Otonomy, Inc.
Form 10-Q
May 12, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2015

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-36591

Otonomy, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-2590070**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

6275 Nancy Ridge Drive, Suite 100

San Diego, California 92121

(858) 242-5200

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The number of shares of the registrant s common stock, par value $0.001, outstanding as of April 30, 2015 was 24,133,864.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Otonomy, Inc.

Condensed Balance Sheets

(in thousands, except share and per share data)

	March 31, 2015 (unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 201,042	$ 139,810
Short-term investments	22,560	16,223
Prepaid and other current assets	4,337	1,669
Total current assets	227,939	157,702
Property and equipment, net	1,617	1,257
Other long-term assets	460	205
Total assets	$ 230,016	$ 159,164
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 1,928	$ 1,710
Accrued expenses	3,708	3,046
Accrued compensation	1,162	575
Current portion of deferred rent	90	86
Total current liabilities	6,888	5,417
Deferred rent, net of current portion	111	134
Total liabilities	6,999	5,551
Commitments and Contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at March 31, 2015 and December 31, 2014; no shares issued or outstanding at March 31, 2015 and December 31, 2014		
Common stock, $0.001 par value; 200,000,000 shares authorized at March 31, 2015 and December 31, 2014; 24,128,977 and 21,173,270 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	24	21

Additional paid-in capital	337,479	256,061
Accumulated deficit	(114,486)	(102,469)
Total stockholders equity	223,017	153,613
Total liabilities and stockholders equity	$ 230,016	$ 159,164

See accompanying notes.

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Otonomy, Inc.

Condensed Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2015	2014
	(unaudited)	
Operating expenses:		
Research and development	$ 8,607	$ 8,991
General and administrative	3,501	1,565
Total operating expenses	12,108	10,556
Loss from operations	(12,108)	(10,556)
Other (expense) income:		
Interest expense		(4)
Change in fair value of convertible preferred stock warrant liability		(263)
Other income	91	2
Total other (expense) income	91	(265)
Net loss and comprehensive loss	(12,017)	(10,821)
Accretion to redemption value of convertible preferred stock		(13)
Net loss attributable to common stockholders	$ (12,017)	$ (10,834)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.52)	$ (129.52)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	23,196,011	83,649

See accompanying notes.

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Otonomy, Inc.

Condensed Statements of Cash Flows

(in thousands)

	Three Months Ended March 31,	
	2015	2014
	(unaudited)	
Cash flows from operating activities:		
Net loss	$ (12,017)	$ (10,821)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	60	49
Stock-based compensation	1,343	156
Non-cash interest expense		4
Change in fair value of convertible preferred stock warrant liability		263
Amortization of discount or premium on short-term investments	7	
Deferred rent	(19)	(17)
Changes in operating assets and liabilities:		
Prepaid and other assets	(2,923)	1,032
Accounts payable	(57)	733
Accrued expenses	643	2,253
Accrued compensation	587	210
Net cash used in operating activities	(12,376)	(6,138)
Cash flows from investing activities:		
Purchases of short-term investments	(7,833)	
Maturities of short-term investments	1,489	
Purchases of property and equipment	(126)	(120)
Net cash used in investing activities	(6,470)	(120)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of transaction costs	80,013	
Proceeds from exercise of stock options, net of early exercise liability	50	33
Proceeds from exercise of common stock warrants	15	
Net cash provided by financing activities	80,078	33
Net change in cash	61,232	(6,225)
Cash and cash equivalents at beginning of period	139,810	37,284
Cash and cash equivalents at end of period	$ 201,042	$ 31,059

Supplemental disclosure of non-cash investing activity:		
Purchase of property and equipment in accounts payable and accrued expenses	$ 294	$

See accompanying notes.

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Otonomy, Inc.

