Otonomy Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

February 28, 2022

- ***OTO-313 Phase 2 trial in tinnitus fully enrolled ahead of schedule with top-line results expected in mid-2022; initiating safety evaluation of higher and bilateral dosing***
- ***OTO-413 Phase 2a cohort in hearing loss fully enrolled with top-line results expected early in second quarter of 2022; enrollment ongoing for higher dose evaluation***
- ***OTO-825 IND-enabling activities ongoing with IND filing expected first half of 2023***
- ***Current capital funds operations through multiple clinical readouts and into second half of 2023***

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

Hosting Investor R&D Event March 22 at 10 a.m. ET

SAN DIEGO, Feb. 28, 2022 (GLOBE NEWSWIRE) -- 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, 2021 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 are very pleased to have completed enrollment in both the OTO-313 Phase 2 and OTO-413 Phase 2a trials ahead of schedule and look forward to reporting the results from these trials in the coming months," said David A. Weber, Ph.D., president and CEO of Otonomy. "We also expect to broaden the clinical data informing our next steps for these programs with the ongoing higher dose evaluation for OTO-413 and upcoming higher dose and bilateral dosing safety evaluation for OTO-313. This is an exciting year for Otonomy with multiple clinical trial readouts that will be highlighted during our upcoming Investor R&D Event next month."

Otonomy Program Updates

- **OTO-313: Phase 2 trial in tinnitus is fully enrolled with top-line results expected in mid-2022; initiating safety evaluation of higher and bilateral dosing.** Otonomy has completed the enrollment of 153 patients with persistent, unilateral tinnitus of at least moderate severity in a Phase 2 trial of OTO-313 (target enrollment was 140 patients). Patients were randomized 1:1 to a single intratympanic injection of OTO-313 (0.32 mg) or placebo and are being followed for four months. The primary endpoint is the same as reported for the successful Phase 1/2 trial: a responder analysis based on the proportion of patients who report a clinically meaningful improvement in the Tinnitus Functional Index (TFI) from baseline to Months 1 and 2 following treatment. To assess durability of the OTO-313 treatment effect, the follow-up period has been extended out to four months. Top-line results for all timepoints are expected to be available in mid-2022. Additionally, Otonomy is initiating a one-month safety study for bilateral and higher (0.64 mg) dosing of OTO-313 with results expected in the second half of 2022. Together, these clinical data are expected to support an End-of-Phase 2 meeting with the FDA and inform the design of the OTO-313 Phase 3 clinical program planned to start in the first half of 2023.

- **OTO-413: Phase 2a cohort in hearing loss is fully enrolled with top-line results expected early in the second quarter of 2022; clinical evaluation of higher dosing ongoing.** Otonomy has also completed enrollment in a Phase 2a cohort for the highest OTO-413 dose (0.3 mg) evaluated in the initial Phase 1/2 trial cohorts. A total of 33 patients with hearing loss were randomized 2:1 to receive a single intratympanic injection of OTO-413 or placebo. Patients are being followed for three months and assessed using three clinically-validated speech-in-noise hearing tests. In addition, Otonomy is enrolling patients to evaluate at least one higher dose of OTO-413 (starting with 0.75 mg). Each dose cohort is expected to enroll approximately 12 hearing loss patients randomized 2:1 to OTO-413 or placebo with patients evaluated as in the Phase 2a. Based on results from the Phase 2a and higher-dose evaluation, Otonomy expects to initiate a full dose-ranging Phase 2 efficacy trial by the end of 2022.

- **OTO-825: preclinical studies validate therapeutic potential of GJB2 gene therapy for congenital hearing loss with Investigational New Drug (IND) filing expected in first half of 2023.** OTO-825 is an AAV-based gene therapy to restore hearing in patients with a mutation in the gap junction beta-2 (GJB2) gene, the most common cause of congenital hearing loss. Preclinical proof-of-concept results, which have been presented at multiple scientific meetings, demonstrate that a single administration of OTO-825 rescues hearing loss and cochlear damage in two preclinical models representing a

range of hearing loss severity caused by GJB2 deficiency. A Pre-IND meeting has been completed with the FDA and IND-enabling activities are ongoing.

- **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. The goal of the OTO-510 program is otoprotection without tumor protection.

- **OTO-6XX: preclinical development ongoing for severe hearing loss program.** Otonomy is evaluating therapeutic approaches to repair or regenerate cochlear hair cells that are damaged due to noise, aging or exposure to ototoxic chemicals. This mechanism is expected to be complementary to repair of cochlear synapses, which is addressed by OTO-413.

Anticipated Upcoming Milestones

- Early second quarter 2022, announce top-line results for OTO-413 Phase 2a cohort.
- In mid-2022, announce top-line results for OTO-313 Phase 2 clinical trial.
- In second half of 2022, announce safety results for OTO-313 bilateral and higher dosing.
- In second half of 2022, announce top-line results for OTO-413 higher dose evaluation.
- By end of 2022, initiate Phase 2 dose-ranging efficacy trial for OTO-413 in hearing loss.
- In first half of 2023, initiate Phase 3 clinical program for OTO-313 in tinnitus.
- In first half of 2023, file IND for OTO-825 in hearing loss associated with GJB2 gene mutation.

