TRANZYME INC

FORM 10-Q
(Quarterly Report)

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Address	4819 EMPEROR BOULEVARD, SUITE 400 DURHAM, NC 27703
Telephone	919 313-4760
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2011

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 001-35119

TRANZYME, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**63-1192270**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4819 Emperor Boulevard, Suite 400 Durham, NC	**27703**
(Address of principal executive offices)	(Zip Code)

(919) 313-4760
(Registrant's telephone number, including area code)

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 ☐ No ☒

The registrant has not been subject to the filing requirements for the past 90 days as it commenced trading following its initial public offering on April 4, 2011 but has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 since such time.

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 ☐ 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 ☒ (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 ☒

The number of shares outstanding of the registrant's Common Stock as of March 31, 2011 was 140,192.

TRANZYME, INC.
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SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS

In addition to historical information, some of the information contained in Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our clinical programs, business and related financing, contains forward-looking statements that involve risks, uncertainties and assumptions. All statements that express expectations, estimates, forecasts or projections are forward-looking statements. Words such as "expects", "anticipates", "intends", "plans", "believes", "seeks", "estimates", "projects", "forecasts", "may", "should", variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future results and our actual results may differ materially from those anticipated or implied in these forward-looking statements as a result of important factors described in the cautionary statements included in this document, particularly those discussed under the heading "Risk Factors" in Item 1A of Part II of this Quarterly Report on Form 10-Q. We undertake no obligation to revise or update any forward-looking statements, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

Unless the context otherwise indicates, references in this report to the terms "Tranzyme", "the Company", "we," "our" and "us" refer to Tranzyme, Inc. and its subsidiaries.

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PART I - FINANCIAL INFORMATION

Item 1. Unaudited Financial Statements

Tranzyme, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	March 31, 2011 (Unaudited)	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 12,479	$ 17,373
Accounts receivable, net	1,240	1,006
Investment tax credits receivable	358	348
Prepaid expenses and other assets	1,184	497
Total current assets	15,261	19,224
Investment tax credits receivable	132	—
Deferred offering costs	1,550	1,068
Furniture, fixtures and equipment, net	1,272	1,302
Total assets	$ 18,215	$ 21,594
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	2,796	806
Accrued liabilities	1,019	1,165
Current portion of deferred revenue	7,292	7,243
Current portion of notes payable	3,056	1,854
Total current liabilities	14,163	11,068
Warrant liability	76	271
Deferred revenue, less current portion	3,178	5,050
Notes payable, less current portion	9,809	10,951
Other long-term liabilities	198	193
Total liabilities	27,424	27,533
Stockholders' deficit:		
Series A convertible preferred stock, $.00001 par value; 69,300,000 shares authorized and 51,038,570 shares issued and outstanding at March 31, 2011 and December 31, 2010; aggregate liquidation preference of $51,039 as of March 31, 2011 and December 31, 2010	1	1
Series A-1 convertible preferred stock, $.00001 par value; 17,500,000 shares authorized and 17,423,094 shares issued and outstanding at March 31, 2011 and December 31, 2010	—	—
Series B convertible preferred stock, $.00001 par value; 1,570,680 shares authorized and 1,047,120 shares issued and outstanding at March 31, 2011 and December 31, 2010; aggregate liquidation preference of $2,000 at March 31, 2011 and December 31, 2010	—	—
Class A common stock, $.00001 par value; 81,000,000 shares authorized and 140,192 shares issued and outstanding at March 31, 2011 and December 31, 2010	—	—
Class C common stock, $.00001 par value; 26,442,262 authorized and 138,860 shares issued and outstanding at March 31, 2011 and December 31, 2010	—	—
Additional paid-in capital	79,210	79,150
Accumulated other comprehensive loss	(633)	(668)
Accumulated deficit	(87,787)	(84,422)
Total stockholders' deficit	(9,209)	(5,939)
Total liabilities and stockholders' deficit	$ 18,215	$ 21,594

(See Notes to Consolidated Financial Statements)

Tranzyme, Inc.

Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2011	2010
Licensing and royalty revenue	$ 1,897	$ 1,047
Research revenue	442	375
Total revenue	2,339	1,422
Operating expenses:		
Research and development	4,501	2,946
General and administrative	971	847
Total operating expenses	5,472	3,793
Operating loss	(3,133)	(2,371)
Interest expense, net	(420)	(379)
Other income (expense), net	188	41
Net loss	$ (3,365)	$ (2,709)
Net loss per share— *basic and diluted*	$ (24.00)	$ (19.32)
Shares used to compute net loss per share— *basic and diluted*	140,192	140,192
Pro Forma:		
Pro forma net loss	$ (3,365)	$ (2,493)
Pro forma net loss per share— *basic and diluted*	$ (0.33)	$ (0.25)
Shares used to compute pro forma net loss per share— *basic and diluted*	10,208,845	9,981,177

(See Notes to Consolidated Financial Statements)

Tranzyme, Inc.

Consolidated Statements of Cash Flows
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2011	2010
Operating activities:		
Net loss	$ (3,365)	$ (2,709)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	77	49
Recognition of deferred revenue	(1,823)	(1,000)
Share-based compensation expense	60	87
Non-cash interest expense	60	240
Fair value adjustment - warrant liability	(195)	—
Changes in operating assets and liabilities:		
Accounts receivable and investment tax credits	(368)	(345)
Prepaid expenses and other assets	(678)	(27)
Accounts payable	1,977	(371)
Accrued liabilities	(159)	(81)
Net cash used in operating activities	(4,414)	(4,157)
Investing activities:		
Purchases of furniture, fixtures, and equipment	(11)	(253)
Net cash used in investing activities	(11)	(253)
Financing activities:		
Principal payments on notes payable	—	(587)
Deferred offering costs	(483)	—
Net cash used in financing activities	(483)	(587)
Effect of exchange rate changes on cash	14	344
Net decrease in cash and cash equivalents	(4,894)	(4,653)
Cash and cash equivalents at beginning of period	17,373	14,373
Cash and cash equivalents at end of period	$ 12,479	$ 9,720

(See Notes to Consolidated Financial Statements)

Tranzyme, Inc.

Consolidated Notes to Financial Statements

1. Description of Business and Basis of Presentation

Description of Business

Tranzyme, Inc. (Tranzyme) was incorporated in the State of Delaware on January 12, 1998. On December 17, 2003, Tranzyme entered into a business combination with Neokimia Inc., a Quebec, Canada-based chemistry company and changed the name to Tranzyme Pharma Inc. (Tranzyme Pharma). The Company, collectively Tranzyme and Tranzyme Pharma, operates in one segment.

The Company is a clinical-stage biopharmaceutical company focused on discovery, development and commercialization of small molecule therapeutics for the treatment of acute (hospital-based) and chronic gastrointestinal (GI) motility disorders. The Company's two most advanced product candidates are:

- *ulimorelin* —an intravenous ghrelin agonist that has commenced Phase 3 clinical development for the management of postoperative ileus, a complication most commonly associated with abdominal surgery.

- TZP-102—an orally administered ghrelin agonist entering Phase 2b clinical development for treatment of diabetic gastroparesis, an upper GI motility disorder.

The Company's business is subject to significant risks consistent with biopharmaceutical companies seeking to develop technologies and product candidates for human therapeutic use. These risks include, but are not limited to, uncertainties regarding research and development, access to capital, obtaining and enforcing patents, receiving regulatory approval and competition with other biotechnology and pharmaceutical companies.

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its subsidiary, Tranzyme Pharma. All significant intercompany balances and transactions have been eliminated. All amounts included in these notes to consolidated financial statements are reported in U.S. dollars, unless otherwise indicated.

The Company's operations since inception have consisted primarily of organizing the Company, conducting research and development including clinical trials and securing financing. In December 2009, the Company entered into its first revenue-generating collaboration agreement consistent with the Company's business objectives and emerged from the development stage. As of March 31, 2011, the Company has incurred losses since inception of $87.8 million. The Company expects to continue to incur losses and requires additional financial resources to advance its products to either commercial stage or liquidity events.

