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 of our results of operations for the three months ended September 30, 2015 and 2014 (in thousands):

	Three Months Ended September 30,		
	2015	2014	Change
Research and development	$ 9,589	$ 7,361	$ 2,228
General and administrative	6,492	2,040	4,452
Change in fair value of convertible preferred stock warrant liability		2,632	(2,632)
Interest income	116	36	80

Research and development expenses. The increase of $2.2 million in research and development expenses was primarily due to a $2.2 million increase in personnel costs, including stock-based compensation expense and overhead, due to additional headcount, an increase of $0.6 million in expenses for outside services, including consulting fees, a $0.5 million increase in preclinical development expenses for OTO-311, an increase of $0.4 million due to a non-cash license fee that was incurred during the three months ended September 30, 2015, and a $0.4 million increase in clinical trial-related expenses for our OTIPRIO product candidate. Phase 3 clinical trials for OTIPRIO were completed during the third quarter of 2014 and, during the three months ended September 30, 2015, OTIPRIO clinical trial-related expenses were primarily incurred for the Phase 2 studies for AOMT and acute otitis externa. These increases were partially offset by a decrease of $1.9 million in clinical trial-related expenses for our OTO-104 product candidate following the completion of enrollment in the Phase 2b study during December 2014.

General and administrative expenses. The increase of $4.5 million in general and administrative expenses was primarily related to the expansion of our operating activities, costs associated with becoming a publicly traded company, and costs related to commercial preparation activities. The overall increase is comprised of a $2.6 million increase in personnel costs, including stock-based compensation expense and overhead, due to additional headcount, and a $1.9 million increase in expenses for outside services, including consulting costs, legal fees, accounting fees, corporate development and market research.

Change in fair value of convertible preferred stock warrant liability. In connection with the IPO, 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. As such, no convertible preferred stock warrants were outstanding as of September 30, 2015 and September 30, 2014. The decrease of $2.6 million was due to the final revaluation of the warrant liability which was performed upon the closing of the IPO in August 2014, resulting in a $2.6 million increase in fair value of the convertible preferred stock warrant liability. The warrant liability was then reclassified to additional paid-in capital.

Interest income. Interest income consists primarily of interest earned on our available-for-sale securities. The increase in interest income is primarily the result of increased available-for-sale securities balances during the three months ended September 30, 2015 compared to the three months ended September 30, 2014. In addition, during the fourth quarter of 2014 we began investing in certificates of deposit, which earn a higher rate of interest than our investments in money market funds, which we invested in during both three month periods ended September 30, 2015 and 2014.

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

The following table sets forth the significant components of our results of operations for the nine months ended September 30, 2015 and 2014 (in thousands):

	Nine Months Ended September 30,		
	2015	2014	Change
Research and development	$ 25,485	$ 24,616	$ 869
General and administrative	15,345	5,169	10,176
Change in fair value of convertible preferred stock warrant liability		3,300	(3,300)
Interest income	305	45	260

Research and development expenses. The increase of $0.9 million in research and development expenses was primarily due to a $4.5 million increase in personnel costs, including stock-based compensation expense and overhead, due to additional headcount, a $2.5 million increase in preclinical development expenses for OTO-311, an increase of $0.8 million in expenses for outside services, including consulting fees, and an increase of $0.4 million due to a non-cash license fee that was incurred during the three months ended September 30, 2015. These increases were partially offset by a $4.7 million decrease in expenses for our OTIPRIO product candidate. Phase 3 clinical trials for OTIPRIO were completed during the third quarter of 2014 and, during the nine months ended September 30, 2015, OTIPRIO clinical trial-related expenses were primarily incurred for the less costly Phase 2 studies for AOMT and acute otitis externa. The decrease in OTIPRIO clinical trial-related expenses is net of an incremental $1.0 million development milestone which was met when we submitted the NDA for OTIPRIO to the FDA in February 2015, compared to no milestones met during the nine months ended September 30, 2014. In addition, there was a decrease of $2.6 million in clinical trial-related expenses for our OTO-104 product candidate following the completion of enrollment in the Phase 2b study during December 2014.

General and administrative expenses. The increase of $10.2 million in general and administrative expenses was primarily related to the expansion of our operating activities, costs associated with becoming a publicly traded company, and costs related to commercial preparation activities. The overall increase is comprised of a $5.4 million increase in personnel costs, including stock-based compensation expense, due to additional headcount, and a $4.8 million increase in expenses for outside services, including consulting costs, legal fees, accounting fees, corporate development and market research.

Change in fair value of convertible preferred stock warrant liability. In connection with the IPO, 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. As such, no convertible preferred stock warrants were outstanding as of September 30, 2015 and September 30, 2014. The decrease of $3.3 million was due to the final revaluation of the warrant liability which was performed upon the closing of the IPO in August 2014, resulting in a $2.6 million increase in fair value of the convertible preferred stock warrant liability, as well as $0.7 million of fair value increases that occurred during the six months ended June 30, 2014. Following the final revaluation, the warrant liability was reclassified to additional paid-in capital.

Interest income. Interest income consists primarily of interest earned on our available-for-sale securities. The increase in interest income is primarily the result of increased available-for-sale securities balances during the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014. In addition, during the fourth

quarter of 2014 we began investing in certificates of deposit, which earn a higher rate of interest than our investments in money market funds, which we invested in during both the nine month periods ended September 30, 2015 and 2014.

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Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations since our inception. As of September 30, 2015, we had an accumulated deficit of $143.0 million and we expect to continue to incur significant losses for the foreseeable future. We expect our research and development and general and administrative expenses to continue to increase substantially for the foreseeable future and, as a result, we will need additional capital to fund our operations, which we may obtain through one or more public or private equity or debt financings, or other sources such as potential collaboration arrangements.

As of September 30, 2015, we had cash, cash equivalents and short-term investments of $199.2 million. We have principally financed our operations through sales and issuances of our equity securities as well as private placements of redeemable convertible preferred stock and convertible notes.

The following table sets forth a summary of the primary sources and uses of cash for the nine months ended September 30, 2015 and 2014 (in thousands):

	Nine Months Ended September 30,	
	2015	**2014**
Net cash (used in) provided by:		
Operating activities	$ (36,024)	$ (27,021)
Investing activities	(7,946)	(327)
Financing activities	80,762	155,219
Net increase (decrease) in cash	36,792	127,871

Operating activities. For both periods presented, the primary use of cash was to fund increased levels of development activities for our product candidates, which activities and uses of cash we expect to continue for the foreseeable future. During the nine months ended September 30, 2015, we used cash in operating activities of $36.0 million, while our net loss was $40.5 million. The difference consisted of $6.0 million of net non-cash adjustments that were primarily comprised of stock-based compensation expense, partially offset by the $1.5 million net change in our operating assets and liabilities.

During the nine months ended September 30, 2014, we used cash in operating activities of $27.0 million, while our net loss was $33.1 million. The difference consisted of the $1.7 million net change in our operating assets and liabilities and $4.4 million of net non-cash adjustments that were primarily comprised of the change in fair value of our convertible preferred stock warrant liability and stock-based compensation expense.

Investing activities. Net cash used in investing activities was $7.9 million and $0.3 million for the nine months ended September 30, 2015 and 2014, respectively. During the nine months ended September 30, 2015, $27.3 million was used to purchase short-term investments, $0.7 was restricted to secure a letter of credit issued by a bank to the landlord under a lease agreement for construction of our new corporate headquarters and $0.9 million was used for capital expenditures, which were partially offset by $21.0 million provided by maturities of short-term investments. Net cash used in investing activities during the nine months ended September 30, 2014 was primarily used for capital expenditures.

Financing activities. Net cash provided by financing activities was $80.8 million and $155.2 million for the nine months ended September 30, 2015 and 2014, respectively. During the nine months ended September 30, 2015, proceeds from our follow-on public offering were $80.0 million after deducting underwriting discounts, commissions

and offering-related transaction costs, and other proceeds from financing activities were $0.8 million for shares issued for stock option exercises and under our employee stock purchase plan.

During the nine months ended September 30, 2014, proceeds from our initial public offering were $104.7 million after deducting underwriting discounts, commissions and offering-related transaction costs paid (which excludes $0.6 million of offering-related transaction costs incurred but not yet paid as of September 30, 2014), net proceeds from the sale of our series D convertible preferred stock were $49.2 million, proceeds from the cash exercise of convertible preferred stock warrants were $1.2 million and proceeds from the exercise of stock options were $0.1 million.