Notes to Condensed Financial Statements

(unaudited)

1. Description of Business and Basis of Presentation

Description of Business

Otonomy, Inc. (the Company) was incorporated in the state of Delaware on May 6, 2008. The Company is a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics for the treatment of diseases and disorders of the ear. The Company s proprietary technology is designed to deliver drug that is retained in the ear for an extended period of time following a single local administration. Utilizing this technology, the Company has advanced three product candidates into development. AuriPro™ is a sustained-exposure formulation of the antibiotic ciprofloxacin for which the Company has completed two Phase 3 clinical trials in pediatric patients with middle ear effusion at the time of tympanostomy tube placement surgery. The Company submitted a New Drug Application for AuriPro to the U.S. Food and Drug Administration (the FDA) in February 2015 and, in April 2015, the Company announced that the FDA accepted the AuriPro NDA for review. OTO-104 is a sustained-exposure formulation of the steroid dexamethasone that is in a Phase 2b clinical trial for the treatment of patients with Ménière s disease. OTO-311 is a sustained-exposure formulation of the N-methyl-D-aspartate (NMDA) receptor antagonist gacyclidine in preclinical development as a potential treatment for tinnitus.

On July 31, 2014, the Company filed an amendment to its amended and restated certificate of incorporation, affecting a one-for-35.16 reverse stock split of its outstanding common and convertible preferred stock, which was approved by the Company s board of directors on July 29, 2014. The accompanying condensed financial statements and notes to the condensed financial statements give retroactive effect to the reverse split for all periods presented.

In August 2014, the Company completed its initial public offering (the IPO) of 7,187,500 shares of common stock, which includes the exercise in full by the underwriters of their option to purchase up to 937,500 shares of common stock, at an offering price of $16.00 per share. Proceeds from the IPO were $104.1 million, net of underwriting discounts and commissions and offering-related transaction costs.

In January 2015, the Company completed a follow-on public offering of 2,932,500 shares of its common stock, which includes the exercise in full by the underwriters of their option to purchase 382,500 shares of common stock, at an offering price of $29.25 per share. Proceeds from the follow-on public offering were approximately $80.0 million, net of underwriting discounts, commissions and offering-related transaction costs.

Basis of Presentation

As of March 31, 2015, the Company has devoted substantially all of its efforts to product development, raising capital, and building infrastructure and has not realized revenues from its planned principal operations. The accompanying condensed financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred operating losses and negative cash flows from operating activities since inception. As of March 31, 2015, the Company had cash, cash equivalents and short-term investments of $223.6 million and an accumulated deficit of $114.5 million. The Company anticipates that it will continue to incur net losses into the foreseeable future as it:

(i) continues the development and begins commercialization of its product candidates AuriPro, OTO-104 and OTO-311; (ii) works to develop additional product candidates through research and development programs; and (iii) expands its corporate infrastructure. The Company plans to continue to fund its losses from operations and capital funding needs through future debt and/or equity financings or other sources, such as potential collaboration agreements. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company s business, results of operations, and future prospects.

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Unaudited Interim Financial Information

The accompanying interim condensed financial statements are unaudited. These unaudited interim condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) and following the requirements of the United States Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. In management s opinion, the unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company s financial position, its results of operations and its cash flows for the periods presented. These statements do not include all disclosures required by GAAP and should be read in conjunction with the Company s audited financial statements and accompanying notes for the year ended December 31, 2014 included in the Company s Form 10-K. The results presented in these unaudited condensed financial statements are not necessarily indicative of the results expected for the full fiscal year or any other interim period or any future year or period.

2. Summary of Significant Accounting Policies

Use of Estimates

The accompanying condensed financial statements have been prepared in accordance with GAAP. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expense during the reporting period. The most significant estimates in the Company s financial statements relate to clinical trial accruals. Although these estimates are based on the Company s knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash balances due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less at the date of purchase. The carrying amounts approximate fair value due to the short maturities of these instruments. Cash and cash equivalents include cash in readily available checking, savings and money market accounts, as well as certificates of deposit.

