Otonomy Reports First Quarter 2021 Financial Results and Provides Corporate Update

May 11, 2021

- ***OTO-313 Phase 2 trial in tinnitus initiated with 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***
- ***OTO-825 IND-enabling activities underway with preclinical proof-of-concept data to be presented at ASGCT meeting; update on program to be provided in mid-2021***
- ***Recent financing extends cash runway into second half of 2023***

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

SAN DIEGO, May 11, 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 March 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 focused on advancing our multiple programs for treating hearing loss and tinnitus as demonstrated by the recent initiation of our Phase 2 trial for OTO-313, ongoing preparation for initiating the expansion of the Phase 1/2 trial for OTO-413 this quarter, and upcoming presentation of preclinical proof-of-concept results for our OTO-825 gene therapy program," said David A. Weber, Ph.D., president and CEO of Otonomy. "Our strengthened balance sheet will fund the Company well beyond our anticipated clinical milestones in mid-2022 and supports the advancement of our multiple preclinical programs including the IND-enabling activities for OTO-825."

Otonomy Program Updates

- **OTO-313: Phase 2 trial in tinnitus initiated with top-line results expected in mid-2022.** Otonomy recently initiated 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 trial expansion in hearing loss 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 approximately 30 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 trial 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: IND-enabling activities underway for GJB2 gene therapy for congenital hearing loss with preclinical proof-of-concept data to be presented at ASGCT.** OTO-825 is 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. Previously presented preclinical data demonstrate that a gene of interest can be expressed in support cells of the cochlea, which are the relevant target cells for treating GJB2 deficiency, and that consistent gene expression can be observed for at least 12 weeks in non-human primates following a single local administration. Otonomy recently announced that preclinical results demonstrating the successful recovery of hearing and cochlear morphology in two preclinical models of GJB2 deficiency will be presented on May 13, 2021 at the American Society of Gene & Cell Therapy (ASGCT) Annual Meeting. These results supported the selection of OTO-825 for advancement into IND-enabling activities, which are

ongoing. An update on this program will be provided in mid-2021.

- **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. The goal of the OTO-510 program is to preserve hearing without protecting the tumor.

- **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.

- **OTIVIDEX®: following completion of analysis, no further support of the program is planned.** In February 2021, Otonomy announced the results of a third Phase 3 trial for OTIVIDEX in Ménière's disease. This trial failed to achieve its primary endpoint, which is based on the intent-to-treat population (p value = 0.312). The trial did achieve statistical significance for the per protocol population (p value = 0.031). Based on a comprehensive analysis of the results, Otonomy has decided not to pursue additional development of the product candidate.

- **OTIPRIO®: evaluating strategic alternatives.** In June 2020, Otonomy entered a co-promotion agreement that provided ALK-Abelló, Inc. (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. Following the negative Phase 3 results for OTIVIDEX, Otonomy notified ALK of its intent to evaluate strategic alternatives for the product, which is ongoing.

Anticipated Upcoming Milestones

- In the second quarter of 2021, initiate an expansion of the Phase 1/2 clinical trial of OTO-413.

- In mid-2021, provide update on OTO-825 gene therapy program.

- 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.

First Quarter Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $73.8 million as of March 31, 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 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 $11.7 million for the first quarter of 2021, compared to $11.5 million for the first quarter of 2020. Non-GAAP operating expenses, which exclude stock-based compensation, were $9.7 million for the first quarter of 2021, compared to $10.1 million for the first quarter of 2020.

- **Research and Development Expenses:** GAAP research and development (R&D) expenses were $7.7 million for the first quarter of 2021 and for the first quarter of 2020.

- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the first quarter of 2021 were $4.0 million, compared to $3.8 million for the first 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: 9497433. 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 plans to advance into IND enabling studies, the co-promotion agreement between Otonomy and ALK with respect to OTIPRIO, including Otonomy's intention to evaluate strategic alternatives for OTIPRIO, 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 and site responses to the pandemic, including current and future impacts to Otonomy's operations, the manufacturing of its product candidates, 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 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 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.

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 March 31, 2021	As of December 31, 2020
	(unaudited)	
Cash and cash equivalents	$ 51,016	$ 30,767
Short-term investments	22,813	55,576
Right-of-use assets	13,724	14,082
Total assets	93,406	106,265
Long-term debt, current	1,957	—
Long-term debt, net of current	13,246	15,158
Leases, net of current	13,440	13,847
Total liabilities	37,382	39,999
Accumulated deficit	(516,834)	(504,624)
Total stockholders' equity	56,024	66,266

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

	Three Months Ended March 31,	
	2021	2020
	(unaudited)	
Product sales, net	$ 90	$ 160
Costs and operating expenses:		
Cost of product sales	230	214
Research and development	7,660	7,672
Selling, general and administrative	4,043	3,836
Total costs and operating expenses	11,933	11,722
Loss from operations	(11,843)	(11,562)
Other expense, net	(367)	(201)
Net loss	$ (12,210)	$ (11,763)
Net loss per share, basic and diluted	$ (0.23)	$ (0.38)

Weighted-average shares used to compute net loss per share, basic and diluted	52,319,101	30,814,211

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

	Three Months Ended March 31,	
	2021	**2020**
	(unaudited)	
GAAP operating expenses		
Research and development	$ 7,660	$ 7,672
Selling, general and administrative	4,043	3,836
Total GAAP operating expenses	11,703	11,508
Non-GAAP adjustments		
R&D stock-based compensation expense	(800)	(568)
SG&A stock-based compensation expense	(1,160)	(841)
Total non-GAAP adjustments	(1,960)	(1,409)
Non-GAAP operating expenses	$ 9,743	$ 10,099

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.