Otonomy Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update

February 27, 2020

- ***Results from three clinical trials expected in 2020 including the Phase 3 trial of OTIVIDEX™ in Ménière's disease***
- ***Current capital funds operations into 2021***

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

SAN DIEGO, Feb. 27, 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 fourth quarter and year ended December 31, 2019 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 positioned Otonomy for a transformational year in 2020 with three clinical trial readouts including the Phase 3 trial of OTIVIDEX in Ménière's disease, Phase 2 trial of OTO-313 in tinnitus, and Phase 1/2 trial of OTO-413 in hearing loss," said David A. Weber, Ph.D., president and CEO of Otonomy. "In addition to these clinical-stage programs that address significant patient populations with high disease burden and no FDA-approved drug treatments, we are also advancing multiple preclinical programs including a gene therapy collaboration targeting congenital hearing loss. I am proud of the progress we have made across our pipeline, which is the broadest in the emerging neurotology field, and look forward to sharing updates during this catalyst rich year."

Product Pipeline Update

- **OTIVIDEX: Enrollment in Phase 3 Clinical Trial in Ménière's Disease is Ongoing with Results Expected by the End of the Third Quarter of 2020.** Otonomy has completed one successful Phase 3 trial and is conducting this additional pivotal trial to support a submission for U.S. registration of OTIVIDEX in Ménière's disease. The company plans to enroll approximately 160 patients in the United States and Europe, with the design and conduct of this trial based on the successful AVERTS-2 trial. Responder rate results from the AVERTS-2 trial and comparable patient population from the Phase 2b trial have recently been provided. These results show good agreement between the trials with almost 75% of patients experiencing at least a 50% reduction in definitive vertigo days from baseline to Month 3 following a single treatment with OTIVIDEX. Also, roughly 60% of patients had at least a 75% reduction from baseline, and approximately 40% of patients had no definitive vertigo days in Month 3. Furthermore, OTIVIDEX consistently demonstrated clear separation from placebo that was comparable across the two studies.

- **OTO-313: Enrollment in Phase 1/2 Clinical Trial in Tinnitus is Ongoing with Results Expected by the End of the Second Quarter of 2020.** OTO-313 is a sustained-exposure formulation of the potent and selective NMDA receptor antagonist gacyclidine. Otonomy has successfully completed the initial safety cohort of this randomized, double-blind, placebo-controlled trial, and is now enrolling patients in the exploratory efficacy part of the study. For this cohort, we expect to enroll up to 50 tinnitus patients who meet a narrow set of entry criteria including that the tinnitus be persistent and at least a moderate level of severity. A number of exploratory efficacy endpoints will be assessed including the Tinnitus Functional Index, which is a validated clinical instrument that measures tinnitus severity and its impact on patients.

- **OTO-413: Enrollment in Phase 1/2 Clinical Trial in Hearing Loss is Ongoing with Results Expected in the Second Half of 2020.** Otonomy is enrolling hearing loss patients in a Phase 1/2 clinical trial of OTO-413, which is a sustained-exposure formulation of brain-derived neurotrophic factor (BDNF). The Phase 1/2 trial is a randomized, double-blind, placebo-controlled, single ascending dose study designed to evaluate the safety and exploratory efficacy of OTO-413 in up to 40 patients with speech-in-noise hearing difficulty. Patients will receive a single intratympanic injection of OTO-413 or placebo and be followed for three months. A number of efficacy endpoints will be evaluated including electro-physiological measurements of hearing function and speech-in-noise hearing tests.

- **GJB2 Gene Therapy Program: Preclinical Data Presented for Novel and Proprietary AAV Capsids.** 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 gene (GJB2) -- the most common cause of congenital hearing loss. Preclinical results presented at the Association for Research in Otolaryngology (ARO) meeting in January 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.

- **OTO-510: Preclinical Data Presented for Novel and Proprietary Class of Otoprotectant Agents.** 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). At ARO, Otonomy presented preclinical results demonstrating varying degrees of otoprotection against CIHL for several classes of therapeutic agents. In particular, a novel class of agents that potently binds to cisplatin demonstrated greater otoprotection than anti-oxidant and anti-apoptotic molecules, and increased potency relative to other cisplatin-binding molecules currently in development.