2. Summary of Significant Accounting Policies

Unaudited Financial Statements

The accompanying balance sheet as of March 31, 2011, statements of operations for the three months ended March 31, 2011 and 2010 and cash flows for the three months ended March 31, 2011 and 2010 are unaudited. These unaudited financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These financial statements should be read in conjunction with the audited financial statements and the accompanying notes for the year ended December 31, 2010 contained in the final prospectus filed by the Company with the SEC on April 4, 2011 relating to the Company's Registration Statement on Form S-1 (File No. 333-170749). The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in

the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of March 31, 2011 and the results of operations for the three months ended March 31, 2011 and 2010 and cash flows for the three months ended March 31, 2011 and 2010. The December 31, 2010 balance sheet included herein was derived from audited financial statements, but does not include all disclosures including notes required by GAAP for complete financial statements.

The financial data and other information disclosed in these notes to the financial statements related to the three months ended March 31, 2011 and 2010 are unaudited. Interim results are not necessarily indicative of results for an entire year.

Common Stock Split

On March 2, 2011, the Company's Board of directors approved a 1-for-7 reverse stock split of the Company's outstanding common stock. In connection with this reverse stock split, the preferred stock conversion price was adjusted to reflect a proportional decrease in the number of shares of common stock to be issuable upon conversion. The reverse stock split became effective on March 31, 2011. The accompanying consolidated financial statements and notes to consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

Investment Tax Credits Receivable

The Company participates in government assistance programs in Quebec, Canada that provide refundable investment tax credits for certain research and development expenditures. The receivable represents management's estimate of amounts expected to be recovered and is subject to adjustment based upon audit by Canadian taxation authorities. The Company reported investment tax credits receivable using the flow-through method of $490,000 and $348,000 as of March 31, 2011 and December 31, 2010, respectively.

Deferred Offering Costs

Deferred offering costs represent legal, accounting and other direct costs related to the Company's efforts to raise capital through an Initial Public Offering (IPO) of the Company's common stock. Future costs related to the Company's IPO activities will be deferred until the completion of the IPO, at which time they will be reclassified to additional paid-in capital as a reduction of the IPO proceeds. In connection with its IPO, the Company has recorded $1,550,000 of deferred offering costs as a non-current asset in the accompanying consolidated balance sheet as of March 31, 2011.

Warrant Liability

Certain warrants to purchase the Company's capital stock are classified as liabilities and are recorded at estimated fair value. At each reporting period, any change in fair value of the freestanding warrants is recorded as other (expense) income. The Company will continue to adjust the liability changes in the estimated fair value of the warrants until the earlier of the exercise of the warrants or the completion of a liquidation event, including the completion of an initial public offering, at which time the liability will be reclassified to stockholders' equity.

Revenue Recognition

The Company's revenues generally consist of licensing and royalty revenue and fees for research services from license or collaboration agreements. The Company recognizes revenues when all four of the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured. Royalty revenue is recognized in licensing and royalty revenue as applicable licensed products are sold.

For arrangements that include multiple deliverables, the Company identifies separate units of accounting if certain separation criteria are met in accordance with ASC Topic 605-25, *Multiple Element Arrangements* . This evaluation requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship. If the Company determines they are separable, the Company will recognize revenue separately for each unit. If management determines the arrangement constitutes a single unit of accounting, revenue will be recognized as a combined unit for the entire arrangement. The consideration for the arrangement is allocated to the separate units of accounting based on their relative fair values. Applicable revenue recognition criteria are considered separately for each unit of accounting. The Company typically receives upfront, nonrefundable payments when licensing its intellectual property in conjunction with a research and development agreement. Management believes that these payments generally are not separable from the activity of providing research and development services because the license does not have stand-alone value separate from the research and development services that the Company provides under applicable agreements. Accordingly, the Company accounts for these elements as one unit of accounting and recognizes upfront, nonrefundable payments as licensing and royalty revenue on a straight-line basis over its contractual or estimated performance period, which is typically the term of its research and development obligations. As a result, the Company is often required to make estimates regarding drug development timelines for compounds being developed pursuant to a strategic collaboration agreement. Amounts received in advance of services performed are recorded as deferred revenue until earned.