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Funding Requirements

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. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to all of the risks incident in the development of new therapeutic products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We expect to incur additional costs associated with operating as a public company and we will need substantial additional funding in connection with our continuing operations.

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.

Until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance our future cash needs through public or private equity or debt financings, or other sources such as potential collaboration agreements. In any event, we do not expect to achieve significant revenue from product sales prior to the use of our existing cash balance. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any collaboration agreements we enter into may provide capital in the near-term but limit our potential cash flow and revenue in the future. Any of the foregoing could significantly harm our business, financial condition and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including:

- the design, initiation, progress, size, timing, costs and results of preclinical studies and clinical trials for our product candidates;

- the outcome, timing and cost of regulatory approvals by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory

authorities to require that we perform more studies than, or evaluate clinical endpoints other than, those that we currently expect;

the timing and costs associated with manufacturing our product candidates for clinical trials, preclinical studies and, if approved, for commercial sale;

the cost of establishing sales, marketing and distribution capabilities for any products for which we may receive regulatory approval and commercialize, including related facilities expansion costs;

the number and characteristics of product candidates that we pursue;

the potential acquisition and in-licensing of other technologies, products or assets;

the extent to which we are required to pay milestone or other payments under our in-license agreements and the timing of such payments;

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the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

our need to expand our development activities, including our need and ability to hire additional employees;

the costs associated with being a public company;

the effect of competing technological and market developments; and

the cost of litigation, including potential patent litigation.

If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the applicable rules of the SEC.

Contractual Obligations and Commitments

In May 2015, we 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 us and has an initial term of 130 months thereafter, with an option by us to extend the lease term for an additional five years. We 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.

During the nine months ended September 30, 2015, there were no other material changes, outside of the ordinary course of business, in our contractual obligations from those disclosed 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Fluctuations

As of September 30, 2015, we had cash, cash equivalents and short-term investments of $199.2 million which were comprised of cash in checking and savings accounts, money market funds and certificates of deposit. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. We do not believe that an immediate 10% increase in interest rates would have a material effect on the fair market value of our portfolio,

and therefore, we do not expect our operating results or cash flows to be materially affected to any degree by a sudden change in market interest rates.

Foreign Currency Exchange Rate Fluctuations

To date, the vast majority of our contractual obligations have been denominated in U.S. dollars; however, we contract with a CRO in the United Kingdom and are subject to fluctuation in foreign currency rates in connection with such contract. In the future, we may contract with investigational sites and other CROs in foreign countries. We do not hedge our foreign currency exchange rate risk. To date, we have not incurred any material effects from foreign currency changes in connection with such contract.

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Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the periods presented.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management, with the participation of our Chief Executive Officer and our Chief Financial and Business Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2015. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2015, our Chief Executive Officer and our Chief Financial and Business Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Disclosure Controls and Internal Control over Financial Reporting

Because of their inherent limitations, our disclosure controls and procedures and our internal control over financial reporting may not prevent material errors or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The effectiveness of our disclosure controls and procedures and our internal control over financial reporting is subject to risks, including that the controls may become inadequate because of changes in conditions or that the degree of compliance with our policies or procedures may deteriorate.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as all other information included in this Quarterly Report on Form 10-Q, including our financial statements, the notes thereto and the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations. If any of the following risks actually occurs, our business, financial condition, operating results, prospects and ability to accomplish our strategic objectives could be materially harmed. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

Risks Related to Our Financial Condition and Capital Requirements

We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We are not profitable and have incurred losses in each year since we commenced operations in 2008. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Drug development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have not obtained any regulatory approvals for any of our product candidates, commercialized our product candidates or generated any revenue. We continue to incur significant research and development and other expenses related to our ongoing clinical trials and operations. We have recorded net losses of $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. As of September 30, 2015, we had an accumulated deficit of $143.0 million.

We currently have no source of product revenue and may never become profitable.

We expect to continue to incur significant losses for the foreseeable future. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals and successfully commercialize our products. We may never succeed in these activities and therefore may never generate revenue that is significant or large enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders equity and working capital and any failure to become and remain profitable may adversely affect the market price of our common stock, our ability to raise capital, and our viability.

We will require substantial additional financing to commercialize OTIPRIO and to obtain regulatory approval for OTO-104, OTO-311 and any other product candidates, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our commercialization efforts, product development, or other operations.

Since our inception, most of our resources have been dedicated to the development of our product candidates, OTIPRIO, OTO-104 and OTO-311. In particular, obtaining regulatory approval for and commercializing OTIPRIO, and commencing and completing clinical trials for OTO-104 and OTO-311, will require substantial funds. We have funded our operations primarily through the sale and issuance of common stock, convertible preferred stock and convertible notes. As of September 30, 2015, we had cash, cash equivalents and short-term investments of $199.2

million. We believe that we will continue to expend substantial resources for the foreseeable future for the commercialization of OTIPRIO and the development of OTO-104, OTO-311 and any other product candidates we may choose to pursue. These expenditures will include costs associated with marketing and selling any products approved for sale, manufacturing, preparing regulatory submissions, and conducting preclinical studies and clinical trials. We cannot estimate with reasonable certainty the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

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Our future capital requirements depend on many factors, including:

- the timing of regulatory approval for OTIPRIO;
- the cost of commercialization activities if our products are approved for sale, including marketing, sales and distribution costs and related facilities expansion costs;
- the timing of, and the costs involved in, clinical development and obtaining regulatory approvals for OTO-104, OTO-311 or any future product candidates;
- the cost of manufacturing our products;
- the number and characteristics of any other product candidates we develop or acquire;
- our ability to establish and maintain strategic collaborations, licensing or other commercialization arrangements and the terms and timing of such arrangements;
- the degree and rate of market acceptance of any approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, future approved products, if any; and
- any product liability or other lawsuits related to our products.

Additional capital may not be available when we need it, on terms that are acceptable to us or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate our establishment of

sales and marketing, manufacturing or distribution capabilities or other activities that may be necessary to commercialize our product candidates, preclinical studies, clinical trials or other development activities.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted and the terms of any new equity securities may have preferential rights over our common stock. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures or specified financial ratios, any of which could restrict our ability to develop and commercialize our product candidates or operate as a business.

Risks Related to Our Product Candidates

We are substantially dependent on the regulatory and commercial success of our lead product candidate, OTIPRIO.

To date, we have invested substantial resources in the development of our lead product candidate, OTIPRIO. OTIPRIO is our only product that has completed Phase 3 clinical development.

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Given the completion of our Phase 3 clinical trials for OTIPRIO, its future success is primarily subject to the risks associated with obtaining regulatory approval from the FDA and commercialization, including risks associated with:

- the eligibility of OTIPRIO for the Section 505(b)(2) regulatory approval pathway which could potentially simplify the FDA approval process;
- the FDA requiring additional studies or information to support our submission;
- the successful and timely receipt of necessary marketing approval from the FDA to allow us to begin commercializing OTIPRIO in the United States;
- the ability to manufacture commercial supplies of OTIPRIO;
- our ability to build a sales organization to market OTIPRIO;
- our success in educating physicians, patients and caregivers about the benefits, administration and use of OTIPRIO;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments for middle ear effusion at the time of TTP surgery, particularly the off-label use of multi-dose, multi-day antibiotic ear drops;
- the demand for the treatment of middle ear effusion in patients requiring TTP surgery;
- the availability of coverage and adequate reimbursement for OTIPRIO;
- our ability to enforce our intellectual property rights in and to OTIPRIO; and
- a continued acceptable safety profile of OTIPRIO following approval.

Many of these clinical, regulatory and commercial matters are beyond our control and are subject to other risks described elsewhere in this Risk Factors section. Accordingly, we cannot assure you that we will be able to successfully obtain regulatory approval of, commercialize or generate significant revenue from OTIPRIO. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

We are also dependent upon the clinical, regulatory and commercial success of OTO-104, our second product candidate.

