Otonomy, Inc.
Form 10-Q
November 10, 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 September 30, 2015

OR

¨ **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 October 30, 2015 was 24,238,269.

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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)

	September 30, 2015 (unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 176,602	$ 139,810
Short-term investments	22,587	16,223
Prepaid and other current assets	5,260	1,669
Total current assets	204,449	157,702
Restricted cash	695	
Property and equipment, net	2,851	1,257
Other long-term assets	489	205
Total assets	$ 208,484	$ 159,164
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 2,094	$ 1,710
Accrued expenses	4,196	3,046
Accrued compensation	2,316	575
Current portion of deferred rent	97	86
Total current liabilities	8,703	5,417
Deferred rent, net of current portion	164	134
Total liabilities	8,867	5,551
Commitments and Contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2015 and December 31, 2014; no shares issued or outstanding at September 30, 2015 and December 31, 2014		
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2015 and December 31, 2014; 24,235,769 and 21,173,270	24	21

shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively		
Additional paid-in capital	342,588	256,061
Accumulated deficit	(142,995)	(102,469)
Total stockholders equity	199,617	153,613
Total liabilities and stockholders equity	$ 208,484	$ 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(unaudited)			
Operating expenses:				
Research and development	$ 9,589	$ 7,361	$ 25,485	$ 24,616
General and administrative	6,492	2,040	15,345	5,169
Total operating expenses	16,081	9,401	40,830	29,785
Loss from operations	(16,081)	(9,401)	(40,830)	(29,785)
Other (expense) income:				
Interest income	116	36	305	45
Interest expense		(31)		(39)
Change in fair value of convertible preferred stock warrant liability		(2,632)		(3,300)
Other expense		(3)	(1)	(4)
Total other (expense) income	116	(2,630)	304	(3,298)
Net loss and comprehensive loss	(15,965)	(12,031)	(40,526)	(33,083)
Accretion to redemption value of convertible preferred stock		(7)		(35)
Net loss attributable to common stockholders	$ (15,965)	$ (12,038)	$ (40,526)	$ (33,118)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.66)	$ (1.23)	$ (1.70)	$ (9.83)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	24,197,160	9,823,690	23,847,988	3,369,437

See accompanying notes.

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Otonomy, Inc.

Condensed Statements of Cash Flows

(in thousands)

	Nine Months Ended September 30,	
	2015	2014
	(unaudited)	
Cash flows from operating activities:		
Net loss	$ (40,526)	$ (33,083)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	212	152
Stock-based compensation	5,321	895
Non-cash license fee	447	
Non-cash interest expense		39
Change in fair value of convertible preferred stock warrant liability		3,300
Amortization of discount or premium on short-term investments	15	
Deferred rent	41	(54)
Changes in operating assets and liabilities:		
Prepaid and other assets	(3,875)	(542)
Accounts payable	(348)	(814)
Accrued expenses	948	2,076
Accrued compensation	1,741	1,010
Net cash used in operating activities	(36,024)	(27,021)
Cash flows from investing activities:		
Purchases of short-term investments	(27,340)	
Maturities of short-term investments	20,961	
Purchases of property and equipment	(872)	(402)
(Increase) decrease in restricted cash	(695)	75
Net cash used in investing activities	(7,946)	(327)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs		49,239
Proceeds from issuance of common stock, net of transaction costs	80,358	104,681
Proceeds from exercise of stock options, net of early exercise liability	389	98
Proceeds from exercise of preferred stock warrants		1,201
Proceeds from exercise of common stock warrants	15	
Net cash provided by financing activities	80,762	155,219
Net change in cash	36,792	127,871

Cash and cash equivalents at beginning of period	139,810	37,284
Cash and cash equivalents at end of period	$ 176,602	$ 165,155
Supplemental disclosure of non-cash investing and financing activities:		
Purchase of property and equipment in accounts payable and accrued expenses	$ 934	$ 19
Deferred public offering costs in accounts payable and accrued expenses	$	$ 555

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. OTIPRIO™ (formerly known as 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 OTIPRIO 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 OTIPRIO NDA for review. The FDA has designated a Prescription Drug User Fee Act target action date for the review of the OTIPRIO NDA of December 25, 2015. OTO-104 is a sustained-exposure formulation of the steroid dexamethasone that completed 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 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 September 30, 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 September 30, 2015, the Company had cash, cash equivalents and short-term investments of $199.2

million and an accumulated deficit of $143.0 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 OTIPRIO, 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.