The Company's strategic collaboration agreements may also contain contingent milestone payments. At the inception of each agreement that includes contingent milestone payments, management must evaluate whether the contingencies underlying each milestone are substantive and at risk to both parties, specifically reviewing factors such as the scientific and other risks that must be overcome to achieve the milestone, as well as the level of effort and investment required. Revenues from milestones, if they are nonrefundable, are recognized in licensing and royalty revenue upon successful accomplishment of the milestones if all of the following conditions are met: (i) achievement of the milestone event was not reasonably assured at the inception of the arrangement; (ii) substantive effort is involved to achieve the milestone event; and (iii) the amount of the milestone payment appears reasonable in relation to the effort expended, the other milestone payments in the arrangement and the related risk associated with the

achievement of the milestone event. If any of these conditions are not met, the milestone payment is deferred and is recognized on a straight-line basis over the remaining performance obligation. Payments received or for which collection is reasonably assured after meeting performance obligations are recognized as earned.

The Company's collaboration agreements may also include payment for research and development services provided by the Company on a contractual rate and direct expense basis. The Company records such payments as revenue in accordance with the agreements when the Company acts as principal in the transaction. In addition, certain of the Company's collaboration agreements contain cost-sharing provisions for development activities. Reimbursable amounts received under these cost sharing provisions are reflected as a reduction of research and development expense.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities including non-cash share-based compensation, costs for third-party contractors to perform research, conduct clinical trials and prepare drug materials, research supplies and facilities costs. The Company accrues for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by the third parties, patient enrollment in clinical trials, administrative costs incurred by the third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as the related services are rendered.

Income Taxes

Income taxes are computed using the asset and liability approach, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's financial statements or tax returns. In estimating future tax consequences, the Company generally considers all expected future events other than enactment of changes in tax law or rates. If it is more likely than not that some or all of a deferred tax asset will not be realized, the Company records a valuation allowance.

Share-based Compensation

Share-based awards, including stock options, are recorded at their fair value as of the grant date and recognized to expense on a straight-line basis over the employee's requisite service period, which is generally the vesting period of the award. Share-based compensation expense is based on awards ultimately expected to vest, and therefore the recorded expense includes an estimate of future forfeitures. Forfeitures are to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The measurement of nonemployee share-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the period over which services are received. The Company estimates the fair value of share-based awards to employees, directors and non-employees using the Black-Scholes option-valuation model. The Black-Scholes model requires the input of subjective assumptions, including volatility, the expected term and the fair value of the underlying common stock on the date of grant, among other inputs.

Fair Value

The Company's financial instruments consist principally of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities and warrant liability. The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to the short-term nature of such instruments. The carrying amounts of borrowings under the Company's debt facilities approximate their fair values as of March 31, 2011 and as of December 31, 2010, based on the determination that the stated rates on such debt are consistent with current interest rates for similar borrowing arrangements available to the Company. The carrying amounts of warrant liabilities are revalued and adjusted using the Black-Scholes valuation model at the end of each reporting period to reflect their fair values.

Fair value measurements are classified and disclosed in one of the following three categories:

Level 1 —Quoted prices in active markets for identical assets or liabilities.

Level 2 —Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 —Unobservable inputs that are supported by little or no market activity and are significant to the fair value of the assets or liabilities.

As of March 31, 2011 and December 31, 2010, the Company measured its warrant liability using significant unobservable prices that are based on little or no verifiable market data, which is Level 3 in the fair value hierarchy, resulting in a fair value estimate of $76,000 and $271,000, respectively.

Recent Accounting Pronouncements

Occasionally, new accounting standards are issued or proposed by the Financial Accounting Standards Board, or other standards-setting bodies that we adopt by the effective date specified within the standard. Unless otherwise discussed, standards that do not require adoption until a future date are not expected to have a material impact on our financial statements upon adoption.

3. Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of the Company's Class A Common stock outstanding for the period, without consideration for common stock equivalents. The Company's Class C Common stock is excluded from the calculated net loss per share because it is a non-participating security and has no liquidation rights upon liquidation or dissolution of the Company. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. Under the treasury-stock method earnings per share data is computed as if the common share equivalents were outstanding at the beginning of the period (or at the time of issuance, if later) and as if the funds obtained from exercise of the common stock equivalents were used to purchase common stock at the average market price during the period. If there is little or no market for the common stock, a reasonable estimate of fair value shall be used. For purposes of this calculation, preferred stock, stock options and warrants to purchase capital stock are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The computation of unaudited pro forma basic and diluted net loss per share calculations assume the conversion of all outstanding shares of preferred stock into shares of common stock using the as-if-converted method as if such conversion occurred as of the beginning of each period presented or as of the original issuance date, if later.

The following table sets forth the computation of basic and diluted net loss per share in thousands, except share and per share data:

	Three Months Ended March 31,	
	2011	2010
Historical		
Numerator:		
Net loss	$ (3,365)	$ (2,709)
Denominator:		
Weighted average common shares outstanding	140,192	140,192
Net loss per share— *basic and diluted*	$ (24.00)	$ (19.32)
Pro forma (unaudited)		
Numerator:		
Net loss	$ (3,365)	$ (2,709)
Add: pro forma adjustment related to interest expense on convertible notes payable	—	216
Pro forma net loss used to compute pro forma net loss per share	$ (3,365)	$ (2,493)
Denominator:		
Weighted average common shares outstanding used in the computation of net loss per share— *basic and diluted*	140,192	140,192
Add: pro forma adjustments to reflect assumed weighted average conversion of common exchangeable shares	138,860	138,860
Add: pro forma adjustments to reflect assumed weighted average conversion of convertible preferred stock	9,929,793	7,428,544
Add: pro forma adjustments to reflect assumed weighted average conversion of convertible notes payable	—	2,273,581
Weighted average shares used to compute pro forma net loss per share— *basic and diluted*	10,208,845	9,981,177
Pro forma net loss per share— *basic and diluted*	$ (0.33)	$ (0.25)

Potentially dilutive securities not included in the calculation of diluted net loss per common share because to do so would be anti-dilutive are as follows (in common equivalent shares on a weighted-average basis):

	Three Months Ended March 31,	
	2011	2010
Series A Convertible Preferred stock	7,291,203	5,307,777
Series B Convertible Preferred Stock	149,588	—
Convertible Debt	—	2,273,581
Common Exchangeable shares	138,860	138,860
Preferred Exchangeable shares	2,489,002	2,120,767
Common stock options	752,943	741,691
Capital stock warrants	67,462	28,570

4. Strategic Collaboration and License Agreements

Norgine B.V.

In June 2010, the Company entered into a collaboration agreement with Norgine B.V. (Norgine) to develop and commercialize the Company's product candidate, *ulimorelin* , in a licensed territory that includes Europe, Australia, New Zealand, Middle East, North Africa and South Africa. Under the terms of the agreement, the Company received a nonrefundable, upfront payment of $8.0 million. The licensing fee was deferred and is being amortized on a straight-line basis over a period of 31 months, which represents the estimated period of time over which the Company's involvement in the core development phase of the collaboration is a substantive performance obligation.

In conjunction with the collaboration agreement, Norgine purchased 1,047,120 shares of the Company's Series B Convertible Preferred stock at $1.91 per share, for total cash proceeds of $2.0 million, net of issuance costs of $28,000 constituting a first closing (Initial Closing) of Series B Convertible Preferred stock. The agreement also obligates Norgine to purchase an additional $1.0 million of equity securities at a subsequent closing (Second Closing) upon the occurrence of a development milestone as specified in the agreement.

During the year ended December 31, 2010, the Company engaged a third party valuation specialist to assist management in determining the estimated fair value of the first tranche issuance of Series B Convertible Preferred shares. The fair value of the equity issuance was determined to be $1.6 million or $1.55 per share. Based on this fair value estimate, it was determined that the shares sold to Norgine in conjunction with the collaboration included a $0.36 per share premium. The Company recorded the $377,000 stock premium as deferred revenue which is being amortized on a straight-line basis over a period of 31 months, representing the estimated period of time over which the Company's involvement in the core development phase of the collaboration is a substantive performance obligation.

