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):

February 11, 2021

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 February 11, 2021, Otonomy, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 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 February 11, 2021
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.

Date: February 11, 2021

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

FOR IMMEDIATE RELEASE

Otonomy Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Corporate Update

- ***OTIVIDEX® Phase 3 trial results in Ménière's disease expected by end of February***
- ***OTO-313 Phase 2 trial in tinnitus planned to start in first quarter of 2021 with top-line results expected in mid-2022***
- ***OTO-413 Phase 1/2 trial expansion in hearing loss expected to start in second quarter of 2021 with results anticipated in mid-2022***

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

SAN DIEGO, February 11, 2021 -- Otonomy, Inc. (Nasdaq: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today reported financial results for the quarter and year ended December 31, 2020 and provided an update on its product pipeline and corporate activities. The company will host a conference call and webcast today at 4:30 p.m. ET to discuss recent highlights and financial results.

"We made great progress in advancing our product pipeline and achieving our corporate objectives during 2020 including positive clinical results for OTO-313 in tinnitus, positive clinical results for OTO-413 in hearing loss, and completion of enrollment for our Phase 3 trial of OTIVIDEX in Ménière's disease," said David A. Weber, Ph.D., president and CEO of Otonomy. "We also selected a product candidate, OTO-825, for our GJB2 gene therapy program, demonstrated preclinical proof-of-concept for our otoprotection program, and licensed a novel compound for our OTO-6XX hair cell repair and regeneration program. We are looking forward to important catalysts this year beginning with the OTIVIDEX Phase 3 results later this month."

Otonomy Program Updates

- **OTIVIDEX: results for Phase 3 trial in Ménière's disease expected by end of February.** This trial enrolled a total of 149 patients from the United States and Europe, exceeding the target of 142 patients. In November 2020, Otonomy announced that a review of the revised statistical analysis plan by the U.S. Food and Drug Administration (FDA) confirmed use of the Negative Binomial model for analysis of the primary endpoint in this trial. The last patient last visit was completed at the end of December 2020 and results are expected by the end of

this month. Assuming positive results, we plan to submit a New Drug Application to the FDA in the third quarter of 2021.

- **OTO-313: Phase 2 trial in tinnitus planned to start in the first quarter of 2021 with top-line results expected in mid-2022.** In July 2020, Otonomy reported positive top-line results from the Phase 1/2 trial of OTO-313 in patients with unilateral tinnitus of at least moderate severity. This trial demonstrated a positive clinical response for a single intratympanic injection of OTO-313 using the Tinnitus Functional Index (TFI) that was correlated with tinnitus loudness, tinnitus annoyance and patient global impression of change measures. Based on these results, Otonomy plans to conduct a Phase 2 trial that will enroll approximately 140 patients with unilateral tinnitus. To enrich the study population, the trial will exclude patients with severe hearing loss and increase the minimum TFI score required for entry. The company will also expand the unilateral patient population eligible for enrollment by increasing the time from tinnitus onset from six months to one year, and will extend the observation period to assess durability of the treatment effect.

- **OTO-413: Phase 1/2 trial expansion planned to start in second quarter of 2021 with top-line results expected in mid-2022.** In December 2020, Otonomy announced positive top-line results from an ascending single dose safety and exploratory efficacy study for OTO-413 in patients with hearing loss. This trial demonstrated that a single intratympanic injection of OTO-413 was well-tolerated across all dose cohorts. Furthermore, the therapeutic activity of OTO-413 versus placebo was demonstrated across multiple clinically-validated speech-in-noise hearing tests at consecutive time points (Days 57 and 85). Beginning in the second quarter of 2021, Otonomy plans to enroll additional hearing loss patients in an expansion of the Phase 1/2 trial to evaluate a refined study protocol in preparation for Phase 2. This expansion will randomize subjects to a single treatment with OTO-413 or placebo and evaluate a reduced number of endpoints focusing on the phrase, word and digit speech-in-noise hearing tests assessed in the initial patient cohorts. Enrollment criteria will continue to target a broad hearing loss population to support design of a Phase 2 trial.

- **OTO-825: GJB2 gene therapy product candidate selected.** 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 (GJB2) gene -- the most common cause of congenital hearing loss. Preclinical results presented at conferences during 2020 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. Also, consistent gene expression was observed for at least 12 weeks in non-human primates following a single local administration. These results supported selection of OTO-825 for advancement into IND enabling studies.

- **OTO-510: preclinical development ongoing for novel and proprietary otoprotection molecule.** 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). Otonomy has identified a novel series of molecules with improved otoprotection in preclinical CIHL studies compared to other agents

in development. Preclinical development continues for a small molecule from this class formulated to provide sustained exposure from a single intratympanic injection.

- **OTO-6XX: preclinical development ongoing for hair cell repair and regeneration program.** In July 2020, Otonomy entered into an exclusive license agreement with KYORIN Pharmaceutical Co., Ltd. (Kyorin) that provides Otonomy with exclusive worldwide rights to develop, manufacture and commercialize a novel compound for the treatment of sensorineural hearing loss. Otonomy is formulating the patent-protected compound utilizing the company's proprietary technology to provide sustained drug exposure in the inner ear following a single local administration. The OTO-6XX program targets hair cell repair and regeneration for the treatment of severe hearing loss.

