Otonomy Reports Second Quarter 2020 Financial Results and Provides Corporate Update

August 4, 2020

- ***Positive top-line results reported for Phase 1/2 trial of OTO-313 in tinnitus patients***
- ***Public offering completed for total gross proceeds of $69.1 million***
- ***Results from Phase 3 trial of OTIVIDEX® in Ménière's disease expected in first quarter of 2021***
- ***Results from Phase 1/2 trial of OTO-413 in hearing loss expected in fourth quarter of 2020***

Conference call and webcast today at 5 p.m. ET

SAN DIEGO, Aug. 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 June 30, 2020 and provided an update on its product pipeline and corporate activities. The company will host a conference call and webcast today at 5 p.m. ET to discuss recent highlights and financial results.

"We have made great strides in advancing our product pipeline and achieving our corporate objectives during the past several months despite the challenges presented by the COVID-19 pandemic," said David A. Weber, Ph.D., president and CEO of Otonomy. "For our clinical programs, we announced positive results for OTO-313 in tinnitus, continued to progress enrollment of our ongoing OTIVIDEX Phase 3 trial in Ménière's disease while strengthening its statistical analysis plan, and have nearly completed enrollment of the OTO-413 trial in hearing loss. We also selected a product candidate for our GJB2 gene therapy program, licensed a novel compound for our OTO-6XX hair cell regeneration program, and demonstrated preclinical proof-of-concept for our otoprotection program. To support this broad and rich pipeline, we completed an oversubscribed financing that extends our cash runway and bolsters our shareholder base."

Otonomy Program Updates

- **OTO-313: positive top-line 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. The exploratory efficacy cohort of the trial included 31 evaluable patients randomized to a single intratympanic injection of OTO-313 or placebo (1:1 randomization) and then followed for eight weeks. Patients reported the severity of their tinnitus symptoms using the Tinnitus Functional Index (TFI), a clinically-validated instrument, and by the daily reporting of their tinnitus loudness and annoyance. The trial achieved its objectives by demonstrating a positive clinical signal for OTO-313 based on a TFI responder analysis, with a favorable safety profile. In particular, 43% of OTO-313 patients were responders based 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 on both Day 29 and Day 57 also reported improvements in tinnitus loudness and annoyance levels based on daily diaries and reported improvement in the Patient Global Impression of Change (PGIC), a general assessment of tinnitus status. Given these results, Otonomy is advancing OTO-313 into full Phase 2 development which may include evaluation of a higher dose and/or retreatment.

- **OTIVIDEX Phase 3 clinical trial in Ménière's disease: patient enrollment is ongoing with results expected in the first quarter of 2021.** This trial is being conducted at approximately 60 trial sites dispersed across different regions of the United States and multiple countries in Europe. 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, AVERTS-2 Phase 3 trial, and integrated dataset from both trials. The Negative Binomial model also provides increased power to detect a treatment benefit enabling us to reduce the target enrollment to 142 patients while maintaining more than 90% power. We expect to complete patient enrollment during the third quarter of 2020 and announce results in the first quarter of 2021.

- **OTO-413 Phase 1/2 clinical trial in hearing loss: patient enrollment is ongoing with results expected in the fourth quarter of 2020.** This is an ascending single dose safety and exploratory efficacy study for OTO-413, a sustained exposure formulation of brain-derived neurotrophic factor (BDNF). We have successfully escalated through three dose levels totaling 24 patients and have nearly completed enrollment of patients in the high dose cohort. We expect to enroll approximately 16 patients in this cohort, randomized 3:1 for a single intratympanic injection of OTO-413 or placebo. Patients enrolled in this trial have a speech-in-noise hearing deficit measured at baseline and can have normal up to moderately-severe hearing loss by conventional testing. Following treatment, patients undergo repeated testing for safety

and exploratory efficacy over 3 months. We expect to announce results from this trial in the fourth quarter of 2020.

- **GJB2 gene therapy program: preclinical results support selection of product candidate.** 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 the American Society of Gene & Cell Therapy (ASGCT) meeting in May 2020 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: preclinical data presented for a 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). Otonomy has 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 molecules currently in development.

- **OTO-6XX: exclusive license completed for novel hearing loss 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 will make an upfront payment to Kyorin as well as 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 with ALK-Abelló, Inc. (ALK).** In June 2020, Otonomy entered a co-promotion agreement that provides 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. 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 for use in AOE.

Second Quarter Financial Highlights

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $41.1 million as of June 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 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 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 $10.6 million for the second quarter of 2020, compared to $11.8 million for the second quarter of 2019. Non-GAAP operating expenses, which exclude stock-based compensation, were $9.1 million for the second quarter of 2020, compared to $10.6 million for the second quarter of 2019.

- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the second quarter of 2020 were $6.9 million, compared to $8.9 million for the second 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 second quarter of 2020 were $3.7 million, compared to $2.9 million for the second 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 5 p.m. ET / 2 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: 3489668. 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, patient enrollment 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; expectations regarding the Negative Binomial model; 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 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 manufacturing of its product candidates, the progression of its current clinical trials, enrollment in its current and future 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 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 (the "SEC") on August 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.

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

	As of June 30, 2020	As of December 31, 2019
	(unaudited)	
Cash and cash equivalents	$ 32,045	$ 25,194
Short-term investments	9,021	35,476
Right-of-use assets	14,787	15,465
Total assets	61,228	83,018
Long-term debt, net	15,069	14,967
Leases, net of current	14,594	15,320
Total liabilities	40,979	42,785
Accumulated deficit	(483,110)	(459,893)
Total stockholders' equity	20,249	40,233

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(unaudited)			
Product sales, net	$ 10	$ 190	$ 170	$ 382
Costs and operating expenses:				
Cost of product sales	511	203	725	416
Research and development	6,935	8,919	14,607	17,714
Selling, general and administrative	3,684	2,884	7,520	6,162
Total costs and operating expenses	11,130	12,006	22,852	24,292
Loss from operations	(11,120)	(11,816)	(22,682)	(23,910)
Other (expense) income, net	(334)	89	(535)	199
Net loss	$ (11,454)	$ (11,727)	$ (23,217)	$ (23,711)
Net loss per share, basic and diluted	$ (0.37)	$ (0.38)	$ (0.75)	$ (0.77)
Weighted-average shares used to compute net loss per share, basic and diluted	30,873,488	30,703,411	30,843,850	30,694,461

Otonomy, Inc.

Reconciliation of GAAP to Non-GAAP Operating Expenses
(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(unaudited)			
GAAP operating expenses				
Research and development	$ 6,935	$ 8,919	$ 14,607	$ 17,714
Selling, general and administrative	3,684	2,884	7,520	6,162
Total GAAP operating expenses	10,619	11,803	22,127	23,876
Non-GAAP adjustments				
R&D stock-based compensation expense	(628)	(572)	(1,196)	(1,231)
SG&A stock-based compensation expense	(906)	(680)	(1,747)	(1,514)
Total non-GAAP adjustments	(1,534)	(1,252)	(2,943)	(2,745)
Non-GAAP operating expenses	$ 9,085	$ 10,551	$ 19,184	$ 21,131

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.