The Company recognized $787,000 of the upfront fee and $36,000 for the amortization of stock premium as licensing revenue for the three month period ended March 31, 2011. No revenue was recognized for the three-month period ended March 31, 2010.

The agreement provides for a co-managed product development campaign, and contains cost-sharing provisions whereby the companies will share certain costs related to manufacturing and development performed by third parties including reimbursement from Norgine for certain raw material costs incurred prior to the effective date of the agreement. These raw material costs will be reimbursable when used in the manufacturing of clinical trial materials for the core development program. Costs for development services provided under the agreement are expensed as incurred. The Company recognized $1.2 million as a reduction in research and development expenses for the three month period ended March 31, 2011 as a result of reimbursement for cost-sharing activities under this agreement.

Bristol-Myers Squibb Company

In December 2009, the Company entered into a collaboration agreement with Bristol-Myers Squibb Company (BMS) to discover, develop and commercialize novel macrocyclic compounds, other than the Company's product candidates and internal programs, directed against a limited number of targets of interest to BMS. Under the terms of the agreement, BMS is funding the Company's lead discovery efforts on these targets and is also primarily responsible for optimizing the identified lead compounds. BMS will be solely responsible for preclinical and clinical development of all products arising from the collaboration and for their commercialization globally. In connection with the agreement, the Company received an upfront license fee of $10.0 million. The upfront licensing fee was deferred and is being amortized on a straight-line basis over a period of 30 months, which represents the estimated period of time over which the Company's involvement in the collaboration is a substantive performance obligation or deliverable. The Company recognized $1.0 million of the upfront fee as licensing revenue for the three month periods ended March 31, 2011 and 2010.

The agreement also provided for up to $1.5 million in year one and $2.5 million in year two in research funding, payable in quarterly installments, over the initial two-year research program to support personnel related expenses, laboratory supplies and equipment to support the discovery efforts. Revenue for development services provided under the agreement is recognized as earned where the Company acts as principal in the transaction. The Company recognized research revenue of $442,000 and $375,000 for the three month period ended March 31, 2011 and 2010, respectively. The research program term expires upon the second anniversary of the agreement and may be extended by BMS for a one-year period with ninety-day notice to the Company and may be further extended by mutual agreement.

Open Biosystems, Inc.

In October 2005, the Company entered into a license and marketing agreement whereby Open Biosystems, Inc. acquired a worldwide royalty-bearing license to certain intellectual property unrelated to the Company's product candidates and Macrocyclic Template Chemistry (MATCH) drug discovery technology, as specified in the agreement. The Company earns royalties on annual net sales at rates that vary by licensed product category as defined in the agreement or, through 2010, minimum annual royalties, if greater than earned royalties, until the expiration date of the last-to-expire licensed patent or twelve years, whichever occurs last. Royalty revenue recognized from the licensing agreement was $64,000 and $47,000 for the three month period ended March 31, 2011 and 2010, respectively.

5. Notes Payable and Other Liabilities

2008 Notes Payable

In December 2008, the Company entered into a loan and security agreement (the 2008 Notes) with two lenders, including the holder of promissory notes issued by the Company in 2006, for a total commitment of $6.3 million, and issued a note in the amount of $3.2 million to each lender. The 2008 Notes carried an interest rate equal to 12.09% per annum, were repayable in monthly installments and were to mature on December 1, 2011. Borrowings were collateralized by all of the assets of the Company excluding intellectual property.

In connection with the 2008 Notes, the Company issued to the two lenders warrants to purchase shares of preferred stock with an aggregate purchase price of $200,000. The warrants are exercisable for Series A Convertible Preferred stock at a price per share of $1.00. The warrants were recorded as a debt discount at estimated fair value of $87,000, which was being amortized as a component of interest expense over the remaining life of the loan. The warrants are exercisable for seven years from the date of issuance and expire on December 3, 2015. The warrants include an automatic conversion feature upon expiration.