In addition to OTIPRIO, we have also invested substantial resources in the development of our second product candidate, OTO-104. In May 2015, we announced topline data from a Phase 2b trial evaluating OTO-104 in patients with unilateral Ménière s disease, which narrowly missed achieving statistical significance for the primary endpoint. We completed our End-of-Phase 2 meeting with the FDA and expect to initiate two parallel Phase 3 trials in Ménière s disease, with the first trial expected to begin by the end of 2015 and the second trial expected to begin during the first quarter of 2016. We have completed enrollment in a multiple-dose safety study for OTO-104 in Ménière s patients in the United Kingdom and plan to initiate one or more additional multiple-dose safety studies during 2015 and 2016 to satisfy our multiple-dose clinical safety requirement for U.S. regulatory approval of OTO-104 in Ménière s patients.

Given the stage of development of OTO-104, it is currently most subject to the risks associated with completing its current clinical trials and future clinical trials, including risks associated with:

- the successful implementation, enrollment and completion of two parallel Phase 3 trials that demonstrate the safety and efficacy of OTO-104;

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- the use of patient reported outcomes in our Phase 2b and anticipated Phase 3 clinical trials;
- our ability to demonstrate the safety and efficacy of OTO-104 in these clinical trials;
- the successful implementation, enrollment and completion of one or more additional open-label safety studies and the ongoing multiple-dose safety study in the United Kingdom; and
- the ability to file an NDA for regulatory approval with the FDA without the need for any additional clinical trials.

If we are able to successfully complete the necessary clinical trials for OTO-104, its success will still remain subject to the risks associated with obtaining regulatory approval from the FDA and being commercialized, including risks associated with:

- the timing of review, as the FDA s grant of Fast Track designation for OTO-104 does not guarantee priority review;
- the FDA s acceptance of our NDA submission for OTO-104;
- the successful and timely receipt of necessary marketing approval from the FDA to allow us to begin commercializing OTO-104 in the United States;
- the ability to manufacture commercial supplies of OTO-104;
- the ability of our future sales organization to sell OTO-104;
- our success in educating physicians and patients about the benefits, administration and use of OTO-104;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments for Ménière s disease;
- patient demand for the treatment of Ménière s disease;
- the availability of coverage and adequate reimbursement for OTO-104;

our ability to enforce our intellectual property rights in and to OTO-104; and

a continued acceptable safety profile of OTO-104 following approval.

Many of these clinical, regulatory and commercial matters are beyond our control and are subject to other risks described elsewhere in this Risk Factors section. Accordingly, we cannot assure you that we will be able to advance OTO-104 further through final clinical development, or obtain regulatory approval of, commercialize or generate significant revenue from OTO-104. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

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In addition to OTIPRIO and OTO-104, our long-term prospects depend in part upon advancing additional product candidates, such as OTO-311, into clinical development and through to regulatory approval and commercialization.

Although we are focused upon potential regulatory approval and commercialization of OTIPRIO and completion of the clinical trials and potential regulatory approval and commercialization of OTO-104, the development of OTO-311 and other potential candidates for the treatment of inner and middle ear disorders is a key element of our long-term strategy. We have recently obtained FDA clearance to commence a Phase 1 clinical safety trial for OTO-311. Therefore, this program is currently most subject to the risks associated with clinical development, including the risks associated with:

- generating sufficient data to support the continuation of clinical trials;
- contracting with the necessary parties to conduct a clinical trial;
- enrolling sufficient numbers of patients in clinical trials;
- the timely manufacture of sufficient quantities of the product candidate for use in clinical trials; and
- adverse events in the clinical trials.

Even if we successfully advance OTO-311 or any other future product candidate into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this Risk Factors section. Accordingly, we cannot assure you that we will ever be able to develop, obtain regulatory approval of, commercialize or generate significant revenue from OTO-311 or any other future product candidate.

Risks Related to Our Business and Strategy

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is a high failure rate for drugs proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the required safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We have in the past experienced delays in our ongoing clinical trials and we may in the future. We do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including failure to:

generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;

obtain regulatory approval, or feedback on trial design, to commence a trial;

identify, recruit and train suitable clinical investigators;

reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;

obtain and maintain institutional review board, or IRB, approval at each clinical trial site;

identify, recruit and enroll suitable patients to participate in a trial;

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have a sufficient number of patients complete a trial or return for post-treatment follow-up;

ensure clinical investigators observe trial protocol or continue to participate in a trial;

address any patient safety concerns that arise during the course of a trial;

address any conflicts with new or existing laws or regulations;

add a sufficient number of clinical trial sites;

timely manufacture sufficient quantities of product candidate for use in clinical trials; or

raise sufficient capital to fund a trial.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians and patients or caregivers perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

OTO-104 was previously subject to Full Clinical Hold that was removed in July 2013 and then subject to Partial Clinical Hold that was removed in June 2014. The removal of Full Clinical Hold allowed us to initiate the current Phase 2b clinical trial. As a result of OTO-104 being placed on Full Clinical Hold, OTIPRIO was also placed on Full Clinical Hold. The OTIPRIO Full Clinical Hold was removed in November 2012. We cannot assure you that our product candidates will not be subject to new clinical holds in the future.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates for any reason, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may be unable to obtain regulatory approval for our product candidates. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, recordkeeping, marketing, distribution, post-approval monitoring and reporting, and export and import of drug products are subject to extensive regulation by the FDA, and by foreign regulatory authorities in other countries. These regulations differ from country to country. To gain approval to market our product candidates, we must provide clinical data that adequately demonstrates the safety and efficacy of the product for the intended indication. We have not yet obtained regulatory approval to market any of our product candidates in the United States or any other country. Our business depends upon obtaining these regulatory approvals.

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The FDA can delay, limit or deny approval of our product candidates for many reasons, including:

- our inability to satisfactorily demonstrate that the product candidates are safe and effective for the requested indication;
- the FDA s disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- the population studied in the clinical trial may not be sufficiently broad or representative to assess safety in the full population for which we seek approval;
- our inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA s determination that additional preclinical or clinical trials are required;
- the FDA s non-approval of the formulation, labeling or the specifications of our product candidates;
- the FDA s failure to accept the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. To the extent we seek regulatory approval in foreign countries, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would materially adversely impact our business, results of operations and prospects.

Even if OTIPRIO, OTO-104, OTO-311 or any future product candidates obtain regulatory approval, they may fail to achieve the broad degree of market acceptance and use necessary for commercial success.

Even if we obtain FDA or other regulatory approvals, our products may not achieve market acceptance among physicians and patients, and may not be commercially successful. There are currently no FDA-approved drug treatments for the indications we are pursuing. Middle ear effusion in pediatric patients requiring TTP surgery, our

proposed indication for our lead candidate OTIPRIO, is currently treated with the off-label use of antibiotic ear drops. Our proposed indication for OTO-104 is the treatment of vertigo associated with Ménière s disease. Currently, Ménière s disease patients are routinely prescribed a low-salt diet and off-label use of diuretics. Physicians may also prescribe the off-label use of antihistamines, anticholinergics, phenothiazines and benzodiazepines as well as corticosteroids. Our proposed indication for OTO-311 is the treatment of tinnitus. Currently, physicians may attempt to treat tinnitus symptoms with the off-label use of steroids, anxiolytics, antidepressants, and antipsychotics. The commercial success of our product candidates, if approved, will depend significantly on the adoption and use of the resulting product by physicians for approved indications. The decision to elect treatment with OTIPRIO for middle ear effusion in pediatric patients requiring TTP surgery, or to elect to utilize OTO-104 for Ménière s disease or OTO-311 for tinnitus, rather than other products or treatments, may be influenced by a number of factors, including:

the cost, safety and effectiveness of our products as compared to other products or treatments;

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physician willingness to adopt a new treatment in lieu of other products or treatments;

the extent to which physicians recommend our products to their patients;

patient or caregiver sentiment about the benefits and risks of our products;

proper training and administration of our products by physicians and medical staff, such that their patients do not experience excessive discomfort during treatment or adverse side effects;

the procedural risks of IT injection, including persistent injection site perforation of the tympanic membrane, which has occurred in our OTO-104 Phase 1b clinical trial;

overcoming any biases physicians or patients may have in favor of other products or treatments;

patient preference for non-injectable treatments;

patient or caregiver satisfaction with the results and administration of our product and overall treatment experience, including relative convenience and ease of administration;

the effectiveness of our sales and marketing efforts;

demand for the treatment of the relevant diseases or disorders;

product labeling or product insert requirements of the FDA or other regulatory authorities;

the prevalence and severity of any adverse events;

the revenue and profitability that our products will offer a physician as compared to other products or treatments;

the availability of coverage and adequate reimbursement by third-party payors and government authorities; and

general patient or caregiver confidence, which may be impacted by economic and political conditions.

