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): July 6, 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)**	**(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 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 July 6, 2020, Otonomy, Inc. issued a press release announcing results for its Phase 1/2 clinical trial of OTO-313 for the treatment of tinnitus. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

On July 6, 2020, Otonomy, Inc. issued a press release announcing an update on the statistical analysis plan related to its ongoing Phase 3 clinical trial of OTIVIDEX in Ménière's disease. A copy of the press release is attached hereto as Exhibit 99.2 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated July 6, 2020.
99.2	Press Release dated July 6, 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: July 6, 2020

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

Otonomy Reports Positive Top-Line Results from Phase 1/2 Clinical Trial of OTO-313 in Patients with Tinnitus

- *OTO-313 demonstrated a higher proportion of responders than placebo*
- *Given clear signal in this proof of concept study, Otonomy plans to advance OTO-313 to full Phase 2 development in tinnitus*
- *OTO-313 was well-tolerated with lower incidence of adverse events than placebo group*
- *Management will review results during conference call today at 4:30 p.m. ET*

SAN DIEGO, July 6, 2020 — Otonomy, Inc. (Nasdaq: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today announced positive top-line results from the Phase 1/2 clinical trial of OTO-313 in patients with persistent tinnitus of at least moderate severity. The exploratory efficacy cohort of the trial included 31 evaluable patients randomized to a single intratympanic injection of OTO-313 or placebo (1:1 randomization) and then followed for eight weeks. Patients reported the severity of their tinnitus symptoms using the Tinnitus Functional Index (TFI), a clinically-validated instrument, and by the daily reporting of their tinnitus loudness and annoyance. The trial achieved its objectives by demonstrating a positive clinical signal for OTO-313 based on a TFI responder analysis, with a favorable safety profile. Given these results, Otonomy intends to advance OTO-313 into full Phase 2 development which may include evaluation of a higher dose and/or retreatment with OTO-313.

Top-line results for the Phase 1/2 trial were as follows:

- 43% of OTO-313 patients were responders at both Day 29 and Day 57 compared to 13% of placebo patients. A responder is a patient whose TFI score decreases by 13-points or more from their baseline score, a change considered clinically meaningful based on the TFI instrument validation.
- For patients who were responders at both Day 29 and Day 57, OTO-313 demonstrated a higher responder rate than placebo at all TFI improvement levels considered clinically meaningful (TFI reduction $\geq$ 13, 15, 20, 25, and 30 points). The difference in responder rate between OTO-313 and placebo was statistically significant on post hoc analysis (p-value < 0.05) for TFI reductions $\geq$ 13, 15, and 20 points.
- OTO-313 patients who were responders at both Day 29 and Day 57 reported improvements in both tinnitus loudness and annoyance levels based on daily diaries and also reported improvement in the Patient Global Impression of Change (PGIC), a general assessment of tinnitus status. There was a very strong relationship demonstrated between the improvement in TFI score reported by these OTO-313 responders and their improvement in tinnitus loudness and annoyance levels as well as PGIC based on the calculated correlation coefficients of $\geq$ 0.8 for these endpoints.

- A single intratympanic injection of OTO-313 was well-tolerated with lower incidence of adverse events than the placebo group.

“We are excited to announce these positive clinical results for OTO-313 and to advance this potential treatment for patients suffering from the high burden of persistent tinnitus,” said David A. Weber, Ph.D., president and CEO of Otonomy. “This is also a great start to our three planned clinical trial readouts with results for our OTO-413 Phase 1/2 trial expected in the fourth quarter of 2020 and results from the Phase 3 trial of OTIVIDEX® in Ménière’s disease expected in the first quarter of 2021.”

“Tinnitus is a common problem that affects millions of people around the world. A significant proportion of patients experience moderate to severe tinnitus, which can negatively impact sleep and relaxation, disrupt the ability to focus at work and at home, create feelings of distress and anxiety, and lower overall quality of life,” said Kenneth Maxwell, M.D., a Neurotologist at Piedmont Ear Nose & Throat Associates in Winston-Salem, North Carolina and an investigator in the OTO-313 Phase 1/2 trial. “Unfortunately, there are no FDA approved drug treatments for tinnitus and existing approaches rely on coping strategies. Therefore, I am very encouraged by the treatment response observed with OTO-313 in this trial as well as the consistency of the improvement for OTO-313 responders across all four tinnitus endpoints examined in this trial, and I look forward to participating in future clinical studies.”

Webcast and Conference Call

Otonomy management will host a webcast and conference call regarding these program updates at 4:30 p.m. ET / 1:30 p.m. PT 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: 4273643. 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.