The Company recorded total interest expense related to the 2008 Notes of $173,000 during the three month period ended March 31, 2010. No interest expense related to the 2008 Notes was recorded during the three month period ended March 31, 2011.

2010 Notes Payable

On September 30, 2010, the Company entered into a loan and security agreement with two lenders for a total commitment $13.0 million. On October 1, 2010, the parties executed the related note agreements (2010 Notes) and the Company repaid the outstanding principal and interest of $3.4 million on the 2008 Notes. The 2010 Notes bear interest at 10.75% per annum and mature on January 1, 2014. The 2010 Notes are payable initially in nine installments of interest only followed by thirty installments of principal plus interest. In connection with the 2010 loan and security agreement, the Company issued warrants to purchase an aggregate of $520,000 in stock of the Company, which are contingently exercisable for a class and series of shares and exercise price as determined by future events as specified in the agreement. The Company determined the fair value of the warrants to be $254,000 (see Note 7) and recorded the warrant as a liability with a related debt discount to be amortized as interest expense over the term of the 2010 Notes. The Company recognized $410,000 in interest expense for the period ended March 31, 2011 including $20,000 from the amortization of the warrants.

6. Other Comprehensive Loss

Accumulated comprehensive income (loss) consists of the following components for the three months ended March 31, 2011 and 2010:

	Three months ended March 31,	
	2011	2010
Net loss	$ (3,365)	$ (2,708)
Foreign currency translation adjustment	35	346
Total comprehensive loss	$ (3,330)	$ (2,362)

7. Equity Transactions

Warrant Liability

In connection with the 2010 loan and security agreement (see Note 5), the Company issued warrants to purchase an aggregate of $520,000 in capital stock of the Company, which are contingently exercisable for a class and series of shares as determined by future events as specified in the agreement. The 2010 warrants expire in September 2017.

The warrants were valued under the level 3 hierarchy in accordance with ASC 820 as there are significant unobservable inputs. The fair value of the warrants was determined using a probability weighted valuation model. Values were determined for the warrants based on assumptions for each liquidity scenario using a Black-Scholes pricing model and

other methods. These values were discounted back to October 1, 2010 (the issuance date) while applying estimated probabilities to each scenario and associated value on a weighted average basis. These scenarios included a potential initial public offering or potential acquisition at different times throughout 2011 and 2012. Accordingly, the Company determined the fair value of the warrants to be $254,000, which was recorded as a convertible preferred stock warrant liability and related debt discount. Based on the March 31, 2011 valuation, a $195,000 decrease was recognized as other income in the consolidated statements of operations for the the three-month period ended March 31, 2011. Upon the completion of the Company's initial public offering, the liability will be reclassified to stockholders' equity.

Share-based Compensation

During 2001, the Company adopted two equity compensation plans, the Tranzyme 2001 Employee Stock Option Plan and the 2001 Nonemployee Stock Option Plan (the 2001 Plans), which authorized up to 1,000,000 and 445,000 shares of common stock, respectively, for granting both incentive and nonqualified stock options to employees, directors, consultants and other individuals set forth in the 2001 Plans. The exercise price and vesting period of the options issued under the plans were determined by the Company's Board of Directors at the date of grant. Options were to be granted up to 10 years after the 2001 Plans' adoption dates and generally expire 10 years from the date of grant. No further options will be granted under the 2001 Plans.

During 2003, the Company adopted an equity compensation plan, the Tranzyme 2003 Equity Incentive Plan (the 2003 Plan), for eligible employees, directors, consultants and other individuals set forth in the 2003 Plan. The terms of the stock option agreements, including vesting requirements, are determined by the Company's Board of Directors, subject to the provisions of the 2003 Plan. Options granted by the Company generally vest over four years and are exercisable after they have been granted for up to ten years from the date of grant. The exercise price of the incentive stock options must equal at least the fair market value of the stock on the date of grant.