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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.

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.

Restricted Cash

The Company s restricted cash consists of cash maintained in a separate deposit account to secure a letter of credit issued by a bank to the landlord under a lease agreement for construction of the Company s new corporate headquarters (see Note 5). The Company has classified the restricted cash as noncurrent on the condensed balance sheet.

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 September 30, 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.

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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.

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 may be 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.

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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.

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 and Nine Months Ended September 30,	
	2015	2014
Warrants to purchase common stock	141,060	142,113
Unvested restricted common stock subject to repurchase	5,629	16,294
Options to purchase common stock	3,354,274	2,058,910
	3,500,963	2,217,317

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 $12.5 million and $18.8 million as of September 30, 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 September 30, 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 September 30, 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.

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4. Balance Sheet Details

Prepaid and Other Current Assets

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

	September 30, 2015	December 31, 2014
Prepaid clinical trial costs	$ 1,485	$ 843
FDA deposit[1]	2,335	
Other	1,440	826
Total	$ 5,260	$ 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 OTIPRIO NDA submission. Prior to the submission of the OTIPRIO NDA, the Company filed a request with the FDA to grant a waiver and refund of the application fee under the small business waiver provision of the Act. During October 2015, the FDA granted the Company s request for a waiver and refunded the application fee in full.

Property and Equipment, Net

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

	September 30, 2015	December 31, 2014
Laboratory equipment	$ 2,230	$ 1,109
Manufacturing equipment	1,433	945
Computer equipment and software	247	116
Leasehold improvements	123	67
Office furniture	29	19
	4,062	2,256
Less: accumulated depreciation and amortization	(1,211)	(999)
Total	$ 2,851	$ 1,257

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2015	December 31, 2014
Accrued clinical trial costs	$ 1,596	$ 2,397
Accrued other	2,600	649
Total	$ 4,196	$ 3,046

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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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
License and other fees	$ 603	$ 7	$ 614	$ 19
Milestone fees			1,000	
Total license and related fees	$ 603	$ 7	$ 1,614	$ 19

Intellectual Property Licenses

The Company has acquired exclusive rights to develop patented rights, information rights and related know-how for the Company s OTIPRIO, 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. The Company is also responsible for patent prosecution costs, in the event such costs are incurred.

Under one of these agreements, the Company has achieved five development milestones and one regulatory milestone, totaling $2.2 million, related to its clinical trials for both OTIPRIO and OTO-104, including the $1.0 million regulatory milestone payment made in March 2015 as a result of submitting the OTIPRIO NDA to the FDA. The Company may be obligated to make additional milestone payments under these agreements as follows (in thousands, except share data):

	Shares of Common Stock	Cash Payments
Development	1,066	$ 2,550
Regulatory	1,066	10,150
Commercialization		1,000
Total	2,132	$ 13,700

In addition, the Company may owe royalties of less than five percent on sales of commercial products, if any, developed using these licensed technologies. The Company may also be obligated to pay to the licensors a percentage of fees received if and when the Company sublicenses the technology. As of September 30, 2015, the Company has not yet developed a commercial product using the licensed technologies and it has not entered into any sublicense agreements for the technologies.

Other Royalty Arrangements

The Company entered into an agreement related to three provisional patents for OTIPRIO under which the Company may be obligated to pay a one-time milestone payment of $0.5 million upon the first commercial sale of an approved product and to pay royalties of less than one percent on product sales. The royalties are payable until the later of: (i) the expiration of the last to expire patent owned by the Company in such country covering OTIPRIO; or (ii) 10 years after the first commercial sale of OTIPRIO after receipt of regulatory approval for OTIPRIO in such country.