If our product candidates are approved for use but fail to achieve the broad degree of market acceptance necessary for commercial success, our operating results and financial condition will be adversely affected. In addition, even if any of our products gain acceptance, the markets for treatment of patients with our target indications may not be as significant as we estimate.

Use of our product candidates could be associated with side effects or adverse events.

As with most pharmaceutical products, use of our product candidates could be associated with side effects or adverse events which can vary in severity and frequency. Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or once a product is commercialized, and any such side effects or adverse events may negatively affect our ability to obtain regulatory approval or market our product candidates. Side effects such as toxicity or other safety issues associated with the use of our product candidates could require us to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits which will harm our business. We may be required by regulatory agencies to conduct additional preclinical or clinical trials regarding the safety and efficacy of our product candidates which we have not planned or anticipated. We cannot assure you that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition.

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Some patients in our clinical trials have reported adverse events after being treated with OTIPRIO and OTO-104. For example, one patient in our Phase 1b clinical trial of OTO-104 experienced a persistent injection site perforation of the tympanic membrane. If we are successful in commercializing our product candidates, the FDA and other foreign regulatory agency regulations will require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or other foreign regulatory agencies could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

Our product candidates, if approved, will face significant competition in the biopharmaceutical industry and our failure to effectively compete with competitor drugs, including off-label drug use, and future competitors may prevent us from achieving significant market penetration and expansion.

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. If approved, our products must compete with off-label drug use by physicians to treat the indications for which we seek approval, such as, in the case of OTIPRIO, the current use of antibiotic ear drops to treat middle ear effusion in patients requiring TTP surgery. We are also aware that other companies, such as Auris Medical Holding AG, Autifony Therapeutics, Kyorin Pharmaceuticals, Merz Pharmaceuticals GmbH, Novartis AG, Otic Pharma Ltd. and Synphora AB, are conducting clinical trials for potential products for the treatment of various otic indications, including ear infections, tinnitus and Ménière s disease. Many companies in the biopharmaceutical industry have greater resources to discover, obtain patents, develop, test and obtain regulatory approvals for products, as well as commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to actual and prospective customers and medical staff. These companies may develop new drugs to treat the diseases and disorders we target, or seek to have existing drugs approved for use for new indications that treat the diseases and disorders we target. Mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated in potential competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in this industry. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis products that are more effective, easier to administer or less costly than our product candidates.

We rely on third parties to conduct many of our preclinical studies and all of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for, or commercialize, our product candidates.

We do not have the ability to independently conduct many of our preclinical studies or any of our clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs, to conduct clinical trials on our product candidates. Third parties play a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. If our CROs or any other third parties upon which we rely for administration and conduct of our clinical trials do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, or if they otherwise perform in a substandard manner, our clinical trials may be extended, delayed, suspended or

terminated, and we may not be able to complete development of, obtain regulatory approval for, or successfully commercialize our product candidates.

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We and the third parties upon which we rely are required to comply with Good Clinical Practice, or GCP, which are regulations and guidelines enforced by regulatory authorities around the world for products in clinical development. Regulatory authorities enforce these GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or our third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, a regulatory authority will determine that any of our clinical trials comply or complied with applicable GCP regulations. In addition, our clinical trials must be conducted with material produced under current Good Manufacturing Practice, or cGMP, regulations, which are enforced by regulatory authorities. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be impacted if our CROs, clinical investigators or other third parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. In order for our clinical trials to be carried out effectively and efficiently, it is imperative that our CROs and other third parties communicate and coordinate with one another. Moreover, our CROs and other third parties may also have relationships with other commercial entities, some of which may compete with us. Our CROs and other third parties may terminate their agreements with us upon as few as 30 days notice under certain circumstances. If our CROs or other third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements with alternative CROs, clinical investigators or other third parties. We may be unable to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. Switching or adding CROs, clinical investigators or other third parties can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationship with our CROs, clinical investigators and other third parties there can be no assurance that we will not encounter such challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition or results of operations.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved products.

We outsource the manufacture of our product candidates. We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. If we were to experience an unexpected loss of supply of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, we may be required to manufacture additional supplies of our product candidates to the extent our estimates of the amounts required prove inaccurate, we suffer unexpected losses of product candidate supplies, or to the extent that we are required to have fresh product candidate supplies manufactured to satisfy regulatory requirements or specifications. Any significant delay or discontinuation in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a contract manufacturer or other third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

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Reliance on third-party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party, and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. The facilities used by our third-party manufacturers must be accepted by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the implementation of the manufacturing process of, and are completely dependent on, our third-party manufacturers for compliance with the regulatory requirements, for manufacture of both active drug substances and finished drug products. If our third-party manufacturers cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or foreign regulatory authorities, we will not be able to secure and/or maintain regulatory acceptance of our contract manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers or other third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. The failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or any other product candidates or products that we may develop. In addition, if the FDA does not accept these facilities for the manufacture of our product candidates or if it withdraws any such acceptance in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any failure or refusal to supply the components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

As we commercialize our products, we may encounter issues with manufacturing.

Our product candidates have never been manufactured for commercial use, and there are risks associated with manufacturing for commercial use including, among others, potential problems with forecasting and cost overruns, process reproducibility, storage availability, stability issues, lot consistency and timely availability of raw materials. Even if we could otherwise obtain regulatory approval for our product candidates, there is no assurance that our contract manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our contract manufacturers are unable to produce sufficient quantities of the approved product for commercialization, our commercial efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We depend on a small number of suppliers for the raw materials necessary to produce our product candidates. The loss of these suppliers, or their failure to supply us with these raw materials, would materially and adversely affect our business.

We depend on the availability of key raw materials, including poloxamer for all of our product candidates, ciprofloxacin for OTIPRIO, dexamethasone for OTO-104, and gacyclidine for OTO-311, from a small number of third-party suppliers. Because there are a limited number of suppliers for the raw materials that we use to manufacture our product candidates, we may need to engage alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the availability of raw materials. If we or our manufacturers are unable to purchase these raw materials on acceptable terms, at sufficient quality levels, or in adequate quantities, if at

all, the commercialization of OTIPRIO and the development of OTO-104, OTO-311 or any future product candidates, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of any approved products.

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Our ability to market our product candidates, if approved, will be limited to certain indications. If we want to expand the indications for which we may market our products, we will need to obtain additional regulatory approvals, which may not be granted.

We are currently developing OTIPRIO for the treatment of middle ear effusion in pediatric patients requiring TTP surgery, OTO-104 for the treatment of vertigo associated with Ménière s disease and OTO-311 for the treatment of tinnitus. The FDA and other applicable regulatory agencies will restrict our ability to market or advertise our products to the scope of the approved label for the applicable product and for no other indications, which could limit physician and patient adoption. We may attempt to develop, and if approved, promote and commercialize new treatment indications for our products in the future, but we cannot predict when or if we will receive the regulatory approvals required to do so. Failure to receive such approvals prevents us from promoting or commercializing the new treatment indications. In addition, we would be required to conduct additional clinical trials or studies to support approvals for additional indications, which would be time consuming and expensive, and may produce results that do not support regulatory approvals. If we do not obtain additional regulatory approvals, our ability to expand our business will be limited.

If our product candidates are approved for marketing, and we are found to have improperly promoted off-label uses, or if physicians misuse our products, we may become subject to prohibitions on the sale or marketing of our products, significant sanctions, product liability claims, and our image and reputation within the industry and marketplace could be harmed.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product s approved labeling. For example, if we receive marketing approval for OTIPRIO for treatment of middle ear effusion in pediatric patients requiring TTP surgery, the first indication we are pursuing, we cannot promote the use of our product in a manner that is inconsistent with the approved label. However, physicians are able to, in their independent medical judgment, use OTIPRIO on their patients in an off-label manner, such as for the treatment of other otic indications. If we are found to have promoted such off-label uses, we may receive warning letters and become subject to significant liability, which would materially harm our business. The federal government has levied large administrative, civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management s attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation with physicians, patients and caregivers, and our position within the industry.

