

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported):
November 10, 2022**

Otonomy, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36591
(Commission
File Number)

26-2590070
(IRS Employer
Identification No.)

**4796 Executive Drive
San Diego, California**
(Address of principal executive offices)

92121
(Zip Code)

(619) 323-2200
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	OTIC	The NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On November 10, 2022, Otonomy, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 30, 2022. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 10, 2022
104	Cover page interactive data file (embedded within the inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OTONOMY, INC.

Date: November 10, 2022

By: /s/ Paul E. Cayer
Paul E. Cayer
Chief Financial and Business Officer



FOR IMMEDIATE RELEASE

Otonomy Reports Third Quarter 2022 Financial Results and Provides Corporate Update

Evaluation of strategic options to realize value from pipeline is ongoing

SAN DIEGO, November 10, 2022 -- 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, 2022 and provided an update on its product pipeline and corporate activities.

Otonomy Program and Corporate Activity Updates

- In August 2022, Otonomy announced that OTO-313 demonstrated no clinically meaningful improvement versus placebo for primary and secondary endpoints in a Phase 2 clinical trial in tinnitus patients.
 - Based on these results, Otonomy discontinued development of OTO-313 and implemented other measures to extend its cash runway. These included a reduction of its workforce by approximately 55%, with the majority of the reduction completed by the end of August.
 - In October 2022, Otonomy announced that the clinical evaluation of higher doses for OTO-413 in patients with hearing loss demonstrated no clinically meaningful improvement for patients from baseline across multiple speech-in-noise hearing tests.
 - Following these results, the company initiated an evaluation of strategic options to realize value from its pipeline including both OTO-413 and OTO-825. Strategic options could include a possible merger, business combination, sale of assets, wind-down, liquidation and dissolution or other strategic transaction. While those evaluations are ongoing, Otonomy has paused its product development activities and taken other steps to reduce costs in order to preserve its cash resources.
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Third Quarter Financial Highlights

- **Cash Position:** Cash and cash equivalents totaled \$40.1 million as of September 30, 2022, compared to \$77.4 million as of December 31, 2021. In October 2022, the term loan with Oxford Finance LLC was terminated in connection with the company's payment of all amounts owed under the agreement totaling approximately \$17.0 million.
- **Operating Expenses:** GAAP operating expenses were \$11.8 million for the third quarter of 2022, compared to \$12.5 million for the third quarter of 2021. Non-GAAP operating expenses, which exclude stock-based compensation, were \$10.5 million for the third quarter of 2022, compared to \$10.7 million for the third quarter of 2021.
- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the third quarter of 2022 were \$8.4 million, compared to \$9.0 million for the third quarter of 2021. The decrease for the quarter was primarily due to lower third-party development costs for Otonomy's product candidates.
- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the third quarter of 2022 were \$3.4 million, compared to \$3.5 million for the second quarter of 2021.

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 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 has been utilized to develop products addressing important unmet medical needs with a current focus on hearing loss. 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 regarding Otonomy's evaluation of strategic options to realize value from its pipeline including both OTO-413 and OTO-825. 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 ability to successfully identify strategic options and consummate a strategic transaction to realize value from its pipeline; the risk of being delisted from Nasdaq for failure to meet Nasdaq's continued listing requirements; Otonomy's ability to obtain additional financing; Otonomy's ability to implement measures to extend its cash runway and manage operating expenses; delays and disruption resulting from the COVID-19 pandemic and governmental responses to the pandemic, including current and future impacts to Otonomy's operations; Otonomy's ability to protect its intellectual property; 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 10, 2022, 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:

Investor Inquiries
ICR Westwicke
Robert H. Uhl
Managing Director
858.356.5932
robert.uhl@westwicke.com

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	As of September 30, 2022		As of December 31, 2021	
	(unaudited)			
Cash and cash equivalents	\$	40,146	\$	77,412
Right-of-use assets		11,481		12,696
Total assets		57,527		95,637
Debt, current		16,130		—
Long-term debt, net of current		—		15,997
Leases, net of current		10,879		12,400
Total liabilities		36,130		40,730
Accumulated deficit		(594,486)		(555,805)
Total stockholders' equity		21,397		54,907

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(unaudited)			
Product sales, net	\$ —	\$ —	\$ —	\$ 125
Costs and operating expenses:				
Cost of product sales	—	—	—	370
Research and development	8,410	8,978	27,048	24,995
Selling, general and administrative	3,431	3,501	10,702	11,213
Total costs and operating expenses	11,841	12,479	37,750	36,578
Loss from operations	(11,841)	(12,479)	(37,750)	(36,453)
Other expense, net	(207)	(401)	(931)	(1,149)
Net loss	\$ (12,048)	\$ (12,880)	\$ (38,681)	\$ (37,602)
Net loss per share, basic and diluted	\$ (0.18)	\$ (0.19)	\$ (0.57)	\$ (0.61)
Weighted-average shares used to compute net loss				
per share, basic and diluted	68,128,113	67,792,425	68,008,741	61,969,780

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(unaudited)			
GAAP operating expenses				
Research and development	\$ 8,410	\$ 8,978	\$ 27,048	\$ 24,995
Selling, general and administrative	3,431	3,501	10,702	11,213
Total GAAP operating expenses	11,841	12,479	37,750	36,208
Non-GAAP adjustments				
R&D stock-based compensation expense	(463)	(823)	(2,241)	(2,443)
SG&A stock-based compensation expense	(905)	(943)	(2,815)	(3,097)
Total non-GAAP adjustments	(1,368)	(1,766)	(5,056)	(5,540)
Non-GAAP operating expenses	\$ 10,473	\$ 10,713	\$ 32,694	\$ 30,668