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During October 2014, the Company entered into an exclusive license agreement with Ipsen that enables the Company to use clinical and non-clinical gacyclidine data generated by Ipsen to support worldwide development and regulatory filings for OTO-311. Under this license agreement, the Company is obligated to pay Ipsen low single-digit royalties on annual net sales of OTO-311 by the Company or its affiliates or sublicensees, up to a maximum cumulative royalty totaling $10.0 million.

Leased Facility

In May 2015, the Company entered into a lease agreement for a new headquarters location to be constructed in San Diego, California. The lease provides for the landlord to construct the building at its cost and to use reasonable efforts to complete the building by October 2016. The lease term will commence upon the substantial completion and delivery of the building to the Company and has an initial term of 130 months thereafter, with an option by the Company to extend the lease term for an additional five years. The Company has the right to terminate the lease at the end of the 94th month of the lease term if it is acquired by a third party and pays an early termination fee. The Company will be responsible for payment of taxes and operating expenses for the building, in addition to monthly base rent in the initial amount of approximately $232,000, with 3% annual increases, which monthly base rent is abated for the first ten months of the lease term. The total estimated base rent payments over the life of the lease are estimated to be approximately $32.7 million. Upon execution of the lease, the Company provided a security deposit in the form of a letter of credit in the amount of approximately $695,000. Cash collateralizing the letter of credit is classified as noncurrent restricted cash on the condensed balance sheet. The Company has determined that the lease is an operating lease for accounting purposes.

6. Fair Value

The accounting guidance defines fair value, establishes a consistency framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring basis or nonrecurring basis. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants on the measurement date. Accounting guidance establishes a three-tier fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. These tiers are based on the source of the inputs and are as follows:

Level 1: Observable inputs such as quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company held no liabilities measured at fair value on a recurring basis as of September 30, 2015 and December 31, 2014. The following fair value hierarchy table presents the Company s assets measured at fair value on a recurring basis as of September 30, 2015 and December 31, 2014 (in thousands):

	Fair Value Measurement at Reporting Date Using			
	Total	Level 1	Level 2	Level 3
September 30, 2015:				
Assets				

Money market funds	$ 11,870	$ 11,870	$	$
Certificates of deposit	23,194		23,194	
	$ 35,064	$ 11,870	$ 23,194	$
December 31, 2014:				
Assets				
Money market funds	$ 17,840	$ 17,840	$	$
Certificates of deposit	17,160		17,160	
	$ 35,000	$ 17,840	$ 17,160	$

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7. Stockholders Equity

Common Stock Subject to Repurchase

The Company s 2010 Equity Incentive Plan allows for early exercise of certain option awards issued under the plan. As of September 30, 2015, options had been exercised for the purchase of 5,629 shares of common stock, which were unvested and subject to repurchase. Under the authoritative guidance, early exercise is not considered an exercise for accounting purposes and, therefore, any payment for unvested shares is recognized as a liability at the original exercise price. As of September 30, 2015, the Company has recorded an early exercise liability of $19,000 and no shares have been repurchased by the Company.

Common Stock Reserved for Future Issuance

Shares of common stock reserved for future issuance are as follows:

	September 30, 2015	December 31, 2014
Warrants for the purchase of common stock	141,060	142,113
Common stock options issued and outstanding	3,354,274	2,707,477
Common stock options available for future grant	2,261,396	1,953,059
Common stock reserved for issuance under ESPP	672,182	380,000
Total common stock reserved for future issuance	6,428,912	5,182,649

8. Stock-Based Compensation

The Company s 2014 Equity Incentive Plan permits the grant of incentive stock options to the Company s employees and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to the Company s employees, directors and consultants. The Company generally issues time-based stock options which vest over a four-year period commencing with the vesting of 25% on the first anniversary of the date of grant with monthly ratable vesting thereafter. Options grants have a per share exercise price equal to at least 100% of the fair market value of a shares of the common stock as of the date of grant and expire 10 years from the date of grant.