Physicians may also misuse our products or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our products are misused or used with improper technique, we may become subject to costly litigation. Product liability claims could divert management s attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. We currently carry product liability insurance covering our clinical trials with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of

our insurance coverage. Furthermore, the use of our products for conditions other than those approved by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

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We currently have limited marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our products, if approved, or generate product revenue.

To commercialize our products, if approved, in the United States and other jurisdictions we seek to enter, we must build our marketing, sales, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our products receive regulatory approval, we expect to market such products in the United States through a focused, specialized sales force, which will be costly and time consuming. We have no prior experience in the marketing and sale of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Outside of the United States, we may consider collaboration arrangements. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our products in certain markets. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products. If we are not successful in commercializing our products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

To establish our sales and marketing infrastructure and expand our manufacturing capabilities, we will need to increase the size of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2015, we had 76 full-time employees, including 49 employees engaged in research and development. As we advance our product candidates through the development process and to commercialization, we will need to continue to expand our development, regulatory, quality, managerial, sales and marketing, operational, finance and other resources to manage our operations and clinical trials, continue our development activities and commercialize our product candidates, if approved. As our operations expand, we expect that we will need to manage additional relationships with various manufacturers and collaborative partners, suppliers and other organizations.

Due to our limited financial resources and our limited experience in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. In addition, the physical expansion of our operations may lead to significant costs and may divert our management and resources. Any inability to manage growth could delay the execution of our development and strategic objectives, or disrupt our operations, which could materially impact our business, revenue and operating results.

Coverage and reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. Recent legislative and regulatory activity may exert downward pressure on potential pricing and reimbursement for our products, if approved, that could materially affect the opportunity to commercialize.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, market acceptance and sales of our products, if approved, in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party or government payors for any of our products and may be affected by existing and future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. While we expect that OTIPRIO will initially be assigned a unique C-Code and eventually a unique J-Code and that

OTO-104 will be assigned a unique J-Code by the U.S. Center for Medicaid and Medicare Services (CMS), there is no assurance that such codes will be issued by CMS. If a C-Code or J-Code is not issued, the cost of these drugs will be absorbed by healthcare providers. If this is the case, our expectations of the pricing we expect to achieve for OTIPRIO and OTO-104, if approved, and the related potential revenue, may be significantly diminished. We cannot be certain that coverage and adequate reimbursement will be available for any of our products, if approved, or that such coverage and reimbursement will be authorized in a timely fashion, even if a unique C-Code or J-Code is assigned for such products. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, any of our products, if approved. If reimbursement is not available or is available on a limited basis for any of our products, if approved, we may not be able to successfully commercialize any such products. Reimbursement by a third-party or government payor may depend upon a number of factors, including, without limitation, the third-party or government payor s determination that use of a product is:

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

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cost-effective; and

neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement or to have pricing set at a satisfactory level. If reimbursement of our products, if any, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels such as may result where alternative or generic treatments are available, we may be unable to achieve or sustain profitability.

Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. In some foreign countries, particularly in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our products to other available therapies. If reimbursement of any of our products, if approved, is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. Any negotiated prices for any of our products, if approved, covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain outside of the Medicare Part D prescription drug plan. Moreover, while Medicare Part D applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment under Medicare Part D may result in a similar reduction in payments from non-governmental payors.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our products profitably, if approved. Among policy-makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

the demand for any of our products, if approved;

the ability to set a price that we believe is fair for any of our products, if approved;

our ability to generate revenues and achieve or maintain profitability;

the level of taxes that we are required to pay; and

the availability of capital.

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In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, ACA), became law in the United States. The goal of ACA is to reduce the cost of healthcare and substantially change the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of any of our products, if they are approved. Provisions of ACA relevant to the pharmaceutical industry include the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, not including orphan drug sales;

- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- new requirements to report annually certain financial arrangements with physicians and teaching hospitals, as defined in ACA and its implementing regulations, including reporting any payment or transfer of value provided to physicians and teaching hospitals and any ownership and investment interests held by physicians and their immediate family members during the preceding calendar year;

- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

The ACA may change in the future.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes or is perceived to cause injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

decreased demand for our products;

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injury to our reputation and significant negative media attention;

withdrawal of clinical trial participants or cancellation of clinical trials;

costs to defend the related litigation;

a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;

exhaustion of any available insurance and our capital resources;

loss of revenue; and

the inability to commercialize any products we develop.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our products. We currently carry product liability insurance covering our clinical trials with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of any approved product, we may be unable to obtain such increased coverage on acceptable terms, or at all. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing our product candidates, we intend to expand our insurance coverage to include the sale of the applicable products; however, we may be unable to obtain this liability insurance on commercially reasonable terms.

If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop and commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We believe that our future success is highly dependent upon the contributions of our senior management, particularly our President and Chief Executive Officer, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals, who all have at-will

employment arrangements with us, could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates.

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all, which may cause our business and operating results to suffer.

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If we are not successful in discovering, developing, acquiring and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our efforts are focused on the development and regulatory approval of our three product candidates, a key element of our strategy is to identify, develop and commercialize additional product candidates for the treatment of inner and middle ear diseases and disorders. We are seeking to do so through our internal research programs and may explore strategic collaborations with third parties for the development or acquisition of new product candidates or products. Research programs to identify new product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified or successfully developed.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced a material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs.

Changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported operating results.

Generally accepted accounting principles in the United States are subject to interpretation by the FASB, the SEC and various bodies formed to promulgate and interpret appropriate accounting principles. A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business.

Issues arising during the upgrade of our enterprise resource planning system could affect our operating results, our ability to manage our business effectively and our ability to comply with the requirements of being a public company, including compliance with the Sarbanes-Oxley Act and SEC reporting requirements, which in turn would significantly harm our reputation and our business.

We purchased a new enterprise resource planning system (ERP) and are currently implementing the new system. ERP implementations are complex and time-consuming and involve substantial expenditures on system software and implementation activities. This project has required and may continue to require investment of capital and human resources, the re-engineering of processes of our business and the attention of many employees who would otherwise be focused on other aspects of our business. Any deficiencies in the design and implementation of the new ERP system could result in potentially much higher costs than we had incurred and could adversely affect our ability to develop and launch solutions, provide services, fulfill contractual obligations, file reports with the SEC in a timely manner, otherwise operate our business or otherwise impact our controls environment. Any of these consequences could have an adverse effect on our results of operations and financial condition. Additionally, if we do not effectively implement the ERP system as planned or the system does not operate as intended, the effectiveness of our internal control over financial reporting could be adversely affected or our ability to assess it adequately could be delayed.

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Our employees, independent contractors, clinical investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, clinical investigators, CROs, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, (ii) manufacturing standards, (iii) federal, state and foreign healthcare fraud and abuse laws, or (iv) laws that require the reporting of financial information or data accurately. Specifically, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, education, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, even if we are successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business. Violations of such laws subject us to numerous penalties, including, but not limited to, the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We or the third parties upon whom we depend may be adversely affected by earthquakes, wildfires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters are located in the San Diego area and we have a small office space in Alamo, California, each of which in the past has experienced severe earthquakes. We do not carry earthquake insurance. The San Diego area has also recently experienced serious wildfires. If a natural disaster or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as product development and research efforts for our current product candidates and finance records, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and may not be adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are geographically concentrated and operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, such as the most recent global financial crisis which caused extreme volatility and disruptions in the capital and credit markets, could result in a variety of risks to our business and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers and third-party payors to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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Risks Related to Our Intellectual Property

If our efforts to protect the intellectual property related to our product candidates are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technology. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in the market.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, it is possible that certain patentable aspects of our inventions may not be protected in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, etc., although we are unaware of any such defects that we believe are of material import. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. If we or our current licensors, or any future licensors or licensees, fail to file patent applications, or, maintain, enforce or protect our patents, such patent rights may be reduced or eliminated. If our current licensors, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The strength of patents in the pharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. The patent applications that we own or in-license may fail to result in issued patents in the United States or foreign countries with claims that cover our product candidates. Even if patents do successfully issue from the patent applications that we own or in-license, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be challenged, also known as opposed, by any person within nine months from the publication of their grant. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our product candidates. Furthermore, even if they are unchallenged, our patents may not adequately protect our product candidates, provide exclusivity for our product candidates, or prevent others from designing around our patents. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize our product candidates.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its effective filing date. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, if we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

Almost all of our patents and patent applications are entitled to effective filing dates prior to March 16, 2013. For U.S. patent applications for which patent claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party, for example a competitor, or instituted by the U.S. Patent and Trademark Office, or the USPTO, to determine who was the first to invent any of the subject matter covered by those patent claims. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our participation in an interference proceeding may fail and, even if successful, may result in substantial costs and distract our management.

