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):

April 9, 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 8.01 Other Events.

On April 9, 2020, Otonomy, Inc. (the "Company") issued a press release providing a business update related to the novel coronavirus (COVID-19) pandemic. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated April 9, 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: April 9, 2020

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

FOR IMMEDIATE RELEASE

Otonomy Provides Business Update Related to COVID-19 Pandemic

SAN DIEGO, April 9, 2020 -- Otonomy, Inc. (Nasdaq: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today provided a business update related to the COVID-19 pandemic.

“Our first priority during this international crisis has been to ensure the health and safety of our employees, patients enrolled in our clinical trials, and healthcare professionals at our study sites in the United States and Europe,” said David A. Weber, Ph.D., president and CEO of Otonomy. “We are fortunate that the primary endpoint for our OTIVIDEX® Phase 3 trial and key exploratory endpoints in our OTO-313 Phase 2 trial are self-reported by the patient from home thereby preserving the integrity of data collection in these trials even in locations with quarantine restrictions. However, new patient enrollment is being impacted so we are suspending our guidance for the timing of trial results until we better understand the timeline for each study. We continue to carefully manage our spending and believe that our existing capital can fund operations through our multiple clinical trial readouts including the OTIVIDEX Phase 3 trial.”

Otonomy Business Updates

Ongoing Operations
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. Other corporate functions including clinical operations were able to quickly and effectively transition to remote working.

OTIVIDEX Phase 3 Clinical Trial in Ménière’s Disease
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 data being collected for enrolled patients because patients report their vertigo episodes via a daily telephone diary and compliance continues to be high. The enrollment of new patients 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
Otonomy has successfully completed the initial safety cohort of this trial, and is conducting the exploratory efficacy study at approximately 15 sites located throughout the United States. Several of the efficacy endpoints are collected by patient-reported daily telephone diary and we switched to completion

of the Tinnitus Functional Index (TFI) questionnaire at the patient's home as well to avoid restrictions on travel or study site visits. The enrollment of new patients is being managed on a site-by-site basis.

OTO-413 Phase 1/2 Clinical Trial in Hearing Loss

This is an ascending single dose safety and exploratory efficacy study being conducted at a limited number of trial sites in the United States. We have successfully completed several dose cohorts but have temporarily paused new patient enrollment because site visits are required for extensive hearing assessments to evaluate both safety and exploratory efficacy. Resumption of enrollment will be determined on a site-by-site basis.

Financial Guidance

We finished 2019 with approximately $61 million in cash, cash equivalents and short-term investments and reiterate that we expect non-GAAP operating expenses for 2020, which reflect spending, to be in the range of $35-$38 million (with GAAP operating expenses that include stock-based compensation to total in the range of $45-$48 million). We believe that this capital is sufficient to fund company operations into 2021 and are managing spending to enable this cash runway to extend through readouts for our three ongoing clinical trials.

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 and activity for, design and conduct of, data collection and preservation of data integrity with respect to, and the risks and impact of COVID-19 to, the Phase 3 clinical trial for OTIVIDEX, the Phase 1/2 clinical trial for OTO-313 and the Phase 1/2 clinical trial for OTO-413; expectations regarding patient self-reporting with respect to the Phase 3 clinical trial for OTIVIDEX and the Phase 1/2 clinical trial for OTO-313; expectations regarding ongoing operations, including with respect to on-site and remote working; expectations regarding operating expenses for 2020; expectations that current capital is sufficient to fund 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: 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 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; the integrity of patient-reported outcomes in its current and future 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 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 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 27, 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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