The following table summarizes stock option activity for the nine months ended September 30, 2015 (share amounts in thousands):

	Options	Weighted-Average Exercise Price Per Share
Outstanding as of December 31, 2014	2,707	$ 10.20
Granted	752	$ 27.75
Exercised	(103)	$ 3.51

Forfeited	(2)	$	20.61
Outstanding as of September 30, 2015	3,354	$	14.34

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Total non-cash stock-based compensation expense recognized in the accompanying condensed statements of operations is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development	$ 819	$ 244	$ 2,094	$ 407
General and administrative	1,401	243	3,227	488
Total stock-based compensation	$ 2,220	$ 487	$ 5,321	$ 895

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the other financial information appearing elsewhere in this Quarterly Report on Form 10-Q. These statements generally relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The following discussion and analysis contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Our actual results and the timing of events may differ materially from those discussed in our forward-looking statements as a result of various factors, including those discussed below and those discussed in the section entitled Risk Factors included in this Quarterly Report on Form 10-Q.

Forward-looking statements include, but are not limited to, statements about:

- *our expectations regarding our clinical development of OTIPRIO, including our plans to initiate a second Phase 2 clinical trial evaluating OTIPRIO for the treatment of pediatric patients with AOMT in the first quarter of 2016;*

- *our expectations regarding our clinical development of OTO-104, including our plans to initiate two parallel Phase 3 trials in Ménière s disease, with the first trial in the United States expected to begin by the end of 2015 and the second trial in the EU expected to begin during the first quarter of 2016, and that results of both Phase 3 trials are expected in the second half of 2017;*

- *our expectations that patients completing the Phase 3 trials in Ménière s disease will enroll in an open label safety study and receive two quarterly doses of OTO-104;*

- *our expectations regarding the clinical development of OTO-311, including our plans to initiate a Phase 1 clinical trial for the treatment of tinnitus before end of 2015, our expectation that this trial will be completed in the first half of 2016, and our plans to initiate a Phase 2 study in tinnitus patients in the second half of 2016;*

- *our expectations regarding our future development of our product candidates for additional indications;*

- *the timing or likelihood of regulatory filings and approvals;*

- *our expectations regarding the future development of other product candidates;*

our expectations regarding the multiple-dose clinical safety requirement for U.S. regulatory approval of OTO-104 in the United States in patients with Ménière s disease;

the potential for commercialization of our product candidates, if approved, including our expectations regarding the timing of the anticipated commercial launch for OTIPRIO in the United States, if approved;

our expectations and statements regarding the potential pricing, market size, opportunity and growth potential for OTIPRIO and OTO-104, if approved for commercial use;

our expectations and statements regarding the adoption and use of OTIPRIO and OTO-104, if approved, by ear, nose and throat physicians, or ENTs;

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our expectations regarding potential coverage and reimbursement relating to OTIPRIO or OTO-104, if approved, or any other approved product candidates;

our plans regarding the use of contract manufacturers for the production of our product candidates for clinical trials and, if approved, commercial use;

our plans and ability to effectively build our own sales and marketing capabilities, or seek and establish collaborative partners, to commercialize our products;

our ability to advance product candidates into, and successfully complete, clinical trials;

the implementation of our business model, strategic plans for our business, products and technology;

the initiation, timing, progress and results of future preclinical studies and clinical trials;

the scope of protection we are able to establish and maintain for intellectual property rights covering our products and technology;

estimates of our expenses, future revenue, capital requirements and our needs for additional financing;

our financial performance;

developments and projections relating to our competitors and our industry;

our expectations regarding the expansion of our facilities; and

our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in Risk Factors . In some cases, you can identify these statements by terms such as anticipate, believe, could, estimate, expects, intend, may, plan, potential, predict, project, should, will, would or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Quarterly Report on Form 10-Q and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled Risk Factors included in Part II, Item 1A and elsewhere in this report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible to predict all risks, nor can we assess the impact of

all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We qualify all of the forward-looking statements in this Quarterly Report on Form 10-Q by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics for the treatment of diseases and disorders of the ear. To overcome many of the limitations of delivering drugs to the middle and inner ear, we have developed a proprietary technology that is designed to deliver drug that is retained in the ear for an extended period of time following a single local administration, which we refer to as sustained-exposure. Utilizing this technology, we have advanced three product candidates into development: OTIPRIO, OTO-104 and OTO-311.