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In addition to the protection afforded by patents, we also rely on trade secret protection to protect proprietary know-how that may not be patentable or that we elect not to patent, processes for which patents may be difficult to obtain or enforce, and any other elements of our product candidates, and our product development processes (such as manufacturing and formulation technologies) that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent information and techniques and we cannot guarantee that our competitors will not independently develop substantially equivalent information and techniques. The FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA s disclosure policies may change in the future, if at all.

In an effort to protect our trade secrets and other confidential information, we require our employees, consultants, advisors, and any other third parties that have access to our proprietary know-how, information or technology, for example, third parties involved in the formulation and manufacture of our product candidates, and third parties involved in our clinical trials, to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by such employees, consultants, advisors, etc., or made known to them by us during the course of our relationship with them be kept confidential and not disclosed to third parties. However, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed despite having such confidentiality agreements. Adequate remedies may not exist in the event of unauthorized use or disclosure of our trade secrets. In addition, in some situations, these confidentiality agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, or advisors have previous employment or consulting relationships. To the extent that our employees, consultants or advisors use any intellectual property owned by third parties in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. If we are unable to prevent unauthorized material disclosure of our trade secrets to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity, and therefore, is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

For our U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or the American Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the AIA, and many of the

substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a first-to-file system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after March 16, 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provided opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party in a district court action.

Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and any patents that we might obtain in the future.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution process. Periodic maintenance fees and various other governmental fees on any issued patent and/or pending patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent or patent application. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are many situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we fail to maintain the patents and patent applications directed to our product candidates, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications, and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. For example, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may

use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement on infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally in those countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Third-party claims alleging intellectual property infringement may adversely affect our business.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties, for example, patents and proprietary rights of competitors. Our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties, including our competitors. There are also patent applications, owned by third parties including competitors, that have been filed but not issued that, if issued as patents, may be asserted against us. Numerous U.S. and foreign issued patents and pending patent applications, exist in the otic fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our product candidates may give rise to claims of infringement of the patent rights of third parties. We cannot assure you that our product candidates will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already issued that a third party, for example a competitor in the otic market, might assert are infringed by our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates, could be found to be infringed by our product candidates.

Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Regardless of the merits of any third-party claims, our defense against such claims, or other related actions we may take, could cause us to incur substantial expenses, and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us by a third party, we may have to (i) pay substantial damages, including treble damages and attorneys fees if we are found to have willfully infringed the third party s patents; (ii) obtain one or more licenses from the third party; (iii) pay royalties to the third party; and/or (iv) redesign any infringing products. Redesigning any infringing products may be impossible or require substantial time and monetary expenditure. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop and commercialize our product candidates, which could harm our business significantly. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors

gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

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Engaging in litigation is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time consuming.

Third parties may infringe or misappropriate our intellectual property, including our existing patents, patents that may issue to us in the future, or the patents of our licensors to which we have a license. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. Further, we may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. If we file an infringement action against such a generic drug manufacturer, that company may challenge the scope, validity or enforceability of our or our licensors patents, requiring us and/or our licensors to engage in complex, lengthy and costly litigation or other proceedings. For example, if we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidates is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent.

In addition, within and outside of the United States, there has been a substantial amount of litigation and administrative proceedings, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions, regarding patent and other intellectual property rights in the pharmaceutical industry. Recently, the AIA introduced new procedures including inter partes review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future, including challenges to those patents perceived by our competitors as blocking entry into the market for their products, and the outcome of such challenges.

Such litigation and administrative proceedings could result in revocation of our patents or amendment of our patents such that they do not cover our product candidates. They may also put our pending patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Additionally, it is also possible that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administrative panel to affect the validity or enforceability of a claim, for example if a priority claim is found to be improper. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Enforcing our or our licensor s intellectual property rights through litigation is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb

significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, during the course of litigation or administrative proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

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On April 17, 2015, we filed a request for interference between one of our U.S. pending applications and a U.S. pending application that appears to be controlled by Auris Medical AG, or Auris. In this request for an interference, known as a Suggestion of Interference, we asked the USPTO for a determination that our pending patent application has priority over the Auris pending patent application, and that the USPTO should grant the interfering claims to us, and not Auris. On July 20, 2015, we received notice from the USPTO that the Patent Trial and Appeal Board (the PTAB) declared an interference between our pending application and the Auris patent (issued as U.S. Patent No. 9,066,865 on June 30, 2015). In the Declaration of Interference (Interference No. 106,030), the PTAB designated us as the Senior Party and Auris as the Junior Party. The interference is ongoing. Under U.S. Patent law, the Junior Party has the burden of showing that they, and not the Senior Party, were the first inventors. If final resolution of the interference and related appeal, if any, are not in our favor, then the USPTO may deny our patent application and allow the Auris patent to remain issued. Although such Auris patent is not expected to be relevant to any of our product candidates, the interference may be time consuming and result in substantial costs to us and distraction to our management. In addition, Auris may file and prosecute patent applications for which we may need to consider similar or other actions.

If we fail to comply with our obligation in any of the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to a number of license agreements under which we are granted intellectual property rights that are crucial to our business. A portion of our patent portfolio for our product candidates is exclusively in-licensed from DURECT Corporation, or Durect, which license includes a sublicense to patents jointly owned by Durect and the Institut National de la Sante et de la Recherche Medicale, or INSERM. Under our existing license agreement with Durect, we are subject to various obligations, including development and commercialization diligence obligations and pre-commercial launch progress reporting obligations, as well as financial obligations such as potential development milestone payments, sublicensing income payments, and royalty payments to both Durect and INSERM. If we fail to comply with the diligence obligations or otherwise materially breach our license agreement, and fail to remedy such failure or cure such breach, Durect may have the right to terminate the license or, in the instance of our failure to meet the diligence obligations, Durect may instead elect to convert our exclusive license to a non-exclusive license. In particular, the loss of the license from Durect would affect a portion of the patent portfolio for OTO-311, which would adversely affect our ability to proceed with any development or potential commercialization of OTO-311, and could subject us to claims of patent infringement by Durect if OTO-311 is covered by the licensed patents.

In addition, a significant portion of our patent portfolio for our product candidates was co-developed and is co-owned with The Regents of the University of California, or UC, which licensed its rights to us through an exclusive worldwide license agreement. Under our existing license agreement with UC, we are subject to various obligations, including development and commercialization diligence obligations, patent prosecution and maintenance obligations, and pre-commercial launch progress reporting obligations, as well as financial obligations such as potential development milestone payments, sublicensing income payments, and royalty payments. If we fail to comply with any of these obligations or otherwise breach other terms of our license agreement, and fail to cure such breach, UC may have the right to terminate the license or, in the instance where we fail to meet our diligence obligations, UC may instead elect to change our exclusive license to a non-exclusive license. The loss of the license from UC would affect a significant portion of the patent portfolio for OTIPRIO, OTO-104 and OTO-311. While we could still proceed with development and, if approved, commercialization of OTIPRIO, OTO-104 and OTO-311 as co-owner of the licensed patents, third parties, such as our competitors, could enter into the market by obtaining a license from UC under UC s rights to such patents.

Licensing of intellectual property rights is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including:

the scope of rights granted under the license agreement and other interpretation-related issues;

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our right to sublicense intellectual property rights to third parties under collaborative development relationships; and

our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations.

While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the patents licensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Generally, the loss of any one of our current licenses, or any other license we may acquire in the future, could materially harm our business, prospects, financial condition and results of operations.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals, consultants and independent contractors who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or their former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants, independent contractors or others who are involved in developing our product candidates. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Government Regulation

Our business and products are subject to extensive government regulation.