Short-Term Investments

The Company carries short-term investments classified as available-for-sale at fair value as determined by prices for identical or similar securities at the balance sheet date. Short-term investments consist of both Level 1 and Level 2 financial instruments in the fair value hierarchy (see Note 6). Realized gains or losses of available-for-sale securities are determined using the specific identification method and net realized gains and losses are included in interest income. The Company periodically reviews available-for-sale securities for other-than temporary declines in fair value below the cost basis, and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

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Fair Value of Financial Instruments

The carrying value of the Company s cash and cash equivalents, short-term investments, prepaid expenses and other current assets, other assets, accounts payable, accrued liabilities, and accrued compensation approximate fair value due to the short-term nature of these items.

Property and Equipment

Property and equipment generally consist of manufacturing equipment, furniture and fixtures, computers, and scientific and office equipment and are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally three to ten years). Leasehold improvements are stated at cost and are depreciated on a straight-line basis over the lesser of the remaining term of the related lease or the estimated useful lives of the assets. Repairs and maintenance costs are charged to expense as incurred.

Impairment of Long-Lived Assets

The Company assesses the value of its long-lived assets, which consist of property and equipment, for impairment on an annual basis and whenever events or changes in circumstances and the undiscounted cash flows generated by those assets indicate that the carrying amount of such assets may not be recoverable. While the Company s current and historical operating losses and negative cash flows are indicators of impairment, management believes that future cash flows to be received support the carrying value of its long-lived assets and, accordingly, has not recognized any impairment losses through March 31, 2015.

Clinical Trial Expense Accruals

As part of the process of preparing the Company s condensed financial statements, the Company is required to estimate expenses resulting from the Company s obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

The Company s objective is to reflect the appropriate clinical trial expenses in its financial statements by recording those expenses in the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of its trials. During the course of a clinical trial, the Company adjusts its clinical expense if actual results differ from its estimates.

Research and Development

Research and development expenses include the costs associated with the Company s research and development activities, including salaries, benefits and occupancy costs. Also included in research and development expenses are third-party costs incurred in conjunction with contract manufacturing for the Company s research and development programs and clinical trials, including the cost of clinical trial drug supply, costs incurred by contract research organizations and regulatory expenses. Research and development costs are expensed as incurred.

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Patent Expenses

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the accompanying condensed statements of operations.

Convertible Preferred Stock Warrants

Prior to the Company s IPO in August 2014, warrants exercisable for shares of the Company s Series A and Series C convertible preferred stock were classified as liabilities based upon the characteristics and provisions of each instrument. Convertible preferred stock warrants were classified as derivative liabilities and were recorded at their fair value on the date of issuance. At each reporting date the convertible preferred stock warrants were revalued, with fair value changes recognized as increases in or decreases to the change in fair value of convertible preferred stock warrant liability in the statements of operations.

In connection with the IPO, all of the Company s outstanding warrants to purchase convertible preferred stock were either (i) exercised and the underlying shares of preferred stock were automatically converted into shares of common stock or (ii) converted into warrants to purchase common stock. Prior to the exercise and conversion of the warrants to purchase convertible preferred stock, the Company performed the final revaluation of the warrant liability upon the closing of the IPO in August 2014 and recorded the $2.6 million increase in fair value to change in fair value of convertible preferred stock warrant liability in the statements of operations. The warrant liability was then reclassified to additional paid-in capital in the balance sheets.

Stock-Based Compensation

The Company accounts for stock-based compensation expense related to stock options and employee stock purchase plan (ESPP) rights by estimating the fair value on the date of grant using the Black-Scholes-Merton option pricing model net of estimated forfeitures. For awards subject to time-based vesting conditions, stock-based compensation expense is recognized using the straight-line method.

The Company accounts for stock options granted to non-employees, including members of the scientific advisory board, using the fair value approach. Stock options granted to non-employees are subject to periodic revaluation over their vesting terms with the related expense being recognized as research and development and/or general and administrative expense in the accompanying condensed statements of operations.

Income Taxes

The accounting guidance for uncertainty in income taxes prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities based on the technical merits of the position.