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OTIPRIO

OTIPRIO (formerly known as AuriPro) is a sustained-exposure formulation of the antibiotic ciprofloxacin for which we have completed two identical Phase 3 clinical trials in 532 pediatric patients with middle ear effusion requiring tympanostomy tube placement, or TTP, surgery. Results of these Phase 3 trials demonstrate that OTIPRIO achieved the primary efficacy endpoint with statistical significance ($p<0.001$) and that OTIPRIO was well tolerated. Based on these results, together with feedback received from a pre-NDA meeting and communications with the U.S. Food and Drug Administration, or FDA, we submitted a New Drug Application, or NDA, for OTIPRIO to the FDA in February 2015. During April 2015, we announced that the FDA had accepted the OTIPRIO NDA for review. The FDA has designated a Prescription Drug User Fee Act, or PDUFA, target action date for the review of the OTIPRIO NDA of December 25, 2015. If approved within the standard review period, we anticipate a commercial launch for OTIPRIO in the United States in the first quarter of 2016. Results from OTIPRIO s Phase 3 trials were the subject of oral presentations at the American Society of Pediatric Otolaryngology (ASPO) meeting in April 2015, at the International Society for Otitis Media (ISOM) symposium in June 2015 and at the American Academy of Otolaryngology Head and Neck Surgery Foundation (AAO-HNSF) annual meeting in September 2015.

During March 2015, we announced that we enrolled the first patients in a Phase 2 clinical trial evaluating OTIPRIO for the treatment of pediatric patients with acute otitis media with tympanostomy tubes, or AOMT, and in May 2015, we announced the completion of enrollment in this trial. The initial results of this trial demonstrated the feasibility of OTIPRIO use in AOMT. In October 2015, we announced that we expect to initiate a second Phase 2 clinical trial evaluating OTIPRIO for the treatment of pediatric patients with AOMT in the first quarter of 2016. In July 2015, we announced enrollment of the first patients in a Phase 2 clinical trial evaluating the feasibility of OTIPRIO for the treatment of patients with acute otitis externa, also known as swimmer s ear. In October 2015, we announced initiation of an open-label Phase 3b clinical trial for OTIPRIO in an expanded population of pediatric patients undergoing TTP surgery.

OTO-104

OTO-104 is a sustained-exposure formulation of the steroid dexamethasone in development for the treatment of Ménière s disease and other inner ear conditions. In May 2015, we announced topline data from a Phase 2b trial evaluating OTO-104 in 154 patients with unilateral Ménière s disease. The primary endpoint of the trial was reduction in vertigo frequency during Month 3 following treatment compared to a one month baseline period. In the topline analysis, OTO-104 demonstrated a 61% reduction from baseline in vertigo frequency in Month 3 vs. 43% for placebo with a p value of 0.067, which narrowly missed achieving statistical significance. In addition to Month 3, a similar positive trend was also observed during Month 2 following treatment. The trial achieved statistical significance ($p < 0.05$) for multiple prospectively defined secondary vertigo endpoints at multiple time points including the count of definitive vertigo days (DVD) based on a Poisson Regression analysis that achieved statistical significance in both Month 3 (p value = 0.030) and Month 2 (p value = 0.035). Based on these results and discussions with the FDA during an End-of-Phase 2 meeting that we announced in September 2015, we intend to initiate two parallel Phase 3 trials in Ménière s disease using DVD during Month 3 as the primary endpoint. We expect a Phase 3 trial in the United States to begin by the end of 2015 and a Phase 3 trial in the EU to begin during the first quarter of 2016. Results of both Phase 3 trials are expected in the second half of 2017. Patients completing the Phase 3 trials will have the opportunity to enroll in an open label safety study and receive two quarterly doses of OTO-104.