- **OTO-6XX: Preclinical Development Ongoing for Regenerative Hearing Loss Program.** Otonomy has demonstrated regeneration of hair cells in a preclinical proof-of-concept model using a class of small molecules formulated for sustained-exposure local delivery, and has selected a lead compound for development. The OTO-6XX program is targeting hair cell regeneration for the treatment of severe hearing loss.

Anticipated Upcoming Milestones

- Report results from the OTO-313 Phase 2 tinnitus trial by the end of the second quarter of 2020.

- Report results from the OTIVIDEX Phase 3 Ménière's disease trial by the end of the third quarter of 2020.

- Report results from the OTO-413 Phase 1/2 hearing loss trial in the second half of 2020.

Board of Directors Updates

- **Appointment of Ciara Kennedy, Ph.D. to Board of Directors:** Otonomy appointed Ciara Kennedy to the board of directors and to the corporate governance and nominating committee effective as of March 1, 2020. Dr. Kennedy currently serves as president, chief executive officer, and a member of the board of directors of Amplyx Pharmaceuticals, a clinical-stage company developing innovative drug therapies for debilitating and life-threatening diseases in patients with compromised immune systems. Prior to Amplyx, she served as chief operating officer at Lumena Pharmaceuticals, until the company's acquisition by Shire Pharmaceuticals, and then continued as vice president, head of cholestatic liver disease at Shire post acquisition. Previously, Dr. Kennedy held several positions at Cypress Bioscience where she played a key role in the company's FDA approval and launch of Savella ® for fibromyalgia, and also held several positions in program and alliance management at Biogen Idec where she managed multiple development projects spanning the drug discovery and development continuum. She is a founder of Reneo Pharmaceuticals and Mirum Pharmaceuticals, and also serves as a member of the board of directors of privately held Aristea Therapeutics. Dr. Kennedy received her doctorate at the Queen's University of Belfast, Northern Ireland, her Master of Business Administration from the Rady School of Management at UCSD, and Bachelor of Science from University of Cork, Ireland.

- **Resignation of Heather Preston, M.D. from Board of Directors:** Dr. Heather Preston has notified the company of her intention to resign from Otonomy's board of directors and from her position on the corporate governance and nominating committee effective as of February 28, 2020 in order to devote additional attention to her responsibilities as a managing partner at Pivotal bioVenture Partners. The decision of Dr. Preston to resign is not the result of any disagreement with the company on any matter relating to its operations, policies or practices.

"I am delighted to welcome Ciara to the board and believe that Otonomy will benefit greatly from her experience in drug development, operations, patient advocacy management and corporate development for biopharmaceutical companies across multiple therapeutic areas," added Dr. Weber. "I would also like to take this opportunity to express my sincere gratitude and appreciation for the long term service and significant contributions made by Heather. Since joining the board with our first syndicated venture financing, Heather's active participation and thoughtful guidance to the company and its board throughout have been greatly appreciated."

Fourth Quarter and Full Year 2019 Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $60.7 million as of December 31, 2019, compared to $97.3 million as of December 31, 2018. The cash balance includes proceeds from a $15.0 million term loan provided by Oxford Finance LLC that was completed in December 2018.

- **Operating Expenses:** GAAP operating expenses were $10.7 million for the fourth quarter of 2019, compared to $13.2 million for the fourth quarter of 2018. For the full year 2019, GAAP operating expenses were $44.5 million compared to $51.9 million for 2018. Non-GAAP operating expenses, which exclude stock-based compensation, were $10.2 million for the fourth quarter of 2019, compared to $10.8 million for the fourth quarter of 2018. For the full year 2019, non-GAAP operating expenses were $39.6 million compared to $39.5 million for 2018.

- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the fourth quarter of 2019

were $7.0 million, compared to $9.7 million for the fourth quarter of 2018. The decrease was primarily due to reduced spending for nonclinical and manufacturing activities to support initiation of clinical trials for OTO-313 and OTO-413 and decreased stock-based compensation expense. For the full year 2019, GAAP R&D expenses were $32.8 million compared to $31.8 million for 2018.

- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the fourth quarter of 2019 were $3.6 million, compared to $3.6 million for the fourth quarter of 2018. For the full year 2019, GAAP SG&A expenses were $11.7 million compared to $20.0 million for 2018. The year-to-year decrease was primarily a result of lower stock-based compensation expense and reduced OTIPRIO® selling expenses as a result of payments from co-promotion partners.