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized. When the Company establishes or reduces the valuation allowance against its deferred tax assets, its provision for income

taxes will increase or decrease, respectively, in the period such determination is made.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and/or circumstances from non-owner sources. For all periods presented, comprehensive loss is equal to net loss.

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Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, potentially dilutive securities are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and therefore, basic and diluted net loss per share were the same for all periods presented.

Potentially dilutive securities excluded from the calculation of diluted net loss per share attributable to common stockholders are as follows (in common stock equivalent shares):

	Three Months Ended March 31,	
	2015	2014
Convertible preferred stock		9,493,489
Warrants to purchase convertible preferred stock		483,517
Warrants to purchase common stock	141,060	
Unvested restricted common stock subject to repurchase	10,961	17,064
Options to purchase common stock	2,760,917	1,384,061
	2,912,938	11,378,131

3. Available-for-Sale Securities

The Company invests in available-for-sale securities consisting of money market funds and certificates of deposit. Available-for-sale securities are classified as part of either cash and cash equivalents or short-term investments in the condensed balance sheets. Available-for-sale securities with maturities of three months or less from the date of purchase have been classified as cash equivalents, and were $12.4 million and $18.8 million as of March 31, 2015 and December 31, 2014, respectively. Available-for-sale securities with maturities of more than three months from the date of purchase have been classified as short-term investments, and were $22.6 million and $16.2 million as of March 31, 2015 and December 31, 2014, respectively. There have been no unrealized gains or losses related to the Company s short-term investments.

The Company determined that there were no other-than-temporary declines in the value of any available-for-sale securities as of March 31, 2015. All of the Company s available-for-sale investment securities mature within one year.

The Company obtains the fair value of its available-for-sale securities from the custodian bank or from a professional pricing service.

4. Balance Sheet Details

Prepaid and Other Current Assets

Prepaid and other current assets are comprised of the following (in thousands):

	March 31, 2015	December 31, 2014
Prepaid clinical trial costs	$ 1,434	$ 843
FDA deposit[1]	2,335	
Other	568	826
Total	$ 4,337	$ 1,669

(1) In February 2015, in accordance with the Federal Food, Drug, and Cosmetic Act (the Act), the Company paid an application fee of $2.3 million to the FDA for its AuriPro NDA submission. Prior to the submission of the AuriPro NDA, the Company filed a request with the FDA to grant a waiver of the application fee under the small business waiver provision of the Act, and such waiver would result in a refund of the application fee. The Company meets the criteria of a small business pursuant to the provisions of the Act. Accordingly, as of March 31, 2015, the application fee was recorded as a deposit within prepaid and other current assets.

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Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	March 31, 2015	December 31, 2014
Laboratory equipment	$ 1,217	$ 1,109
Manufacturing equipment	1,257	945
Computer equipment and software	116	116
Leasehold improvements	67	67
Office furniture	19	19
	2,676	2,256
Less: accumulated depreciation and amortization	(1,059)	(999)
Total	$ 1,617	$ 1,257

Depreciation expense was approximately $0.1 million for each of the three month periods ended March 31, 2015 and 2014.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31, 2015	December 31, 2014
Accrued clinical trial costs	$ 3,132	$ 2,397
Accrued other	576	649
Total	$ 3,708	$ 3,046

5. Commitments and Contingencies

License Agreements

The following table summarizes costs recognized, in research and development, under the Company s license agreements and other non-cancellable royalty and milestone obligations (in thousands):

	Three Months Ended March 31,	
	2015	2014
License and other fees	$ 6	$ 6

Milestone fees	1,000	
Total license and related fees	$ 1,006	$ 6

Intellectual Property Licenses

The Company has acquired exclusive rights to develop patented rights, information rights and related know-how for the Company s AuriPro, OTO-104 and OTO-311 product candidates and potential future product candidates under licensing agreements with third parties in the course of its research and development activities. The licensing rights obligate the Company to make payments to the licensors for license fees, milestones, license maintenance fees and royalties. Annual license and maintenance fees related to these agreements is $25,000. The license and maintenance fees will continue until the first commercial sale of a product. In addition, the Company