During October 2014, we began enrollment in a multiple-dose safety study in Ménière s patients in the United Kingdom. In April 2015, we announced that we achieved the target patient enrollment in this prospective, randomized, placebo-controlled study, designed to evaluate the safety of multiple doses of OTO-104, with a total of 128 enrolled patients across multiple trial sites in the United Kingdom. In the first part of the study, patients will be

randomized to receive two doses of either placebo or 12 mg OTO-104 by intratympanic, or IT, injection given at quarterly intervals. Patients completing the double-blind portion of the study will receive two IT injections of OTO-104 at quarterly intervals. We intend to use data from this U.K. study together with results from the open label safety studies in the United States and EU and a small open label safety study to be initiated in Canada to satisfy our multiple-dose clinical safety requirement for U.S. regulatory approval of OTO-104 in patients with Ménière s disease. We believe, based on discussions from an End-of-Phase 1 meeting with the FDA, that the FDA will require multiple-dose clinical safety data from 100 patients treated for one year and 300 patients treated for six months. The FDA has granted OTO-104 Fast Track designation, which is a process designed to facilitate the development and expedite the FDA s review of drugs to treat serious conditions and fill unmet medical needs.

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OTO-311

OTO-311 is a sustained-exposure formulation of the N-methyl-D-aspartate receptor antagonist gacyclidine in development for the treatment of tinnitus. In October 2015, we announced that the FDA had cleared the Investigational New Drug application (IND) for OTO-311 and that we expected to initiate a Phase 1 clinical safety trial before the end of 2015. This trial will be a single-center, dose escalating study in normal healthy volunteers. We expect this trial to be completed in the first half of 2016, with initiation of a Phase 2 trial in tinnitus patients to begin in the second half of 2016.

In November 2014, we announced the completion of an exclusive license agreement with Ipsen that enables us to use clinical and non-clinical gacyclidine data generated by Ipsen to support worldwide development and regulatory filings for OTO-311.

Sensorineural Hearing Loss Program

In October 2015, we announced that we had secured rights to multiple potential product candidates for a fourth program targeting sensorineural hearing loss. According to the National Institute on Deafness and Other Communication Disorders, there are 36 million adults in the U.S. who report hearing loss, which we believe represents the largest market opportunity in the otology field. We are evaluating several different approaches to treat this condition including repair of damaged ribbon synapses and regeneration of cochlear hair cells. Formulation and preclinical development is underway.

We have global commercialization rights to our product candidates. Our strategy is to advance our product candidates through regulatory approval and self-commercialize in the United States. In October 2014, we announced the appointment of Anthony Yost as our Chief Commercial Officer; in April 2015, we announced the appointment of Dean Hakanson, M.D. as our Chief Medical Officer; and in May 2015, we announced the appointment of Eric Loumeau as General Counsel and Chief Compliance Officer, all of whom are working to prepare for the commercialization of OTIPRIO, if approved. In addition, during April 2015 and September 2015, we announced the appointments of George Morrow and Theodore Schroeder, respectively, to our board of directors. Both Mr. Morrow and Mr. Schroeder have significant experience in pharmaceutical commercial operations. We plan to build a focused sales force targeting ENTs, who specialize in the treatment of patients affected by diseases and disorders of the ear. Outside the United States, we plan to evaluate whether to commercialize our products on our own or in collaboration with partners. We have a broad patent portfolio of approximately 75 issued patents and allowed patent applications and approximately 90 pending patent applications covering our product candidates and indications, as well as other potential applications of our technology in major markets around the world.

We have a limited operating history. Since our inception in 2008, we have devoted substantially all of our efforts to developing our product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. We do not have any approved products and have not generated any revenue from product sales or otherwise. As of September 30, 2015, we had cash, cash equivalents and short-term investments of $199.2 million.

In January 2015, we completed a follow-on public offering of 2,932,500 shares of our 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.

We have never been profitable, and as of September 30, 2015, we had an accumulated deficit of $143.0 million. Our net losses were $16.0 million and $12.0 million for the three months ended September 30, 2015 and 2014, respectively, and $40.5 million and $33.1 million for the nine months ended September 30, 2015 and 2014, respectively. Substantially all of our net losses have resulted from costs incurred in connection with our development programs and from general and administrative costs associated with our operations.

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We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we continue to develop, seek regulatory approval, and commercialize our product candidates. In the near term, we anticipate that our expenses will increase substantially as we:

- prepare for commercialization of OTIPRIO in the United States;
- conduct clinical development in additional indications for OTIPRIO;
- conduct our clinical development program for OTO-104;
- initiate clinical development of OTO-311;
- conduct preclinical development of our sensorineural hearing loss program;
- contract to manufacture our product candidates;
- evaluate opportunities for development of additional product candidates;
- maintain and expand our intellectual property portfolio;
- hire additional staff, including clinical, scientific, operational, financial, sales and marketing and management personnel, to execute our business plan; and
- operate as a public company.

