Otonomy Reports Third Quarter 2020 Financial Results and Provides Corporate Update

November 4, 2020

- ***Enrollment completed in Phase 3 clinical trial of OTIVIDEX® in Ménière's disease with results expected in the first quarter of 2021***
- ***Positive results reported for Phase 1/2 clinical trial of OTO-313 in tinnitus patients***
- ***Enrollment completed in Phase 1/2 clinical trial of OTO-413 in hearing loss with results expected by end of year***
- ***Public offering completed for total gross proceeds of $69.1 million***

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

SAN DIEGO, Nov. 04, 2020 (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, 2020 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 to successfully execute our business plan by completing patient enrollment in the OTIVIDEX Phase 3 trial in Ménière's disease and the OTO-413 Phase 1/2 trial in hearing loss, as well as announcing positive results from the OTO-313 Phase 1/2 trial in tinnitus. Completion of enrollment keeps us on track for announcing the hearing loss trial results by end of year and results for our Phase 3 Ménière's trial in the first quarter," said David A. Weber, Ph.D., president and CEO of Otonomy. "I am also pleased with the progress we are making in our preclinical programs that extend our efforts across additional hearing loss pathologies and patient populations. When combined with our clinical-stage programs, we have the broadest pipeline in the neurotology field. And thanks to the over-subscribed financing we completed in the third quarter, we are well-capitalized to advance our pipeline through upcoming milestones."

Otonomy Program Updates

- **OTIVIDEX Phase 3 clinical trial in Ménière's disease: patient enrollment completed at the beginning of October with results expected in the first quarter of 2021.** This trial enrolled a total of 149 patients from the United States and Europe, exceeding the target of 142 patients. After randomization to treatment with a single intratympanic injection of OTIVIDEX or placebo, patients are followed for three months. In July 2020, Otonomy provided an update on the statistical analysis plan for the ongoing trial. In response to questions received from the U.S. Food and Drug Administration (FDA), Otonomy submitted a revised plan that uses the Negative Binomial model for primary analysis of the daily vertigo count data reported by patients. We believe that the Negative Binomial model provides the best fit of the OTIVIDEX clinical data based on the Phase 2b trial, the AVERTS-2 Phase 3 trial, and the integrated dataset from both trials. Assuming positive results in this additional Phase 3 trial, we plan to submit a New Drug Application to the FDA in the third quarter of 2021.

- **OTO-313: positive results reported from Phase 1/2 clinical trial in tinnitus.** In July 2020, Otonomy reported positive top-line results from the Phase 1/2 trial of OTO-313 in patients with persistent tinnitus of at least moderate severity. Patients reported the severity of their tinnitus symptoms using the Tinnitus Functional Index (TFI), a clinically-validated instrument, and by daily reporting of their tinnitus loudness and annoyance. The trial achieved its objectives by demonstrating a positive clinical signal for a single intratympanic injection of OTO-313 using a TFI responder analysis, with a favorable safety profile. In particular, 43% of OTO-313 patients were responders on the TFI at both Day 29 and Day 57 compared to 13% of placebo patients (p-value < 0.05). Furthermore, OTO-313 patients who were TFI responders also reported improvements in tinnitus loudness and annoyance levels using daily diaries and improvement in the Patient Global Impression of Change (PGIC). Based on these results, Otonomy has submitted a Type C meeting request to review aspects of the Phase 2 clinical plan with the FDA.

- **OTO-413 Phase 1/2 clinical trial in hearing loss: patient enrollment completed with results expected by end of year.** This ascending single dose safety and exploratory efficacy study for OTO-413, a sustained exposure formulation of brain-derived neurotrophic factor (BDNF), enrolled a total of 39 patients including 15 patients in the high dose cohort. Patients were randomized 3:1 for a single intratympanic injection of OTO-413 or placebo and then followed for 3 months. All patients have a speech-in-noise hearing deficit measured at baseline and can have normal up to moderately-severe hearing loss by conventional testing. In this first clinical evaluation of BDNF delivered via intratympanic injection, the primary objective is the assessment of safety and tolerability with multiple assessments of hearing function also conducted at baseline and during follow-up to evaluate signs of clinical activity. The Company expects to announce top-line results from this trial by end of year.

- **GJB2 gene therapy program: product candidate selected.** Otonomy and Applied Genetic Technologies Corporation (AGTC) are collaborating to co-develop and co-commercialize 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. Preclinical results presented at conferences earlier this year demonstrated that a gene of interest can be expressed in support cells of the cochlea, which are the relevant target cells for treating GJB2 deficiency, using novel and proprietary AAV capsids. Also, consistent gene expression was observed for at least 12 weeks following a single local administration. These results supported selection of the product candidate for further development.

- **OTO-510 otoprotection program: preclinical development ongoing for novel and proprietary 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 otoprotectant activity 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.

- **OTO-6XX program for severe hearing loss: exclusive license completed for novel compound.** 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. Under the terms of the agreement, Otonomy made an upfront payment to Kyorin and will make success-based milestone payments and pay a royalty on worldwide net sales. 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 is targeting hair cell regeneration for the treatment of severe hearing loss.