- **OTIPRIO®: co-promotion partnership initiated and expanded with ALK-Abelló, Inc. (ALK).** In June 2020, Otonomy entered a co-promotion agreement that provided ALK with an exclusive right to promote OTIPRIO for acute otitis externa (AOE). This agreement was expanded in October 2020 to include OTIPRIO's other FDA-approved indication, use during ear tube surgery. During the multi-year agreement, Otonomy will receive co-promotion fees and reimbursement of a proportion of product support costs while also retaining a share of adjusted gross profits from the sale of OTIPRIO by ALK.

Fourth Quarter and Full Year 2020 Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $86.3 million as of December 31, 2020, compared to $60.7 million as of December 31, 2019. In July 2020, Otonomy completed an underwritten public offering of 17,275,000 shares of its common stock, which includes the underwriters' full exercise of their option to purchase additional shares, and the Company sold pre-funded warrants to purchase up to 4,000,000 shares of its common stock, for total gross proceeds of approximately $69.1 million, before deducting underwriting discounts and commissions and other offering expenses payable by Otonomy. All of the securities were sold by Otonomy.

- **Long-term Debt:** Otonomy obtained a $15.0 million term loan from Oxford Finance LLC in December 2018. In July 2020, the terms of the loan were amended to extend the interest-only repayment period from 24 months to 36 months, followed by 23 months of amortization.

- **Operating Expenses:** GAAP operating expenses were $10.1 million for the fourth quarter of 2020, compared to $10.7 million for the fourth quarter of 2019. For the full year 2020, GAAP operating expenses were $42.6 million compared to $44.5 million for 2019. Non-GAAP operating expenses, which exclude stock-based compensation, were $8.5 million for the fourth quarter of 2020, compared to $10.2 million for the fourth quarter of 2019. For the full year 2020, non-GAAP operating expenses were $36.5 million compared to $39.6 million for 2019.

- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the fourth quarter of 2020 were $6.4 million, compared to $7.0 million for the fourth 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. For the full year 2020, GAAP R&D expenses were $28.0 million compared to $32.8 million for 2019.

- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the fourth quarter of 2020 were $3.7 million, compared to $3.6 million for the fourth quarter of 2019. For the full year 2020, GAAP SG&A expenses were $14.6 million compared to $11.7 million for 2019.

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: 3372182. 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 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 related to the design and conduct of, activity, enrollment plans and patient population for, and timing of initiation and results for current and planned clinical trials; statements relating to the use of and expectations regarding the Negative Binomial model for the Phase 3 clinical trial of OTIVIDEX; statements regarding plans to submit a New Drug Application for OTIVIDEX; the potential benefits and opportunities of, and activities under the collaboration agreement between Otonomy and AGTC, including but not limited to plans to advance into IND enabling studies, the co-promotion agreement between Otonomy and ALK, and the license agreement between Otonomy and Kyorin; expectations regarding preclinical programs, including the potential benefits and development activities; expectations regarding Otonomy's ability to advance its pipeline and regarding upcoming catalysts; 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 and site 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, 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, 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 the collaboration agreement between Otonomy and AGTC, the co-promotion agreement between Otonomy and ALK, or the license agreement between Otonomy and Kyorin, 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 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 11, 2021, 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 December 31, 2020	As of December 31, 2019
Cash and cash equivalents	$ 30,767	$ 25,194
Short-term investments	55,576	35,476
Right-of-use assets	14,082	15,465
Total assets	106,265	83,018
Long-term debt, net	15,158	14,967
Leases, net of current	13,847	15,320
Total liabilities	39,999	42,785
Accumulated deficit	(504,624)	(459,893)
Total stockholders' equity	66,266	40,233

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

	Three Months Ended December 31,		Years Ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
Product sales, net	$ 53	$ 93	$ 273	$ 600
Costs and operating expenses:				
Cost of product sales	274	276	1,188	912
Research and development	6,374	7,034	27,997	32,805
Selling, general and administrative	3,692	3,625	14,575	11,690
Total costs and operating expenses	10,340	10,935	43,760	45,407
Loss from operations	(10,287)	(10,842)	(43,487)	(44,807)
Other (expense) income, net	(360)	(83)	(1,244)	132
Net loss	$ (10,647)	$ (10,925)	$ (44,731)	$ (44,675)
Net loss per share, basic and diluted	$ (0.20)	$ (0.36)	$ (1.10)	$ (1.45)
Weighted-average shares used to compute net loss per share, basic and diluted	52,257,321	30,768,174	40,845,844	30,726,786

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

	Three Months Ended December 31,		Years Ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
GAAP operating expenses				
Research and development	$ 6,374	$ 7,034	$ 27,997	$ 32,805
Selling, general and administrative	3,692	3,625	14,575	11,690
Total GAAP operating expenses	10,066	10,659	42,572	44,495
Non-GAAP adjustments				
R&D stock-based compensation expense	(632)	183	(2,456)	(2,085)
SG&A stock-based compensation expense	(950)	(628)	(3,642)	(2,793)
Total non-GAAP adjustments	(1,582)	(445)	(6,098)	(4,878)
Non-GAAP operating expenses	$ 8,484	$ 10,214	$ 36,474	$ 39,617