.3 million for the first quarter of 2019. The increase this quarter was primarily the result of discontinued cost reimbursement received from OTIPRIO co-promotion partners.

- **Financial Guidance:**
  - **2020 Operating Expenses:** Otonomy expects that GAAP operating expenses will be in the range of $45-$48 million, and that non-GAAP operating expenses will be in the range of $35-$38 million.
  - **Cash Runway:** Otonomy expects that its current cash, cash equivalents, and short-term investments will be sufficient to fund company operations into 2021 and we are managing spending to enable this cash runway to extend through readouts for our three ongoing clinical trials.

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, statements relating to the timing of results, patient recruitment and activity for, conduct of, and the impact of COVID-19 on, ongoing clinical trials; expectations regarding operating expenses for 2020 and cash runway; 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: delays and disruption resulting from the COVID-19 pandemic and governmental responses to the pandemic, including current and future impacts to Otonomy's operations, the manufacturing of its product candidates, the progression of its current clinical trials, enrollment in its current and future clinical trials and patient conduct and compliance; 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; the integrity of patient-reported outcomes in its current and future clinical trials; 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, and for the manufacture of its product candidates; Otonomy's ability to protect its intellectual property in the United States and throughout the world; expectations regarding potential therapy benefits, 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; general economic and market conditions; 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 7, 2020, 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, 2020	As of December 31, 2019
	(unaudited)	
Cash and cash equivalents	$ 31,038	$ 25,194
Short-term investments	17,568	35,476
Right-of-use assets	15,131	15,465
Total assets	70,051	83,018
Long-term debt, current	1,286	—
Long-term debt, net of current	13,731	14,967
Leases, net of current	14,951	15,320
Total liabilities	40,114	42,785
Accumulated deficit	(471,656)	(459,893)
Total stockholders' equity	29,937	40,233

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

	Three Months Ended March 31,	
	2020	2019
	(unaudited)	
Product sales, net	$ 160	$ 192
Costs and operating expenses:		
Cost of product sales	214	213
Research and development	7,672	8,795
Selling, general and administrative	3,836	3,278
Total costs and operating expenses	11,722	12,286
Loss from operations	(11,562)	(12,094)
Other (expense) income, net	(201)	110
Net loss	$ (11,763)	$ (11,984)
Net loss per share, basic and diluted	$ (0.38)	$ (0.39)
Weighted-average shares used to compute net loss per share, basic and diluted	30,814,211	30,658,412

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

	Three Months Ended March 31,	
	2020	**2019**
	(unaudited)	
GAAP operating expenses		
Research and development	$ 7,672	$ 8,795
Selling, general and administrative	3,836	3,278
Total GAAP operating expenses	11,508	12,073
Non-GAAP adjustments		
R&D stock-based compensation expense	(568)	(659)
SG&A stock-based compensation expense	(841)	(834)
Total non-GAAP adjustments	(1,409)	(1,493)
Non-GAAP operating expenses	$ 10,099	$ 10,580

Otonomy, Inc.
Reconciliation of 2020 GAAP to Non-GAAP Operating Expense Guidance
(in millions)

GAAP operating expenses	$45 - $48
Non-GAAP adjustments	
Stock-based compensation expense	$10
Non-GAAP operating expenses	$35 - $38