Otonomy Reports Third Quarter 2021 Financial Results and Provides Corporate Update

November 10, 2021

- ***OTO-313 Phase 2 trial in tinnitus ongoing with results expected in mid-2022***
- ***Enrollment nearly complete in OTO-413 Phase 2a cohort in hearing loss with results moved forward to early in second quarter of 2022***
- ***Initiating clinical safety evaluation of higher dosing for OTO-413 to support full dose-ranging Phase 2 efficacy trial expected to start by the end of 2022***
- ***OTO-825 IND-enabling activities ongoing with IND filing expected first half of 2023***

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

SAN DIEGO, Nov. 10, 2021 (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 September 30, 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 have continued the strong momentum in enrollment for the OTO-313 Phase 2 trial in tinnitus with results still expected in mid-2022, and we are ahead of schedule for the OTO-413 Phase 2a cohort with results now expected early in the second quarter of 2022," said David A. Weber, Ph.D., president and CEO of Otonomy. "Because all OTO-413 doses tested in the initial Phase 1/2 cohorts were well-tolerated, we undertook additional work to support evaluation of higher dosing. We have shared this information with the FDA and are pleased to initiate enrollment of a higher dose cohort in the next month. Results from the Phase 2a cohort and higher dose safety evaluation will support our strategy to identify several OTO-413 doses to evaluate in a full dose-ranging Phase 2 efficacy trial expected to start by the end of 2022."

Otonomy Program Updates

- **OTO-313: Phase 2 trial in tinnitus is ongoing with top-line results expected in mid-2022; results of positive Phase 1/2 trial recently published in leading otolaryngology journal.** Otonomy is conducting a Phase 2 trial of OTO-313, based on the design of the successful Phase 1/2 trial, that will enroll approximately 140 patients with persistent, unilateral tinnitus of at least moderate severity. To enrich the study population, this trial is excluding patients with severe or profound hearing loss and has an increased minimum Tinnitus Functional Index (TFI) score required for entry. Otonomy is expanding the patient population eligible for enrollment by increasing the maximum time from tinnitus onset from six months up to one year. The primary endpoint is the same as reported for the Phase 1/2 trial: a responder analysis based on the proportion of patients who report a clinically meaningful improvement in TFI from baseline to Months 1 and 2 following treatment. The follow-up period has also been extended out to four months to assess durability of the treatment effect. Results from the positive Phase 1/2 trial were recently published in *Otology & Neurotology*, a leading peer-reviewed journal in otolaryngology.

- **OTO-413: Phase 2a cohort in hearing loss is ahead of schedule with top-line results now expected early in second quarter of 2022; initiating safety evaluation of higher dosing.** Based on the positive Phase 1/2 trial results, Otonomy is conducting an expansion cohort for the highest OTO-413 dose evaluated in the initial trial cohorts reported in December 2020. This Phase 2a cohort is a randomized, double-blind, placebo-controlled study that is expected to complete enrollment of approximately 30 hearing loss patients in the next few weeks: 20 patients will be treated with a single intratympanic injection of 0.3 mg OTO-413 and 10 will receive placebo. Patients will be followed for three months and assessed using clinically-validated speech-in-noise hearing tests. Once enrollment is complete in the Phase 2a cohort, Otonomy will initiate enrollment to evaluate safety of at least one higher dose of OTO-413. This dose cohort will enroll approximately 12 hearing loss patients randomized 2:1 to OTO-413 or placebo. Based on results from the Phase 2a cohort and higher-dose safety 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, being developed under the company's collaboration with Applied Genetic Technologies Corporation (Nasdaq: AGTC). Preclinical proof-of-concept results for OTO-825 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 U.S. Food and Drug Administration (FDA) that provided guidance regarding nonclinical study design, manufacturing requirements and clinical trial considerations. Based on this feedback, IND-enabling activities are underway with an IND filing anticipated in the first half of 2023.

