Otonomy Reports Second Quarter 2021 Financial Results and Provides Corporate Update

August 4, 2021

- ***OTO-313 Phase 2 trial in tinnitus ongoing with results expected in mid-2022***
- ***OTO-413 Phase 1/2 trial expansion in hearing loss ongoing with results expected in mid-2022***
- ***OTO-825 preclinical proof-of-concept results presented at ASGCT meeting; Pre-IND meeting complete and IND-enabling activities underway with IND filing anticipated in first half of 2023***
- ***Financing completed in April 2021 extends cash runway into second half of 2023***

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

SAN DIEGO, Aug. 04, 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 June 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 are off to a good start for enrollment in our OTO-313 Phase 2 trial in tinnitus and OTO-413 Phase 1/2 extension study in hearing loss, with both studies on track for results in mid-2022," said David A. Weber, Ph.D., president and CEO of Otonomy. "We have also made progress in our other hearing loss programs including demonstration that a single administration of our OTO-825 gene therapy rescues hearing loss and cochlear damage in two preclinical proof-of-concept models for GJB2-related congenital hearing loss. Following a productive Pre-IND meeting we have initiated IND-enabling activities for this program that we expect to support an IND filing in the first half of 2023."

Otonomy Program Updates

- **OTO-313: Phase 2 trial in tinnitus is ongoing with top-line results expected in mid-2022.** 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 hearing loss and has an increased minimum Tinnitus Functional Index (TFI) score required for entry. Otonomy is expanding the unilateral 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 at both Month 1 and Month 2 following treatment. The follow-up period has also been extended out to four months to assess durability of the observed treatment effect.

- **OTO-413: Phase 1/2 expansion study in hearing loss is ongoing with top-line results expected in mid-2022.** In June 2021, Otonomy initiated an expansion of the Phase 1/2 trial reported in December in order to support endpoint selection and powering for a more formal Phase 2 trial. The expansion cohort is a randomized, double-blind, placebo-controlled study that will enroll approximately 30 hearing loss patients: 20 will be treated with a single intratympanic injection of OTO-413 and 10 will receive placebo. As in the prior efficacy cohort that demonstrated therapeutic activity for OTO-413 versus placebo, patients will be followed for three months and assessed using the same three clinically-validated speech-in-noise hearing tests: the American English Matrix phrase test, the Words-in-Noise test and the Digits-in-Noise test. The enrollment criteria of the expansion study will continue to target a broad hearing loss patient population.

- **OTO-825: preclinical studies validate therapeutic potential of GJB2 gene therapy for congenital hearing loss with 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). In May 2021, preclinical proof-of-concept results for OTO-825 were presented at the American Society of Gene & Cell Therapy (ASGCT) Annual Meeting. These results 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 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.

- **OTIPRIO®: divestiture completed to ALK.** As previously disclosed, Otonomy initiated an evaluation of strategic alternatives for OTIPRIO in the first quarter of 2021 that resulted in the sale of product-related assets to ALK-Abelló, Inc. (ALK) in May 2021.

Anticipated Upcoming Milestones

- In mid-2022, announce top-line results for OTO-313 Phase 2 clinical trial.
- In mid-2022, announce top-line results for OTO-413 Phase 1/2 expansion trial.
- In first half of 2023, file IND for OTO-825.

Second Quarter Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $97.9 million as of June 30, 2021, compared to $86.3 million as of December 31, 2020. In April 2021, Otonomy completed an underwritten public offering of 8,298,890 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 7,111,110 shares of its common stock, for total gross proceeds of approximately $34.7 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 June 2021, the terms of the loan were modified to increase the loan balance to $16.0 million and extend the interest-only repayment period to June 2023, followed by 34 months of amortization.

- **Operating Expenses:** GAAP operating expenses were $12.0 million for the second quarter of 2021, compared to $10.6 million for the second quarter of 2020. Non-GAAP operating expenses, which exclude stock-based compensation, were $10.2 million for the second quarter of 2021, compared to $9.1 million for the second quarter of 2020.

- **Research and Development Expenses:** GAAP research and development (R&D) expenses were $8.4 million for the second quarter of 2021, compared to $6.9 million for the second quarter of 2020. The year over year increase is related to higher development expenses for OTO-313 and OTO-413 offset by reduced costs for OTIVIDEX.

- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses were $3.7 million in the second quarter of both 2021 and 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: 8157418. 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 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; 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 August 4, 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 June 30, 2021	As of December 31, 2020

	(unaudited)	
Cash and cash equivalents	$ 85,096	$ 30,767
Short-term investments	12,782	55,576
Right-of-use assets	13,367	14,082
Total assets	115,419	106,265
Long-term debt, net	15,913	15,158
Leases, net of current	13,023	13,847
Total liabilities	37,766	39,999
Accumulated deficit	(529,346)	(504,624)
Total stockholders' equity	77,653	66,266

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(unaudited)			
Product sales, net	$ 35	$ 10	$ 125	$ 170
Costs and operating expenses:				
Cost of product sales	140	511	370	725
Research and development	8,357	6,935	16,017	14,607
Selling, general and administrative	3,669	3,684	7,712	7,520
Total costs and operating expenses	12,166	11,130	24,099	22,852
Loss from operations	(12,131)	(11,120)	(23,974)	(22,682)
Other expense, net	(381)	(334)	(748)	(535)
Net loss	$ (12,512)	$ (11,454)	$ (24,722)	$ (23,217)
Net loss per share, basic and diluted	$ (0.19)	$ (0.37)	$ (0.42)	$ (0.75)
Weighted-average shares used to compute net loss per share, basic and diluted	65,627,778	30,873,488	59,010,204	30,843,850

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(unaudited)			
GAAP operating expenses				
Research and development	$ 8,357	$ 6,935	$ 16,017	$ 14,607

Selling, general and administrative	3,669	3,684	7,712	7,520
Total GAAP operating expenses	12,026	10,619	23,729	22,127
Non-GAAP adjustments				
R&D stock-based compensation expense	(817)	(628)	(1,617)	(1,196)
SG&A stock-based compensation expense	(994)	(906)	(2,154)	(1,747)
Total non-GAAP adjustments	(1,811)	(1,534)	(3,771)	(2,943)
Non-GAAP operating expenses	$ 10,215	$ 9,085	$ 19,958	$ 19,184

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.