We will need substantial additional funding to support our operating activities, especially as we approach the potential commercial launch of OTIPRIO in the United States and as we build our sales and marketing capabilities. We anticipate that our existing cash and cash equivalents and short-term investments will not be sufficient for us to commercialize OTIPRIO, register and commercialize OTO-104, and complete clinical development of OTO-311. Accordingly, we will continue to require substantial additional capital. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts, the timing and nature of the regulatory approval process for our product candidates, and our ability to effectively begin commercializing OTIPRIO. We anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources, such as potential collaboration arrangements. We may not be able to raise capital on terms acceptable to us, or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We believe that our existing cash and cash equivalents and short-term investments, together with expected future cash flows from sales of OTIPRIO, if approved, should be sufficient to fund our currently planned operations into 2018. In the event that we are unable to launch

OTIPRIO in the first quarter of 2016 as planned, or do not generate sufficient sales of OTIPRIO, we may be required to raise additional debt or equity capital prior to 2018, which we may not be able to do on commercially reasonable terms, if at all.

In November 2008, we entered into an exclusive license agreement with the Regents of the University of California, or UC. Under the license agreement, UC granted us an exclusive license under their rights to patents and applications that are co-developed and co-owned with us for the treatment of human otic diseases. Our financial obligations under the license agreement include annual license maintenance payments until we commercialize the first product covered under the license agreement, development milestone payments of up to $2.7 million per licensed product, of which $1.9 million has been paid for OTIPRIO and $0.3 million has been paid for OTO-104 (but such milestone payments are reduced by 75% for any orphan indication product), and a low single-digit royalty on net sales by us or our affiliates of licensed products. In addition, for each sublicense we grant we are obligated to pay UC a fixed percentage of all royalties as well as a sliding-scale percentage of non-royalty sublicense fees received by us under such sublicense, with such percentage depending on the licensed product s stage of development when sublicensed to such third party. We have the right to offset a certain amount of third-party royalties, milestone fees or sublicense fees against the foregoing financial obligations, provided such third-party royalties or fees are paid by us in consideration for intellectual property rights necessary to commercialize a licensed product.

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In April 2013, we entered into an exclusive license agreement with DURECT Corporation, or Durect, as part of an asset transfer agreement between us and IncuMed LLC, an affiliate of the NeuroSystec Corporation. Under this license agreement, Durect granted us an exclusive, worldwide, royalty-bearing license under Durect s rights to certain patents and applications that cover our OTO-311 product candidate, as well as certain related know-how. Under this license agreement and the asset transfer agreement, we are obligated to make one-time milestone payments of up to $7.5 million for the first licensed product. Upon commercializing a licensed product, we are obligated to pay Durect tiered, low single-digit royalties on annual net sales by us or our affiliates or sublicensees of the licensed products, and we have the right to offset a certain amount of third-party license fees or royalties against such royalty payments to Durect. In addition, each sublicense we grant to a third party is subject to payment to Durect of a low double-digit percentage of all non-royalty payments we receive under such sublicense. Additionally, we are also obligated to pay the Institut National de la Sante et de la Recherche Medicale, or INSERM, on behalf of Durect, for a low single-digit royalty payment on net sales by us or our affiliates or sublicensees upon commercialization of the licensed product. The foregoing royalty payment obligation to Durect would continue on a product-by-product and country-by-country basis until expiration or determination of invalidity of the last valid claim within the licensed patents that cover the licensed product, and the payment obligation to INSERM would continue so long as Durect s license from INSERM remains in effect.

Financial Operations Overview

Revenue

To date, we have not generated any revenue. We do not expect to generate any revenue from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our products or enter into collaborative agreements with third parties. In the future, if OTIPRIO is approved for commercial sale in the United States, we may generate revenue from product sales. We do not expect to commercialize OTIPRIO before 2016, if ever.