We are subject to extensive, complex, costly and evolving regulation by federal and state governmental authorities in the United States, principally by the FDA, the U.S. Drug Enforcement Administration, or DEA, the Centers for Disease Control and Prevention, or CDC, the U.S. Department of Health and Human Services, and its various agencies, and also from foreign regulatory authorities. Failure to comply with all applicable regulatory requirements, including those promulgated under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and, the Public Health Service Act, and the Controlled Substances Act, among others, may subject us to operating restrictions and criminal prosecution, monetary penalties and other disciplinary actions, including, sanctions, warning letters, product seizures, recalls, fines, injunctions, suspension, revocation of approvals, or exclusion from future participation in the Medicare and Medicaid programs. After our products receive regulatory approval or clearance, we, and our direct and indirect suppliers, remain subject to the periodic inspection of our plants and facilities, review of production processes, and testing of our products to confirm that we are in compliance with all applicable regulations. Adverse findings during regulatory inspections may result in the implementation of Risk Evaluation and Mitigation Strategies, or REMS, programs, completion of government mandated clinical trials, and government enforcement action relating to labeling, advertising, marketing and promotion, as well as regulations governing cGMPs.

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The regulatory approval process is highly uncertain and we may not obtain regulatory approval for the commercialization of OTIPRIO, OTO-104, OTO-311 or any future product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA. We have not obtained marketing approval for our product candidates anywhere in the world. Obtaining regulatory approval of a product can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable United States and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

warning letters;

civil and criminal penalties;

injunctions;

withdrawal of approved products;

product seizure or detention;

product recalls;

total or partial suspension of production; and

refusal to approve pending NDAs or supplements to approved NDAs.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled preclinical studies and clinical trials, and to the satisfaction of the FDA or other foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways, and insufficient or adverse results from preclinical studies can affect the ability to conduct clinical trials. For example, following completion of a Phase 1b clinical trial, the OTO-104 program was put on Full Clinical Hold due to adverse findings in a preclinical study evaluating the safety of repeated doses of OTO-104. OTO-104 was subsequently removed from Full Clinical Hold in July 2013, allowing for initiation of the current Phase 2b single-dose clinical trial, and placed on Partial Clinical Hold prohibiting the initiation of multiple-dose clinical trials in the United States pending the submission and review of additional preclinical data. We submitted additional preclinical data to the FDA and OTO-104 was removed from Partial Clinical Hold in June 2014. As a result of OTO-104 being placed on Full Clinical Hold, OTIPRIO was also placed on Full Clinical Hold. The OTIPRIO Full Clinical Hold was removed in November 2012. We cannot assure you that our product candidates will not be subject to new clinical holds in the future.

Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a product candidate for any or all targeted indications.

Regulatory approval is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense expended, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including the following:

a product candidate may not be deemed safe, effective, pure or potent;

FDA officials may not find the data from preclinical studies and clinical trials sufficient;

the FDA might not accept our third-party manufacturers processes or facilities; or

the FDA may change its approval policies or adopt new regulations.

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If OTIPRIO does not gain regulatory approval or OTO-104, OTO-311 or any future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain approval, our business and results of operations will be materially and adversely harmed.

If the FDA does not conclude that OTIPRIO satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for approval of OTIPRIO under Section 505(b)(2) are not as we expect, the development and approval of OTIPRIO will likely take significantly longer, cost significantly more and entail significantly greater complexity and risks than anticipated, and in any case may not be successful.

We are seeking FDA approval through the Section 505(b)(2) regulatory pathway for OTIPRIO. Section 505(b)(2) of the FFDCA permits the submission of an NDA where some or all of the data required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Our ability to rely on certain of the FDA s findings of safety and effectiveness in approval of another NDA or on studies published in the scientific literature will depend on our ability to demonstrate the relevance to OTIPRIO. We may be required to conduct additional studies or provide additional information to fully demonstrate the safety and effectiveness of our modifications to the approved product.

By pursuing the Section 505(b)(2) regulatory pathway for OTIPRIO, our reliance on the prior FDA findings of safety and effectiveness of the reference product may require any approved labeling for OTIPRIO to include certain information that is included in the labeling of the reference product.

If the FDA disagrees with our position that reliance on data for the reference product is appropriate, or if the data required for approval of our Section 505(b)(2) NDA are different than anticipated, we may need to conduct additional development activities, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for OTIPRIO would likely substantially increase. Moreover, the inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than OTIPRIO, which could materially adversely impact our competitive position and prospects.

In addition, our competitors may file citizens petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical trials that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, or the limiting or withdrawal of regulatory approval and subject us to penalties if we fail to comply with applicable regulatory requirements.

If and when regulatory approval has been granted, our product candidates or any approved product will be subject to continual regulatory review by the FDA and/or non-U.S. regulatory authorities. Additionally, any product candidates, if approved, will be subject to extensive and ongoing regulatory requirements, including labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indications for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. In addition, if the applicable regulatory agency approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive

and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or problems with our third-party manufacturers processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

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fines, warning letters or holds on clinical trials;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;

product seizure or detention, or refusal to permit the import or export of products; and

injunctions or the imposition of civil or criminal penalties.

Our ongoing regulatory requirements may also change from time to time, potentially harming or making costlier our commercialization efforts. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or other countries. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Our relationships with healthcare professionals, independent contractors, clinical investigators, CROs, consultants and vendors in connection with our current and future business activities are subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties.

We are subject to the various U.S. federal and state health care laws, including those intended to prevent healthcare fraud and abuse.

The federal anti-kickback statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid Remuneration has been broadly defined to include anything of value, including, but not limited to, cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state health care programs as well as private payors.

The federal False Claims Act, or FCA, and civil monetary penalties law impose penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or making a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. The FCA has been used to, among other things, prosecute persons and entities submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims.

Additionally, state and federal authorities have aggressively targeted medical technology companies for, among other things, alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper

promotional practices.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

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Additionally, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without proper written authorization.

Our operations will also be subject to the federal transparency requirements under the Affordable Care Act, which requires manufacturers of drugs, devices, biologicals and medical supplies to annually report to the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, information related to payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members.

If any of our business activities, including but not limited to our relationships with healthcare providers, violate any of the aforementioned laws, we may be subject to administrative, civil and/or criminal penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations. Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Legislative or regulatory healthcare reforms in the United States or abroad may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates or any future product candidates and to produce, market, and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress in the United States or by governments in foreign jurisdictions that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA or foreign regulatory agency regulations and guidance are often revised or reinterpreted by the FDA or the applicable foreign regulatory agency in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates or any future product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

changes to manufacturing methods;

recall, replacement, or discontinuance of one or more of our products; and

additional recordkeeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition, and results of operations.

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If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

We maintain workers compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has been and may continue to be volatile, and you could lose all or part of your investment.

Prior to our initial public offering, there was no public market for our common stock. An active trading market for our shares may never develop or, if developed, may not be sustained. Moreover, the trading price of our common stock may fluctuate substantially. The stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including:

- regulatory or legal developments;
- results from or delays in clinical trials of our product candidates;
- announcements of regulatory approval or disapproval of our product candidates;
- commercialization of our products;
- FDA or other regulatory actions affecting us or our industry;

introductions and announcements of new products by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;

variations in our financial results or those of companies that are perceived to be similar to us;

changes in the structure of healthcare payment systems;

announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;

market conditions in the pharmaceutical and biopharmaceutical sectors and issuance of securities analysts reports or recommendations;

actual or anticipated quarterly variations in our results of operations or those of our future competitors;

changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;

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sales of substantial amounts of our stock by insiders and large stockholders, or the expectation that such sales might occur;

general economic, industry and market conditions;

additions or departures of key personnel;

intellectual property, product liability or other litigation against us;

expiration or termination of our potential relationships with strategic partners;

limited trading volume of our common stock; and

the other factors described in this Risk Factors section.

If securities or industry analysts do not continue to publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced in part on the research and reports that equity research analysts publish about us and our business. Although certain equity research analysts currently cover us, we do not have any control of the analysts or the content and opinions included in their reports or whether any such analysts will continue to, or whether new analysts will, cover us for any given period of time. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Sales of substantial amounts of our common stock in the public markets, or the perception that such sales might occur, could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

On August 13, 2014, we filed a registration statement on Form S-8 registering 2,093,580 shares of common stock reserved for issuance pursuant to awards outstanding under our Amended and Restated 2010 Equity Incentive Plan, 2,606,875 shares of common stock reserved for issuance pursuant to future awards under our 2014 Plan, and 380,000 shares reserved for issuance pursuant to future awards under our ESPP. On March 18, 2015, we filed a registration statement on Form S-8 registering 1,058,663 additional shares of common stock under our 2014 Plan and 317,599 additional shares of common stock under our ESPP. Shares registered under this registration statement on Form S-8 will be available for sale in the public market subject to vesting arrangements and the exercise of such options, the lock-up arrangements described above and, in the case of our affiliates, the restrictions of Rule 144. As of September 30, 2015, options to purchase 1,203,678 shares of our common stock were exercisable.