Fourth Quarter and Full Year 2021 Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $77.4 million as of December 31, 2021, compared to $86.3 million as of December 31, 2020.
- **Operating Expenses:** GAAP operating expenses were $13.2 million for the fourth quarter of 2021, compared to $10.1 million for the fourth quarter of 2020. For the full year 2021, GAAP operating expenses were $49.4 million compared to $42.6 million for 2020. Non-GAAP operating expenses, which exclude stock-based compensation, were $11.3 million for the fourth quarter of 2021, compared to $8.5 million for the fourth quarter of 2020. For the full year 2021, non-GAAP operating expenses were $42.0 million compared to $36.5 million for 2020.
- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the fourth quarter of 2021 were $9.7 million, compared to $6.4 million for the fourth quarter of 2020. The increase for the quarter was primarily due to higher development expenses for OTO-313 and OTO-413. For the full year 2021, GAAP R&D expenses were $34.7 million compared to $28.0 million for 2020.
- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the fourth quarter of 2021 were $3.5 million, compared to $3.7 million for the fourth quarter of 2020. For the full year 2021, GAAP SG&A expenses were $14.7 million compared to $14.6 million for 2020.
- **Financial Guidance:**
    - **2022 Operating Expenses:** Otonomy expects that GAAP operating expenses will be in the range of $52-$54 million, and that non-GAAP operating expenses will be in the range of $42-$44 million.
    - **Cash Runway:** Otonomy expects that its current cash, cash equivalents, and short-term investments will be sufficient to fund company operations into the second half of 2023.

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 GAAP operating expenses to Non-GAAP operating expenses and a reconciliation of GAAP operating expense guidance to Non-GAAP operating expense guidance.

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: 5169343. 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 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 related to the design and conduct of, activity, enrollment plans and patient populations for, and timing of initiation and results for current and planned clinical trials; Otonomy's development plans and timelines for its product candidates and programs; the potential benefits and advantages of Otonomy's product candidates and programs; expectations regarding preclinical programs, including the potential benefits, development activities and plans to file an IND; expectations regarding Otonomy's ability to advance its pipeline and regarding upcoming catalysts; Otonomy's anticipated upcoming milestones; expectations regarding operating expenses for 2022 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 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 expectation that it will incur significant losses for the foreseeable future; 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 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.

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Otonomy, Inc.
Condensed Balance Sheet Data
(in thousands)

	As of December 31, 2021	As of December 31, 2020
Cash and cash equivalents	$ 77,412	$ 30,767
Short-term investments	—	55,576
Right-of-use assets	12,696	14,082
Total assets	95,637	106,265
Long-term debt, net	15,997	15,158
Leases, net of current	12,400	13,847
Total liabilities	40,730	39,999
Accumulated deficit	(555,805)	(504,624)
Total stockholders' equity	54,907	66,266

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

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
	(unaudited)			
Product sales, net	$ —	$ 53	$ 125	$ 273
Costs and operating expenses:				
Cost of product sales	—	274	370	1,188
Research and development	9,678	6,374	34,673	27,997
Selling, general and administrative	3,494	3,692	14,707	14,575
Total costs and operating expenses	13,172	10,340	49,750	43,760
Loss from operations	(13,172)	(10,287)	(49,625)	(43,487)
Other expense, net	(407)	(360)	(1,556)	(1,244)
Net loss	$ (13,579)	$ (10,647)	$ (51,181)	$ (44,731)
Net loss per share, basic and diluted	$ (0.20)	$ (0.20)	$ (0.81)	$ (1.10)
Weighted-average shares used to compute net loss per share, basic and diluted	67,807,995	52,257,321	63,441,330	40,845,844

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

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020

	(unaudited)			
GAAP operating expenses				
Research and development	$ 9,678	$ 6,374	$ 34,673	$ 27,997
Selling, general and administrative	3,494	3,692	14,707	14,575
Total GAAP operating expenses	13,172	10,066	49,380	42,572
Non-GAAP adjustments				
R&D stock-based compensation expense	(915)	(632)	(3,355)	(2,456)
SG&A stock-based compensation expense	(942)	(950)	(4,039)	(3,642)
Total non-GAAP adjustments	(1,857)	(1,582)	(7,394)	(6,098)
Non-GAAP operating expenses	$ 11,315	$ 8,484	$ 41,986	$ 36,474

Otonomy, Inc.
Reconciliation of 2022 GAAP to Non-GAAP Operating Expense Guidance
(in millions)

GAAP operating expenses	$52 - $54
Non-GAAP adjustments	
Stock-based compensation expense	$10
Non-GAAP operating expenses	$42 - $44

Source: Otonomy, Inc.