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 20, 2022

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 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 20, 2022, Otonomy, Inc. issued a press release announcing results for its Phase 2a clinical trial of OTO-413 in patients with hearing loss. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated April 20, 2022
104	Cover page interactive data file (embedded within the inline XBRL document)

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.

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

Date: April 20, 2022

Exhibit 99.1

FOR IMMEDIATE RELEASE

Otonomy Reports Positive Top-Line Results from Phase 2a Clinical Trial of OTO-413 in Patients with Hearing Loss

- *Clinical benefit again observed for OTO-413 versus placebo for multiple efficacy endpoints based on responder analysis at both Days 57 and 85*
- *Results support clinical activity and tolerability findings from previous Phase 1/2 trial*
- *Enrollment in higher dose cohorts is ongoing with results expected in second half of 2022*
- *Otonomy expects to initiate full dose-ranging Phase 2 efficacy trial by the end of 2022*
- *Management will review results during a conference call today at 8:30 a.m. ET*

SAN DIEGO, April 20, 2022 — 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 2a clinical trial of OTO-413 in subjects with hearing loss. The randomized, double-blind, placebo-controlled trial demonstrated that a single intratympanic injection of 0.3 mg OTO-413, a sustained exposure formulation of brain-derived neurotrophic factor (BDNF), provided clinically meaningful treatment benefit versus placebo across multiple speech-in-noise (SIN) hearing tests as well as the Patient Global Impression of Change (PGIC) at consecutive time points (Days 57 and 85). These results support the clinical activity of OTO-413 observed in the prior Phase 1/2 trial and provide a second, independent demonstration of the treatment potential of OTO-413 for patients over a broad range of hearing loss levels.

“The most common complaint of patients seeking treatment for hearing loss is difficulty hearing a conversation in a noisy setting,” said Barbara Shinn-Cunningham, Ph.D., Director, Carnegie Mellon Neuroscience Institute and Cowan Professor of Auditory Neuroscience, Biomedical Engineering, Psychology, and Electrical & Computer Engineering at Carnegie Mellon University. “Breakthrough research conducted over the last decade suggests that damage to cochlear synapses plays a role in this speech-in-noise hearing difficulty and that treatment with a neurotrophic factor, such as BDNF, offers potential for repair. I am encouraged by these results for OTO-413 and look forward to its continued development as an option for patients to regain functional hearing.”

The design of the Phase 2a trial was the same as the previous Phase 1/2 trial. All subjects self-reported hearing difficulty in a noisy environment that was confirmed by SIN testing. Subjects could also have up to moderately-severe hearing loss by standard audiometric testing. As in the Phase 1/2 trial, multiple clinically-validated SIN hearing tests including Digits-in-Noise, Words-in-Noise, and the American English Matrix test were administered at baseline and following treatment. The assessment of treatment benefit was based on demonstration of a clinically-meaningful improvement from baseline versus placebo at both Days 57 and 85. The results below are for the 30 evaluable subjects (out of 33 total enrolled), which includes 20 treated with OTO-413 and 10 who received placebo.

Top-line results are provided below with additional details included in a presentation that will be reviewed during today's conference call and is available online in the investor relations section of Otonomy's website at www.otonomy.com.

- 40% (8 of 20) OTO-413 subjects demonstrated a clinically-meaningful improvement on at least one of the three SIN tests at both Days 57 and 85 versus 20% (2 out of 10) for placebo.
- 15% (3 of 20) OTO-413 subjects demonstrated a clinically-meaningful improvement by two or more different SIN tests at both Days 57 and 85 versus 0% (0 of 10) for placebo.
- For the Words-in-Noise test that has been well-established and validated in hearing loss patients, 40% (6 of 15 with evaluable tests) OTO-413 subjects demonstrated a clinically-meaningful improvement at both Days 57 and 85 versus 0% (0 of 9 with evaluable tests) for placebo.
- Most of the patients enrolled in this trial also had moderate-to-severe high-frequency hearing loss measured with standard audiometric testing. The responder rate for OTO-413 was favorable in this subset as well with 41% (7 of 17) OTO-413 subjects demonstrating a clinically-meaningful improvement in at least one SIN test at both Days 57 and 85 compared to 13% (1 of 8) placebo subjects.
- The PGIC demonstrated a treatment benefit with 50% (10 of 20) OTO-413 subjects reporting an improvement from baseline at both Days 57 and 85 compared to only 10% (1 of 10) for placebo.
- Treatment with OTO-413 was well tolerated. There were no serious adverse events and no discontinued patients due to an adverse event (AE). 32% of OTO-413 and 46% of placebo subjects reported an AE, most of which were mild.