- **Financial Guidance:**
  - **Operating Expenses:** Otonomy expects that non-GAAP operating expenses for 2020 will be in the range of $35-$38 million, and that 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 through completion of the OTIVIDEX Phase 3 trial, OTO-313 Phase 1/2 trial, and OTO-413 Phase 1/2 trial in 2020, and will support company operations into 2021.

Webcast and Conference Call

Otonomy management will host a webcast and conference call regarding this announcement 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: 2048824. 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 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, timing of results, patient recruitment and enrollment plans for, and design and conduct of, the Phase 3 clinical trial for OTIVIDEX, and expectations regarding submission for U.S. registration; timing of results, patient recruitment and enrollment plans for, and design and conduct of, the Phase 1/2 clinical trial for OTO-313; timing of results, patient recruitment and enrollment plans for, and design and conduct of, the Phase 1/2 clinical trial for OTO-413; expectations regarding the status, timing and nature of upcoming milestones; expectations regarding advancement of preclinical programs; the potential benefits of and activity under the collaboration agreement between AGTC and Otonomy, including but not limited to development and commercialization activity; expectations regarding operating expenses for 2020; expectations that current capital is sufficient to fund the company through completion of the OTIVIDEX Phase 3 trial, OTO-313 Phase 1/2 trial, and OTO-413 Phase 1/2 trial, and will support company operations into 2021; 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: Otonomy's limited operating history and its expectation that it will incur significant losses for the foreseeable future; 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 in clinical trials; Otonomy's ability to obtain regulatory approval for its product candidates; the risks of the occurrence of any event, change or other circumstance that could give rise to the termination of the collaboration agreement between AGTC and Otonomy; the risks of the occurrence of any event, change or other circumstance 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; Otonomy's dependence on third parties for the manufacture of its product candidates; Otonomy's dependence on a small number of suppliers for raw materials; Otonomy's ability to protect its intellectual property related to its product candidates in the United States and throughout the world; 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; and other risks. Information

regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in Otonomy's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 27, 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.

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

	As of December 31, 2019	As of December 31, 2018
Cash and cash equivalents	$ 25,194	$ 33,633
Short-term investments	35,476	63,651
Right-of-use assets	15,465	—
Total assets	83,018	104,992
Long-term debt, net	14,967	14,764
Leases, net of current	15,320	—
Total liabilities	42,785	25,255
Accumulated deficit	(459,893)	(415,218)
Total stockholders' equity	40,233	79,737

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

	Three Months Ended December 31,		Years Ended December 31,	
	2019	2018	2019	2018
	(unaudited)			

Product sales, net	$ 93	$ 208	$ 600	$ 745
Costs and operating expenses:				
Cost of product sales	276	271	912	946
Research and development	7,034	9,669	32,805	31,844
Selling, general and administrative	3,625	3,580	11,690	20,008
Total costs and operating expenses	10,935	13,520	45,407	52,798
Loss from operations	(10,842)	(13,312)	(44,807)	(52,053)
Other (expense) income, net	(83)	467	132	1,685
Net loss	$ (10,925)	$ (12,845)	$ (44,675)	$ (50,368)
Net loss per share, basic and diluted	$ (0.36)	$ (0.42)	$ (1.45)	$ (1.65)
Weighted-average shares used to compute net loss per share, basic and diluted	30,768,174	30,646,951	30,726,786	30,610,244

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

	Three Months Ended December 31,		Years Ended December 31,	
	2019	**2018**	**2019**	**2018**
GAAP operating expenses				
Research and development	$ 7,034	$ 9,669	$ 32,805	$ 31,844
Selling, general and administrative	3,625	3,580	11,690	20,008
Total GAAP operating expenses	10,659	13,249	44,495	51,852
Non-GAAP adjustments				
R&D stock-based compensation expense	183	(1,075)	(2,085)	(4,447)
SG&A stock-based compensation expense	(628)	(1,375)	(2,793)	(7,955)
Total non-GAAP adjustments	(445)	(2,450)	(4,878)	(12,402)
Non-GAAP operating expenses	$ 10,214	$ 10,799	$ 39,617	$ 39,450

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.