Otonomy Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 9, 2022

- ***Positive top-line results announced for OTO-413 Phase 2a in hearing loss; enrollment ongoing for higher dose evaluation***
- ***OTO-313 Phase 2 trial in tinnitus fully enrolled with top-line results expected in August 2022; clinical safety evaluation of higher and bilateral dosing ongoing***
- ***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

SAN DIEGO, May 09, 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 ended March 31, 2022 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 excited about the positive OTO-413 Phase 2a trial results that we recently announced 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. "We look to build on this momentum with results from the OTO-313 Phase 2 tinnitus trial this summer followed by results from the evaluation of higher doses for OTO-413 in hearing loss patients and higher and bilateral dosing with OTO-313 in tinnitus patients later in the year."

Otonomy Program Updates

- **OTO-413: positive top-line results announced for Phase 2a cohort in hearing loss patients; clinical evaluation of higher dosing ongoing.** In April 2022, Otonomy announced that a single intratympanic injection of 0.3 mg OTO-413 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). The randomized, double-blind, placebo-controlled trial enrolled a total of 33 patients (30 evaluable) with self-reported hearing difficulty in a noisy environment that was confirmed by SIN testing. Overall, 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. For the Words-in-Noise test, which is 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. The PGIC also 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. Additionally, treatment with OTO-413 was well tolerated.

  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 (five times the dose in the Phase 2a trial). Results from the higher dose evaluation are expected in the second half of 2022.

- **OTO-313: Phase 2 trial in tinnitus is fully enrolled with top-line results expected in August 2022; safety evaluation of higher and bilateral dosing ongoing.** 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 August 2022. Additionally, Otonomy is conducting 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-825: preclinical studies demonstrate 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 focused on the repair of cochlear hair cells 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

- In August 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.

First Quarter Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $62.9 million as of March 31, 2022, compared to $77.4 million as of December 31, 2021.
- **Operating Expenses:** GAAP operating expenses were $13.2 million for the first quarter of 2022, compared to $11.7 million for the first quarter of 2021. Non-GAAP operating expenses, which exclude stock-based compensation, were $11.3 million for the first quarter of 2022, compared to $9.7 million for the first quarter of 2021.
- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the first quarter of 2022 were $9.4 million, compared to $7.7 million for the first quarter of 2021. The increase for the quarter was primarily due to higher third-party development costs for Otonomy's product candidates.
- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the first quarter of 2022 were $3.7 million, compared to $4.0 million for the first quarter of 2021.
- **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: 5359095. 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 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 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 9, 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 March 31, 2022 (unaudited)	As of December 31, 2021

Cash and cash equivalents	$ 62,874	$ 77,412
Right-of-use assets	12,302	12,696
Total assets	81,232	95,637
Long-term debt, net	16,040	15,997
Leases, net of current	11,905	12,400
Total liabilities	37,983	40,730
Accumulated deficit	(569,357)	(555,805)
Total stockholders' equity	43,249	54,907

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

	Three Months Ended March 31,	
	2022	**2021**
	(unaudited)	
Product sales, net	$ -	$ 90
Costs and operating expenses:		
Cost of product sales	-	230
Research and development	9,406	7,660
Selling, general and administrative	3,748	4,043
Total costs and operating expenses	13,154	11,933
Loss from operations	(13,154)	(11,843)
Other expense, net	(398)	(367)
Net loss	$ (13,552)	$ (12,210)
Net loss per share, basic and diluted	$ (0.20)	$ (0.23)
Weighted-average shares used to compute net loss per share, basic and diluted	67,845,685	52,319,101

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

	Three Months Ended March 31,	
	2022	**2021**
	(unaudited)	
GAAP operating expenses		
Research and development	$ 9,406	$ 7,660
Selling, general and administrative	3,748	4,043
Total GAAP operating expenses	13,154	11,703
Non-GAAP adjustments		
R&D stock-based compensation expense	(924)	(800)
SG&A stock-based compensation expense	(970)	(1,160)
Total non-GAAP adjustments	(1,894)	(1,960)

Non-GAAP operating expenses	$ 11,260	$ 9,743

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.