Based on these positive results, Otonomy intends to initiate a full dose-ranging Phase 2 trial in hearing loss patients by the end of 2022. This trial will also incorporate learnings from the ongoing higher dose evaluations that are assessing the tolerability and treatment activity of two higher doses of OTO-413: 0.75 mg and 1.50 mg, which is five times the dose evaluated in the Phase 2a trial. Results from the higher dose evaluation are expected in the second half of 2022.

"As an investigator in the OTO-413 study program, I am delighted to again see the treatment benefit of OTO-413 for patients across a broad range of hearing loss severity," said Victoria Sanchez, Au.D., Ph.D., Assistant Professor, Department of Otolaryngology—Head & Neck Surgery at the University of South Florida. "It is also encouraging to see the significant improvement in speech intelligibility of OTO-413 responders using the Words-in-Noise test, which has been extensively validated as an instrument to quantify the ability of listeners to understand speech in background noise among many hearing loss patient populations."

“We are excited to announce these positive results that are important because they provide a second independent, placebo-controlled trial demonstrating the treatment benefit of OTO-413 in a broad hearing loss patient population,” said David A. Weber, Ph.D., president and CEO of Otonomy. “This study also furthers our understanding of the target patient population, speech-in-noise test performance, and study conduct considerations for future trials. We’re looking forward to reviewing results from the ongoing higher dose evaluations in the second half of this year and then initiating a full dose-ranging Phase 2 efficacy trial by the end of 2022.”

Webcast and Conference Call

Otonomy management will host a webcast and conference call regarding these clinical results at 8:30 a.m. ET 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: 8882504. 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 Speech-in-Noise Hearing Loss

Recent scientific advances have shown that the loss of synaptic connections between inner ear hair cells and auditory nerve fibers contributes to hearing impairment. This cochlear synaptopathy is proposed as an underlying pathology in age-related and noise-induced hearing loss and is believed to contribute to the common difficulty of hearing speech in the presence of background noise. Overall, there are more than 50 million people in the U.S. who self-report having a problem hearing in background noise. The disease burden associated with hearing loss is significant as it has been shown to lead to social isolation, depression and early cognitive decline. Hearing aids typically provide limited benefit addressing patients’ speech-in-noise hearing and there are no FDA-approved drug treatments for this condition.

About OTO-413

OTO-413 is a proprietary, sustained-exposure formulation of brain-derived neurotrophic factor (BDNF), which is a naturally occurring protein involved in neuron growth and repair. Nonclinical studies have demonstrated that local administration of BDNF repairs the connections between inner hair cells and auditory nerve fibers in the cochlea that are damaged due to noise trauma or exposure to ototoxic chemicals. Furthermore, Otonomy has demonstrated in preclinical studies that repair of synaptic connections is associated with a restoration of hearing function. Initial clinical studies have demonstrated that a single intratympanic injection of OTO-413 is well-tolerated and improves hearing function across multiple clinically-validated speech-in-noise hearing tests.

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 with a focus on 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 regarding the development plans and timelines for OTO-413; the potential benefits of OTO-413; anticipated timing of results of the OTO-413 higher dose evaluations, and the expectations regarding such clinical data; the anticipated timing of the start of the full dose-ranging OTO-413 Phase 2 trial; statements relating to potential treatment for patients suffering from hearing loss; statements by Barbara Shinn-Cunningham, Ph.D.; statements by Victoria Sanchez, Au.D., Ph.D.; 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 initiation and progression of, and enrollment in, its planned and current 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 and the potential for clinical trials to differ from preclinical, early clinical, preliminary, top-line or expected results, which may not support further development, and challenges related to patient enrollment, conduct and compliance 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 the performance under or give rise to the termination of any promotional, collaboration or license agreements, or 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 obtain regulatory approval and 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 and to ensure compliance with various laws and regulations in countries in which it conducts clinical trials; 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 (SEC) on February 28, 2022, 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
Lauren Benton
Senior Account Executive
212.899.9731
lbenton@spectrumscience.com

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

###