# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, DC 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):**

**August 8, 2018**

# Otonomy, Inc.
**(Exact name of registrant as specified in its charter)**

| Delaware | 001-36591 | 26-2590070 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**4796 Executive Drive**
**San Diego, CA 92121**
**(Address of principal executive offices, including 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))

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 August 8, 2018, Otonomy, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2018. 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 August 8, 2018. |

**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 hereunto duly authorized.

**OTONOMY, INC.**

Date: August 8, 2018

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

**Exhibit 99.1**

**FOR IMMEDIATE RELEASE**

# Otonomy Reports Second Quarter 2018 Financial Results and Provides Corporate Update

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

**SAN DIEGO, August 8, 2018** -- Otonomy, Inc. (NASDAQ: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for otology, today reported financial results for the quarter ended June 30, 2018 and provided an update on its corporate activities and product pipeline.

**Second Quarter 2018 and Subsequent Highlights**

- **Initiated Phase 3 Trial for OTIVIDEXä in Ménière's Disease:** In July 2018, Otonomy announced initiation of the additional Phase 3 trial required to support submission for U.S. registration of OTIVIDEX in Ménière's disease. The design and conduct of this pivotal trial, which will enroll approximately 160 patients, is based on the successful AVERTS-2 Phase 3 trial. Otonomy expects top-line results in the first half of 2020.

- **Completed Co-Promotion Partnership for OTIPRIOÒ in Acute Otitis Externa:** In August 2018, Otonomy announced the signing of a co-promotion agreement with Mission Pharmacal, a well-established privately held pharmaceutical company, that provides Mission with an exclusive right to promote OTIPRIO for acute otitis externa (AOE) in pediatrician and primary care physician offices as well as urgent care clinics in the United States. This agreement is expected to generate positive cashflow for Otonomy, which retains all commercial rights for other OTIPRIO indications and customer segments.

- **Other Pipeline Development Efforts on Track:** Otonomy's product pipeline includes multiple programs addressing important unmet medical needs and broad patient populations in neurotology. The company advanced all of these programs during the second quarter of 2018.
  - **OTO-313** is a sustained-exposure formulation of the NMDA receptor antagonist gacyclidine in development for the treatment of tinnitus. A Phase 1 clinical safety trial for gacyclidine has been completed, with no safety concerns observed. The company expects to initiate a Phase 1/2 clinical trial in tinnitus patients in the first half of 2019.
  - **OTO-413** is a sustained-exposure formulation of brain-derived neurotrophic factor (BDNF) in development for the repair of cochlear synaptopathy and the treatment of speech-in-noise hearing difficulties. The company expects to initiate a Phase 1/2 clinical trial in hearing loss patients in the first half of 2019.
  - **OTO-5XX** is an otoprotectant in preclinical development for the prevention of cisplatin-induced hearing loss.

- **OTO-6XX** induces hair cell regeneration; preclinical development is ongoing for the treatment of severe hearing loss.

- **Favorable Ruling in Patent Interference Case:** Although not involving issued patents covering OTIPRIO or our product candidates, Otonomy filed a request for interference in April 2015 against a U.S. patent application controlled by Auris Medical Holding in order to broadly protect our technology in the field of sustained-exposure otic drug delivery. Otonomy appealed an initial ruling by the Patent Trial and Appeal Board, and in August 2018, the Federal Circuit Court issued a final ruling in Otonomy's favor.

- **Elected James Breitmeyer, M.D., Ph.D., to Board of Directors:** Dr. Breitmeyer was elected to the Otonomy board of directors at the Annual Meeting of Stockholders in June 2018. He has significant experience in pharmaceutical product development acquired through senior management roles at a number of companies including Bavarian Nordic, Cadence Pharmaceuticals, Applied Molecular Evolution, and Serono Laboratories. Dr. Breitmeyer currently serves as president, CEO and director of Oncternal Therapeutics, and a director of Zogenix. He replaces George Morrow, who did not stand for reelection to the Otonomy board of directors.

“Initiation of the remaining Phase 3 trial for OTIVIDEX and completion of a co-promotion partnership for OTIPRIO are significant accomplishments for Otonomy. Moreover, achievement of these milestones demonstrates that we are on track to execute the business plan we implemented at the beginning of the year,” said David A. Weber, Ph.D., president and CEO of Otonomy. “I believe that the value of our broad development pipeline, which addresses the most significant unmet medical needs and largest market opportunities in the untapped neurotology field, is highly undervalued and substantially underappreciated by investors today. I am committed to addressing this disconnect through upcoming investor outreach initiatives and future informational activities."

**Anticipated Upcoming Milestones**

- By the end of 2018, select a candidate for clinical development for both OTO-5XX and OTO-6XX hearing loss programs.

- In first half of 2019, initiate a Phase 1/2 clinical trial of OTO-313 in tinnitus patients.