Certain holders of approximately 7,136,039 shares of our common stock, including shares issuable upon the exercise of outstanding options and warrants, are entitled to certain rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

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Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities, or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person s conduct was unlawful.

- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

- We are not obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.

- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, the market price of our common stock may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing

or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. In September 2015, our shelf registration statement on Form S-3 (File No. 333-206752) was declared effective by the Securities and Exchange Commission, pursuant to which we may offer debt securities, preferred stock, common stock and certain other securities from time to time. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, the market price of our common stock may decline.

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Concentration of ownership of our common stock among our existing principal stockholders may effectively limit the voting power of other stockholders.

As of September 30, 2015, our executive officers, directors and current beneficial owners of 5% or more of our common stock, in aggregate, beneficially owned approximately 59.7 % of our outstanding common stock. Accordingly, these stockholders, acting together, may significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. These stockholders may therefore delay or prevent a change of control, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the market price of our common stock due to investors perception that conflicts of interest may exist or arise.

Anti-takeover provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult, which could discourage takeover attempts and lead to management entrenchment, and the market price of our common stock may be lower as a result.

Certain provisions in our certificate of incorporation and bylaws may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. Our board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents contain other provisions that could have an anti-takeover effect, including provisions that:

- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three year terms;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may only be removed for cause;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issues shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;

permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;

prohibit stockholders from calling a special meeting of stockholders;

require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;

authorize our board of directors, by a majority vote, to amend the bylaws; and

require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

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In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Finally, our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that certain investors are willing to pay for our stock.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock has been and will likely to continue to be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management s attention from other business concerns, which could seriously harm our business.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains.

We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be subject to certain limitations.

As of December 31, 2014 we had U.S. federal and California net operating loss carryforwards, or NOLs, of approximately $60.5 million and $59.4 million, respectively, which expire in various years beginning in 2030, if not utilized. As of December 31, 2014, we had federal and California research and development tax credit carryforwards of approximately $2.8 million and $1.6 million, respectively. The federal research and development tax credit carryforwards expire in various years beginning in 2030, if not utilized. The California research and development credit will carry forward indefinitely. Under Sections 382 and 383 of Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an ownership change, the corporation s ability to use its pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its future post-change income and taxes may be limited. In general, an ownership change occurs if there is a cumulative change in our ownership by 5% shareholders that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We believe we have experienced certain ownership changes in the past and have reduced our deferred tax assets related to NOLs and research and development tax credit carryforwards accordingly. In the event that it is determined that we have in the past experienced additional ownership changes, or if we experience one or more ownership changes as a result of future transactions in our stock, then we may be further limited in our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we earn in the event that we attain profitability. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability.

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We have incurred and will continue to incur costs as a result of operating as a public company and our management has been and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices, including maintaining an effective system of internal control over financial reporting.

As a public company listed in the United States, and increasingly after we are no longer an emerging growth company, we have incurred and will continue to incur significant additional legal, accounting and other expenses that we did not incur as a private company. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and regulations implemented by the SEC and The NASDAQ Stock Market, or NASDAQ, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management s time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

As a public company in the United States, we are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. We need to disclose any material weaknesses identified by our management in our internal control over financial reporting, and, when we are no longer an emerging growth company, we will need to provide a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting. We expect that our first report on compliance with Section 404 will be furnished in connection with our financial statements for the year ending December 31, 2015. The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC, is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We are in the early stages of conforming our internal control procedures to the requirements of Section 404 and we may not be able to complete our evaluation, testing and any required remediation needed to comply with Section 404 in a timely fashion. Our independent registered public accounting firm was not engaged to perform an audit of our internal control over financial reporting for the year ended December 31, 2014 or for any other period. Accordingly, no such opinion was expressed.

Even after we develop these new procedures, these new controls may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate and material weaknesses in our internal control over financial reporting may be discovered. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no absolute assurance that all control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction.

To fully comply with Section 404, we will need to retain additional employees to supplement our current finance staff, and we may not be able to do so in a timely manner, or at all. In addition, in the process of evaluating our internal control over financial reporting, we expect that certain of our internal control practices will need to be updated to comply with the requirements of Section 404 and the regulations promulgated thereunder, and we may not be able to do so on a timely basis, or at all. In the event that we are not able to demonstrate compliance with Section 404 in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or

investigations by regulatory authorities, such as the SEC or NASDAQ, and investors may lose confidence in our operating results and the price of our common stock could decline. Furthermore, if we are unable to certify that our internal control over financial reporting is effective and in compliance with Section 404, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or stock exchanges, and we could lose investor confidence in the accuracy and completeness of our financial reports, which could hurt our business, the price of our common stock and our ability to access the capital markets.

We also expect that being a public company will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

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We are an emerging growth company, and the reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act enacted in April 2012, and may remain an emerging growth company for up to five years following the completion of our initial public offering, or December 31, 2019, although, if we have more than $1.0 billion in annual revenue, the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30 of any year, or we issue more than $1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an emerging growth company as of the following December 31. For as long as we remain an emerging growth company, we are permitted and intend to continue to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced Management s discussion and analysis of financial condition and results of operations disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, as a result, we have and will continue to adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. We cannot predict whether investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the market price of our common stock may be reduced or more volatile.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sale of Unregistered Securities

None.

Use of Proceeds for Public Offering of Common Stock

On August 12, 2014, our Registration Statement on Form S-1 (File No. 333- 197365) was declared effective by the SEC for our initial public offering of common stock. We started trading on The NASDAQ Global Select Market on August 13, 2014, and the transaction formally closed on August 18, 2014. In conjunction with the IPO, we issued 7,187,500 shares of common stock, including exercise of the underwriters option to purchase an additional 937,500 shares, at an offering price of $16.00 per share. J.P. Morgan Securities LLC, Merrill Lynch, Pierce, Fenner & Smith Incorporated, Piper Jaffray & Co. and Sanford C. Bernstein & Co., LLC acted as the underwriters. We received aggregate proceeds of approximately $104.1 million, net of underwriting discounts, commissions and offering-related transaction costs. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on August 13, 2014 pursuant to Rule 424(b).

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On January 22, 2015, our Registration Statement on Form S-1 (File No. 333- 201401) was declared effective by the SEC for our follow-on public offering of common stock. The transaction formally closed on January 28, 2015. In conjunction with the offering, we issued 2,932,500 shares of common stock, including exercise of the underwriters option to purchase an additional 382,500 shares, at an offering price of $29.25 per share. J.P. Morgan Securities LLC, Piper Jaffray & Co., Cowen and Company, LLC and Sanford C. Bernstein & Co., LLC acted as the underwriters. We received aggregate proceeds of approximately $80.0 million, net of underwriting discounts, commissions and offering-related transaction costs. There has been no material change in the planned use of proceeds from our public offering as described in our final prospectus filed with the SEC on January 23, 2015 pursuant to Rule 424(b).

ITEM 3. DEFAULT UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

See the Exhibit Index which follows the signature page of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

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SIGNATURES

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

OTONOMY, INC.

Date: November 10, 2015

By: /s/ David A. Weber
David A. Weber, Ph.D.
President and Chief Executive Officer

OTONOMY, INC.

Date: November 10, 2015

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

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EXHIBIT INDEX

Exhibit		Incorporated by Reference Herein			
Number	**Description of Document**	**Form**	**File No.**	**Exhibit**	**Filing Date**
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended, as currently in effect.	S-1/A	333-197365	3.2	August 1, 2014
3.2	Amended and Restated Bylaws of the Registrant.	S-1/A	333-197365	3.4	August 1, 2014
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1+	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2+	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	XBRL Instance Document.				
101.SCH	XBRL Taxonomy Extension Schema Document.				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				

+ In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule; Management s Reports on Internal Control over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the Certification furnished in Exhibit 32.1 and 32.2 hereto is deemed to accompany this Form 10-Q and will not be filed for purposes of Section 18 of the Exchange Act. Such certification will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Registrant specifically incorporates it by reference.