Otonomy Reports Third Quarter 2019 Financial Results and Provides Corporate Update

November 5, 2019

- ***Results from three clinical trials expected in 2020 including the Phase 3 trial of OTIVIDEX™ in Ménière's disease***
- ***Broadest pipeline in neurotology field expanded to include gene therapy collaboration targeting most common cause of congenital hearing loss***
- ***Current capital funds operations into 2021***

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

SAN DIEGO, Nov. 05, 2019 (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, 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 made significant progress in the third quarter toward our goal of reporting results from three clinical trials in 2020: we advanced enrollment in the Phase 3 trial of OTIVIDEX in Ménière's disease; we successfully completed the initial safety cohort and initiated enrollment in the exploratory efficacy cohort in the Phase 1/2 trial of OTO-313 in tinnitus patients; and we received FDA clearance to initiate the Phase 1/2 trial of OTO-413 in patients with hearing loss, an important milestone for this innovative program," said David A. Weber, Ph.D., president and CEO of Otonomy. "While successful completion of these clinical trials is our highest priority, we also continue to advance multiple preclinical programs including the recently announced gene therapy collaboration targeting congenital hearing loss. Importantly, we are effectively managing our spending in order to enable our existing capital to fund operations through the three clinical trial readouts next year and into 2021. To this point, we are reducing our operating expense estimate for 2019."

Product Pipeline Update

- **OTIVIDEX: Enrollment in Phase 3 Clinical Trial in Ménière's Disease is Ongoing with Results Expected in 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.

- **OTO-313: Enrollment in Phase 1/2 Clinical Trial in Tinnitus is Ongoing with Results Expected in the Second Quarter of 2020.** Otonomy has successfully completed the initial safety cohort of this randomized, double-blind, placebo-controlled trial, and has initiated enrollment of approximately 50 patients with persistent tinnitus in the exploratory efficacy study cohort. OTO-313 is a sustained-exposure formulation of the potent and selective NMDA receptor antagonist gacyclidine.

- **OTO-413: Enrollment in Phase 1/2 Clinical Trial in Hearing Loss is Ongoing with Results Expected in the Second Half of 2020.** Otonomy has initiated a Phase 1/2 clinical trial of OTO-413, which is a sustained-exposure formulation of brain-derived neurotrophic factor (BDNF) in development for hearing loss. 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 patients with speech-in-noise hearing difficulty.

- **Announced Strategic Collaboration to Develop and Commercialize Gene Therapy for Congenital Hearing Loss:** In October, Otonomy and Applied Genetic Technologies Corporation (AGTC) announced that they had entered into a strategic collaboration to co-develop and co-commercialize an AAV-based gene therapy to restore hearing in patients with sensorineural hearing loss caused by a mutation in the gap junction protein beta 2 gene (GJB2) -- the most common cause of congenital hearing loss.

Anticipated Upcoming Milestones

- Report results from the OTO-313 Phase 1/2 tinnitus trial in the second quarter of 2020.

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

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

Third Quarter Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $68.2 million as of September 30, 2019, compared to $97.3 million as of December 31, 2018.

- **Operating Expenses:** GAAP operating expenses were $10.0 million for the third quarter of 2019, compared to $13.0 million for the third quarter of 2018. Non-GAAP operating expenses, which exclude stock-based compensation, were $8.3 million for the third quarter of 2019, compared to $10.1 million for the third quarter of 2018.

- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the third quarter of 2019 were $8.1 million, compared to $8.3 million for the third quarter of 2018. A slight net decrease in expenses for this quarter compared to a year ago resulted from a decrease in OTO-413 nonclinical and manufacturing activities partially offset by an increase in expenses for the OTO-313 and OTO-413 clinical trials.

- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the third quarter of 2019 were $1.9 million, compared to $4.7 million for the third quarter of 2018. The decrease this quarter was primarily a result of reduced stock-based compensation expense together with OTIPRIO cost reimbursement received from our OTIPRIO co-promotion partners.

- **Financial Guidance:**
  - **2019 Operating Expenses:** Otonomy is revising its financial guidance for 2019 to reflect reduced operating expenses for the year. GAAP operating expenses are expected to be in the range of $50-$55 million, a decrease from previous guidance of $55-$60 million. Non-GAAP operating expenses are expected to be in the range of $40-$45 million, compared to the previous estimate of $45-$50 million.
  - **2020 Operating Expenses:** Otonomy expects that operating expenses will be lower than 2019 as multiple clinical trials are completed.
  - **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: 6045449. 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 2019 and 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 5, 2019, 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 September 30, 2019	As of December 31, 2018
	(unaudited)	
Cash and cash equivalents	$ 16,257	$ 33,633
Short-term investments	51,897	63,651
Right-of-use assets	15,792	—
Total assets	92,008	104,992
Long-term debt, net	14,917	14,764
Leases, net of current	15,673	—
Total liabilities	41,388	25,255
Accumulated deficit	(448,968)	(415,218)
Total stockholders' equity	50,620	79,737

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

	Three Months Ended	Nine Months Ended

	September 30,		September 30,	
	2019	2018	2019	2018
	(unaudited)			
Product sales, net	$ 125	$ 113	$ 507	$ 537
Costs and operating expenses:				
Cost of product sales	220	162	636	675
Research and development	8,057	8,300	25,771	22,175
Selling, general and administrative	1,903	4,652	8,065	16,428
Total costs and operating expenses	10,180	13,114	34,472	39,278
Loss from operations	(10,055)	(13,001)	(33,965)	(38,741)
Other income, net	16	455	215	1,218
Net loss	$ (10,039)	$ (12,546)	$ (33,750)	$ (37,523)
Net loss per share, basic and diluted	$ (0.33)	$ (0.41)	$ (1.10)	$ (1.23)
Weighted-average shares used to compute net loss per share, basic and diluted	30,748,995	30,630,125	30,712,839	30,597,874

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(unaudited)			
GAAP operating expenses				
Research and development	$ 8,057	$ 8,300	$ 25,771	$ 22,175
Selling, general and administrative	1,903	4,652	8,065	16,428
Total GAAP operating expenses	9,960	12,952	33,836	38,603
Non-GAAP adjustments				
R&D stock-based compensation expense	(1,037)	(1,037)	(2,268)	(3,372)
SG&A stock-based compensation expense	(651)	(1,770)	(2,165)	(6,580)
Total non-GAAP adjustments	(1,688)	(2,807)	(4,433)	(9,952)
Non-GAAP operating expenses	$ 8,272	$ 10,145	$ 29,403	$ 28,651

Otonomy, Inc.
Reconciliation of 2019 GAAP to Non-GAAP Operating Expense Guidance
(in millions)

GAAP operating expenses	$50 - $55
Non-GAAP adjustments	
Stock-based compensation expense	$10
Non-GAAP operating expenses	$40 - $45

Source: Otonomy, Inc.