- **OTIPRIO®: co-promotion partnership initiated and expanded with ALK-Abelló, Inc. (ALK).** In June 2020, Otonomy entered a co-promotion agreement that provided ALK with an exclusive right to promote OTIPRIO for acute otitis externa (AOE) to office-based health care professionals in the United States including ear, nose and throat (ENT) physicians, pediatricians and primary care physicians. In October 2020, this agreement was expanded to enable ALK to also promote OTIPRIO for its second FDA-approved indication, use during ear tube surgery, in all provider facilities including hospitals and ambulatory surgery centers. During the multi-year agreement, Otonomy will receive co-promotion fees and reimbursement of a proportion of product support costs while also retaining a share of adjusted gross profits from the sale of OTIPRIO.

Third Quarter Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $94.5 million as of September 30, 2020, compared to $60.7 million as of December 31, 2019. In July 2020, Otonomy completed an underwritten public offering of 17,275,000 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 4,000,000 shares of its common stock, for total gross proceeds of approximately $69.1 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 $10.4 million for the third quarter of 2020, compared to $10.0 million for the third quarter of 2019. Non-GAAP operating expenses, which exclude stock-based compensation, were $8.8 million for the third quarter of 2020, compared to $8.3 million for the third quarter of 2019.

- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the third quarter of 2020 were $7.0 million, compared to $8.1 million for the third quarter of 2019. The decrease for the quarter was primarily due to reduced third-party development costs that were partially offset by increased compensation expense.

- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the third quarter of 2020 were $3.4 million, compared to $1.9 million for the third quarter of 2019. The increase this quarter was primarily the result of discontinued cost reimbursement received from OTIPRIO co-promotion partners.

- **Financial Update and Guidance:**
  - **2020 Operating Expenses:** Otonomy continues to expect that non-GAAP operating expenses will be in the range of $35-$38 million, and GAAP operating expenses will be in the range of $45-$48 million.
  - **Cash Runway:** Otonomy expects that its current cash, cash equivalents, and short-term investments will be sufficient to fund the company's operations for at least two years.

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: 5179918. 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 including Ménière's disease, 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 relating to the potential benefits, development activity and advancement of clinical trials; statements relating to the timing of results, activity for, and conduct of, ongoing clinical trials; statements relating to the updated statistical analysis plan for the ongoing Phase 3 clinical trial of OTIVIDEX and expectations regarding the Negative Binomial model; statements regarding plans to submit a New Drug Application for OTIVIDEX; the potential benefits and opportunities of, and activities under the collaboration agreement between Otonomy and AGTC, the co-promotion agreement between Otonomy and ALK, and the license agreement between Otonomy and Kyorin; expectations regarding preclinical programs, including the potential benefits and development activities; expectations regarding operating expenses for 2020, cash runway, and Otonomy's ability to advance its pipeline; 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 progression of its 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 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 November 4, 2020, 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

Condensed Balance Sheet Data
(in thousands)

	As of September 30, 2020	As of December 31, 2019
	(unaudited)	
Cash and cash equivalents	$ 54,235	$ 25,194
Short-term investments	40,250	35,476
Right-of-use assets	14,434	15,465
Total assets	115,312	83,018
Long-term debt, net	15,114	14,967
Leases, net of current	14,229	15,320
Total liabilities	40,187	42,785
Accumulated deficit	(493,977)	(459,893)
Total stockholders' equity	75,125	40,233

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(unaudited)			
Product sales, net	$ 50	$ 125	$ 220	$ 507
Costs and operating expenses:				
Cost of product sales	189	220	914	636
Research and development	7,016	8,057	21,623	25,771
Selling, general and administrative	3,363	1,903	10,883	8,065
Total costs and operating expenses	10,568	10,180	33,420	34,472
Loss from operations	(10,518)	(10,055)	(33,200)	(33,965)
Other (expense) income, net	(349)	16	(884)	215
Net loss	$ (10,867)	$ (10,039)	$ (34,084)	$ (33,750)
Net loss per share, basic and diluted	$ (0.22)	$ (0.33)	$ (0.92)	$ (1.10)
Weighted-average shares used to compute net loss per share, basic and diluted	49,220,921	30,748,995	37,014,253	30,712,839

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
			(unaudited)	
GAAP operating expenses				
Research and development	$ 7,016	$ 8,057	$ 21,623	$ 25,771
Selling, general and administrative	3,363	1,903	10,883	8,065
Total GAAP operating expenses	10,379	9,960	32,506	33,836
Non-GAAP adjustments				
R&D stock-based compensation expense	(628)	(1,037)	(1,824)	(2,268)
SG&A stock-based compensation expense	(945)	(651)	(2,692)	(2,165)
Total non-GAAP adjustments	(1,573)	(1,688)	(4,516)	(4,433)
Non-GAAP operating expenses	$ 8,806	$ 8,272	$ 27,990	$ 29,403

Otonomy, Inc.
Reconciliation of 2020 GAAP to Non-GAAP Operating Expense Guidance
(in millions)

GAAP operating expenses	$45 - $48
Non-GAAP adjustments	
Stock-based compensation expense	$10
Non-GAAP operating expenses	$35 - $38

Source: Otonomy, Inc.