Operating Expenses

Research and development expenses

Our research and development expenses primarily consist of costs associated with the preclinical and clinical development of our product candidates. Our research and development expenses include:

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- external development expenses incurred under arrangements with third parties, such as fees paid to CROs in connection with our clinical trials, costs of acquiring and evaluating clinical trial data such as investigator grants, patient screening fees, laboratory work and statistical compilation and analysis, and fees paid to consultants and our scientific advisory board;
- costs to acquire, develop and manufacture clinical trial materials, including fees paid to contract manufacturers;

payments related to licensed products and technologies;

costs related to compliance with drug development regulatory requirements; and

facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, and laboratory and other supplies.

We expense our internal and third-party research and development expenses as incurred.

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The following table summarizes our research and development expenses (in thousands) by product candidate:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Third-party development costs:				
OTIPRIO	$ 1,707	$ 1,351	$ 5,111	$ 9,815
OTO-104	1,510	3,425	5,544	8,135
OTO-311	715	243	3,033	567
Total third-party development costs	3,932	5,019	13,688	18,517
Other unallocated internal research and development costs	5,657	2,342	11,797	6,099
Total research and development costs	$ 9,589	$ 7,361	$ 25,485	$ 24,616

We expect our research and development expenses to increase substantially for the foreseeable future as we pursue expanded indications for OTIPRIO and advance our other product candidates through their respective development programs. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving regulatory approval for any of our product candidates. The probability of success for each product candidate will be affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability and commercial viability. We are responsible for all of the research and development costs for our programs.

Completion dates and completion costs for our clinical development programs can vary significantly for each current and future product candidate and are difficult to predict. We therefore cannot estimate with any degree of certainty the costs we will incur in connection with development of our product candidates. We anticipate that we will make determinations as to which programs and product candidates to pursue and how much funding to direct to each program and product candidate on an ongoing basis in response to the results of ongoing and future clinical trials, regulatory developments, and our ongoing assessments as to each current or future product candidate s commercial potential. We will need to raise substantial additional capital in the future to complete clinical development for our product candidates. We may enter into collaborative agreements in the future in order to conduct clinical trials and gain regulatory approval of our product candidates, particularly in markets outside of the United States. We cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and overall capital requirements.

The costs of clinical trials may vary significantly over the life of a program owing to the following:

- per patient trial costs;
- the number of sites included in the trials;

the countries in which the trials are conducted;

the length of time required to enroll eligible patients;

the number of patients that participate in the trials;

the number of doses that patients receive;

the drop-out or discontinuation rates of patients;

potential additional safety monitoring or other studies requested by regulatory agencies;

the duration of patient follow-up;

the phase of development of the product candidate; and

the efficacy and safety profile of the product candidate.

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General and administrative expenses

Our general and administrative expenses consist primarily of salaries, benefits, travel and stock-based compensation expense, and other related costs for our employees and consultants in executive, commercial, administrative, finance and human resource functions. Other general and administrative expenses include facility-related costs not otherwise included in research and development and professional fees for accounting, auditing, tax and legal fees, and other costs associated with obtaining and maintaining our patent portfolio, and commercial preparation activities for our product candidates.

We expect our general and administrative expenses to increase substantially as we hire additional personnel to support commercialization of our product candidates. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with stock exchange listing and SEC requirements, director s and officer s liability insurance premiums, and investor relations-related expenses. Additionally, if and when we believe that a regulatory approval of a product candidate appears likely, we expect to incur significant increases in our general and administrative expenses relating to the sales and marketing of the product candidate.

Other (Expense) Income

Other (expense) income has included the change in fair value of the convertible preferred stock warrant liability and interest income earned on cash and cash equivalents and short-term investments. In connection with our initial public offering, or IPO, in August 2014, all of our 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.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our condensed financial statements. Our financial statements are prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, actual results may differ significantly from our estimates.

We believe that the estimates, assumptions and judgments involved in the accounting policies described in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2014 have the greatest potential impact on our financial statements, so we consider them to be our critical accounting policies and estimates. There were no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2015.

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Results of Operations

Comparison of the Three Months Ended September 30, 2015 and 2014

The following table sets forth the significant components