About Tinnitus

Tinnitus is the medical term for the perception of noise when there is no sound. It is often described as a ringing in the ear but can also sound like roaring, clicking, hissing or buzzing. Tinnitus is often caused by cochlear injury due to excessive noise, physical trauma, persistent ear infection or exposure to ototoxic agent, leading to over-activation of auditory nerve fibers and the perception of noise in the absence of an external stimulus. Approximately 10 percent of U.S. adults suffer from the condition, which can severely impact daily activities and result in anxiety and depression. Tinnitus also accounts for the most prevalent service-connected disability among veterans with an estimated cost exceeding $2 billion. There are currently no FDA approved drug treatments for tinnitus.

About OTO-313

OTO-313 is a sustained-exposure formulation of the potent and selective N-Methyl-D-Aspartate (NMDA) receptor antagonist gacyclidine providing localized drug administration to the inner ear. We believe that gacyclidine can reduce the severity of tinnitus symptoms following cochlear injury by decreasing the over-activation of damaged auditory nerve fibers in the cochlea and their connections. The therapeutic potential of gacyclidine for tinnitus has been demonstrated in preclinical models and several pilot clinical studies. OTO-313 utilizes a novel, patent-protected formulation technology to provide several weeks of gacyclidine drug exposure in the inner ear compartment following a single intratympanic injection.

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, expectations regarding the potential benefits, development activity and advancement of clinical trials; statements relating to the timing of results, patient recruitment and activity for, conduct of, ongoing clinical trials; statements relating to potential treatment for patients suffering from the high burden of persistent tinnitus; statements by an investigator in the OTO-313 Phase 1/2; statements by Otonomy's president and CEO; and estimated costs of tinnitus. 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 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; 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 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.

Contacts:

Media Inquiries
Spectrum Science
Chloé-Anne Ramsey
Vice President
404.865.3601
cramsey@spectrumscience.com

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

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FOR IMMEDIATE RELEASE

Otonomy Provides Update on OTIVIDEX® Program

Management will review the OTIVIDEX statistical analysis plan update together with the positive top-line OTO-313 Phase 1/2 trial results during a conference call today at 4:30 p.m. ET

SAN DIEGO, July 6, 2020 — Otonomy, Inc. (Nasdaq: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today provided an update on the statistical analysis plan related to the ongoing Phase 3 clinical trial of OTIVIDEX in Ménière's disease. In response to questions received from the U.S. Food and Drug Administration (FDA) regarding use of the Generalized Poisson model to analyze the daily vertigo count data reported by patients, Otonomy submitted a revised statistical analysis plan that uses a statistical test called the Negative Binomial model for the primary analysis of the ongoing trial.

Otonomy selected the Negative Binomial model to address the FDA's questions because it believes it provides the best fit of the OTIVIDEX clinical data based on the Phase 2b trial (for patients with vertigo enrollment criteria matching the Phase 3 clinical trials), the AVERTS-2 Phase 3 clinical trial, and the integrated dataset from both trials. As the table below indicates, the ad hoc analysis of the Definitive Vertigo Day (DVD) count data reported by patients for Month 3 is statistically significant (p value < 0.05) using the Negative Binomial model for each of these prior trial populations as well as the integrated summary.

p value for Analysis of DVD Count in Month 3	Phase 2b* (n = 97)	AVERTS-2** (n = 111)	Integrated Dataset
Generalized Poisson Model	0.002	0.013	< 0.001
Negative Binomial Model	0.016	0.008	< 0.001

* Patients with baseline DVD count of 4-22 days during the one-month baseline period

** Patients who completed 3-month follow-up period (of which 105 completed daily diaries)

"We have recently completed an extensive review of the statistical analysis model that we believe best fits the OTIVIDEX clinical data, which is characterized by approximately 40% of OTIVIDEX-treated patients having no DVD's in Month 3," said David A. Weber, Ph.D., president and CEO of Otonomy. "Based on this review, we determined that the Negative Binomial model provides an improved fit and reduced Type 1 error compared to the Generalized Poisson model. The Negative Binomial model also gives us additional power to detect a treatment benefit enabling us to comfortably reduce the target patient enrollment in the ongoing trial from 160 to 142 patients while maintaining more than 90% power. We look forward to completing the enrollment of this trial during the third quarter of 2020 and announcing results in the first quarter of 2021."

Webcast and Conference Call

Otonomy management will review this update for the OTIVIDEX program together with a review of the OTO-313 Phase 1/2 trial results (announced under a separate release) during a webcast and conference call at 4:30 p.m. ET / 1:30 p.m. PT 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: 4273643. 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.

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enrollment in clinical trials; the integrity of patient-reported outcomes in its current and future clinical trials; side effects or adverse events associated with Otonomy's product candidates; Otonomy's dependence on third parties to conduct nonclinical studies and clinical trials; expectations regarding potential therapy benefits; 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.

Contacts:

Media Inquiries
Spectrum Science
Chloé-Anne Ramsey
Vice President
404.865.3601
cramsey@spectrumscience.com

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

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