- In first half of 2019, initiate a Phase 1/2 clinical trial of OTO-413 in hearing loss patients.

**Second Quarter Financial Highlights**

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $100.0 million as of June 30, 2018, compared to $120.0 million as of December 31, 2017.

- **Operating Expenses:** GAAP operating expenses were $13.8 million for the second quarter of 2018, compared to $23.5 million for the second quarter of 2017. Non-GAAP operating expenses, which exclude stock-based compensation and rent abatement

expense, were $9.4 million for the second quarter of 2018, compared to $19.3 million for the second quarter of 2017.

- **Research and Development Expenses:** GAAP research and development (R&D) expenses for the second quarter of 2018 were $8.2 million, compared to $12.7 million for the second quarter of 2017. The decrease was primarily a result of decreased clinical trial activities for OTIPRIO and OTIVIDEX versus the prior year period.

- **Selling, General and Administrative Expenses:** GAAP selling, general and administrative (SG&A) expenses in the second quarter of 2018 were $5.6 million, compared to $10.7 million for the second quarter of 2017. The decrease was primarily a result of reduced selling expenses due to the discontinuation of promotional support for OTIPRIO.

- **Financial Guidance:** Otonomy reaffirms its expectations that GAAP operating expenses for 2018 will be in the range of $52-$57 million, and that non-GAAP operating expenses for 2018 will be in the range of $40-$45 million.

**Webcast and Conference Call**

Otonomy management will host a webcast and conference call regarding this announcement at 4:30 p.m. EDT/1:30 p.m. PDT 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: 6977596. 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 and rent abatement expense. 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 otology. 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, the potential benefits of the co-promotion agreement and other information relating to the transaction between Otonomy and Mission, timing of top-line results and patient recruitment and enrollment plans for the Phase 3 trial for OTIVIDEX, timing of a Phase 1/2 clinical trial for OTO-313, timing of a Phase 1/2 clinical trial for OTO-413, timing of candidate selection for OTO-5XX and OTO-6XX programs, financial guidance for 2018, 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 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; 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 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 May 9, 2018, 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, 2018 | As of December 31, 2017 |
|---|---|---|
| | (unaudited) | |
| Cash and cash equivalents | $ 19,024 | $ 18,456 |
| Short-term investments | 80,984 | 101,548 |
| Total assets | 108,191 | 128,364 |
| Total liabilities | 8,455 | 11,085 |
| Accumulated deficit | (389,827) | (364,850) |
| Total stockholders' equity | 99,736 | 117,279 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| | (unaudited) | | (unaudited) | |
| Product sales, net | $ 123 | $ 326 | $ 424 | $ 684 |
| Costs and operating expenses: | | | | |
| Cost of product sales | 241 | 397 | 513 | 860 |
| Research and development | 8,225 | 12,714 | 13,875 | 25,899 |
| Selling, general and administrative | 5,619 | 10,747 | 11,776 | 24,839 |
| Total costs and operating expenses | 14,085 | 23,858 | 26,164 | 51,598 |
| Loss from operations | (13,962) | (23,532) | (25,740) | (50,914) |
| Interest income | 409 | 311 | 763 | 615 |
| Net loss | $ (13,553) | $ (23,221) | $ (24,977) | $ (50,299) |
| Net loss per share, basic and diluted | $ (0.44) | $ (0.77) | $ (0.82) | $ (1.66) |
| Weighted-average shares used to compute net loss per share, basic and diluted | 30,594,288 | 30,269,190 | 30,581,481 | 30,263,042 |

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

| | Three Months Ended March 31, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| | (unaudited) | | (unaudited) | |
| GAAP operating expenses | | | | |
| Research and development | $ 8,225 | $ 12,714 | $ 13,875 | $ 25,899 |
| Selling, general and administrative | 5,619 | 10,747 | 11,776 | 24,839 |
| Total GAAP operating expenses | 13,844 | 23,461 | 25,651 | 50,738 |
| Non-GAAP adjustments | | | | |
| R&D stock-based compensation expense | (1,698) | (1,359) | (2,335) | (2,344) |
| SG&A stock-based compensation expense | (2,738) | (2,126) | (4,810) | (4,861) |
| Rent abatement | - | (695) | - | (1,389) |
| Total non-GAAP adjustments | (4,436) | (4,180) | (7,145) | (8,594) |
| Non-GAAP operating expenses | $ 9,408 | $ 19,281 | $ 18,506 | $ 42,144 |

**Otonomy, Inc.**
**Reconciliation of 2018 GAAP to Non-GAAP Operating Expense Guidance**
**(in millions)**

| | |
|---|---|
| GAAP operating expenses | $52 - $57 |
| Non-GAAP adjustments | |
| Stock-based compensation expense | 12 |
| Non-GAAP operating expenses | $40 - $45 |