- **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.
- By end of 2022, initiate Phase 2 dose-ranging efficacy trial for OTO-413.
- In first half of 2023, file IND for OTO-825.

Third Quarter Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $87.1 million as of September 30, 2021, compared to $86.3 million as of December 31, 2020.
- **Operating Expenses:** GAAP operating expenses were $12.5 million for the third quarter of 2021, compared to $10.4 million for the third quarter of 2020. Non-GAAP operating expenses, which exclude stock-based compensation, were $10.7 million for the third quarter of 2021, compared to $8.8 million for the third quarter of 2020.
- **Research and Development Expenses:** GAAP research and development (R&D) expenses were $9.0 million for the third quarter of 2021, compared to $7.0 million for the third quarter of 2020. The year-over-year increase is due to higher development expenses for OTO-313 and OTO-413.
- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses were $3.5 million for the third quarter of 2021, compared to $3.4 million for the third quarter of 2020.
- **Financial Guidance:**
    - **2021 Operating Expenses:** Otonomy expects that GAAP operating expenses will be in the range of $46-$48 million, and that non-GAAP operating expenses will be in the range of $38-$40 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.

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: 3812898. 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.

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

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; the potential benefits and opportunities of, and activities under, the collaboration agreement between Otonomy and AGTC, including but not limited to Otonomy's IND-enabling activities and plans to support an IND filing; expectations regarding preclinical programs, including the potential benefits and development activities; expectations regarding Otonomy's ability to advance its pipeline and regarding upcoming catalysts; Otonomy's anticipated upcoming milestones; expectations regarding operating expenses for 2021 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 10, 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.

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

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

	As of September 30, 2021	As of December 31, 2020
	(unaudited)	
Cash and cash equivalents	$ 81,843	$ 30,767
Short-term investments	5,253	55,576
Right-of-use assets	13,079	14,082
Total assets	104,878	106,265

Long-term debt, net	15,955	15,158
Leases, net of current	12,643	13,847
Total liabilities	38,340	39,999
Accumulated deficit	(542,226)	(504,624)
Total stockholders' equity	66,538	66,266

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
			(unaudited)	
Product sales, net	$ —	$ 50	$ 125	$ 220
Costs and operating expenses:				
Cost of product sales	—	189	370	914
Research and development	8,978	7,016	24,995	21,623
Selling, general and administrative	3,501	3,363	11,213	10,883
Total costs and operating expenses	12,479	10,568	36,578	33,420
Loss from operations	(12,479)	(10,518)	(36,453)	(33,200)
Other expense, net	(401)	(349)	(1,149)	(884)
Net loss	$ (12,880)	$ (10,867)	$ (37,602)	$ (34,084)
Net loss per share, basic and diluted	$ (0.19)	$ (0.22)	$ (0.61)	$ (0.92)
Weighted-average shares used to compute net loss per share, basic and diluted	67,792,425	49,220,921	61,969,780	37,014,253

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
			(unaudited)	
GAAP operating expenses				
Research and development	$ 8,978	$ 7,016	$ 24,995	$ 21,623
Selling, general and administrative	3,501	3,363	11,213	10,883
Total GAAP operating expenses	12,479	10,379	36,208	32,506
Non-GAAP adjustments				
R&D stock-based compensation expense	(823)	(628)	(2,440)	(1,824)
SG&A stock-based compensation expense	(943)	(945)	(3,097)	(2,692)
Total non-GAAP adjustments	(1,766)	(1,573)	(5,537)	(4,516)
Non-GAAP operating expenses	$ 10,713	$ 8,806	$ 30,671	$ 27,990

Otonomy, Inc.
Reconciliation of 2021 GAAP to Non-GAAP Operating Expense Guidance

(in millions)

GAAP operating expenses	$46 - $48
Non-GAAP adjustments	
Stock-based compensation expense	$8
Non-GAAP operating expenses	$38 - $40

Source: Otonomy, Inc.