In 2004, Tranzyme Pharma adopted an equity compensation plan, the Tranzyme Pharma 2004 Stock Option Plan (2004 Plan), which authorized shares of Tranzyme Pharma's common exchangeable stock for granting stock options to employees, directors and consultants and other individuals set forth in the 2004 Plan. The terms of the stock option agreements, including vesting requirements, are determined by Tranzyme Pharma's Board of Directors, subject to the provisions of the 2004 Plan. Options granted by the Company generally vest over four years and are exercisable after they have been granted for up to ten years from the date of grant.

As of March 31, 2011, the Company could grant up to 8,001,272 options, collectively, under all of the Company's equity compensation plans, including the 2004 Plan.

The following table summarizes stock option awards and activity in the Company's stock option plans as of March 31, 2011:

	Consolidated Options Outstanding	Weighted Average Exercise Price
Balance at December 31, 2009	751,249	$ 3.57
Options granted during 2010	17,142	8.89
Options exercised during 2010	—	—
Options forfeited during 2010	(9,390)	4.27
Options expired during 2010	(220)	220.50
Balance at December 31, 2010	758,781	$ 3.64
Options granted during the period	—	—
Options exercised during the period	—	—
Options forfeited during the period	(6,250)	5.95
Options expired during the period	—	—
Balance at March 31, 2011	752,531	$ 3.62

The following table summarizes information about the Company's stock options outstanding at:

	March 31, 2011				
	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$1.75 to $2.45	330,912	4.91	$ 1.97	330,912	$ 1.97
$3.78	320,276	6.90	3.78	260,443	3.78
$5.95 to $12.88	101,343	5.09	8.49	81,791	8.48
Total	752,531			673,146	

The aggregate intrinsic value of options outstanding as of March 31, 2011 was $741,000. The aggregate intrinsic value of options exercisable as of December 31, 2010 was $3.6 million. No options were exercised during the three month period ended March 31, 2011. At March 31, 2011 and December 31, 2010, there was approximately $243,000 and $303,000 of total unrecognized compensation costs related to outstanding options granted which is expected to be recognized over a weighted average period of 1.58 and 1.74 years, respectively.

Compensation cost for stock options granted to employees is based on the estimated grant-date fair value and is recognized over the vesting period of the applicable option on a straight-line basis. There were no stock options granted to employees during the three month period ended March 31, 2011.

The Company recognized non-cash share-based compensation expense to employees in its research and development and selling, general and administrative functions as follows:

	Three Months Ending March 31,	
	2011	2010
Research and development	$ 24,000	$ 33,000
General and administrative	36,000	54,000
	$ 60,000	$ 87,000

8. Subsequent Events

On April 6, 2011, the Company completed its IPO of common stock pursuant to a Registration Statement that was declared effective on April 1, 2011. The Company sold 13,500,000 shares of its common stock, at a price of $4.00 per share for an aggregate gross proceeds of $54,000,000. The underwriters had 30 days to exercise their option to purchase up to an additional 1,481,250 shares at the initial public offering price per share pursuant to an over-allotment option granted to the underwriters. The underwriters partially exercised their over-allotment option on April 29, 2011, and purchased an additional 850,000 shares of our common stock for aggregate gross proceeds of $3,400,000.

As a result of the IPO, the Company raised a total of $51.4 million in net proceeds after deducting underwriting discounts and commissions of $4.0 million and estimated offering expenses of $2.0 million. Costs directly associated with the Company's IPO were capitalized and recorded as deferred IPO costs prior to the closing of the IPO. These costs will be recorded as a reduction of the proceeds received in arriving at the amount to be recorded in additional paid-in capital.

Upon the closing of the IPO, 18,395,156 shares of the Company's common and preferred exchangeable shares of the Company's subsidiary Tranzyme Pharma automatically exchanged into a total of 2,627,862 shares of its common stock. In addition, 52,085,690 shares of the Company's outstanding preferred stock automatically converted into a total of 7,440,791 share of its common stock. Also as a result of the IPO, the preferred stock warrant liability will be reclassified to additional paid in capital upon the conversion of warrants to purchase preferred stock into warrants to purchase common stock.

The following table summarizes certain actual balance sheet data and proforma balance sheet data to reflect the activities related to our IPO noted above, as of March 31, 2011 (in thousands):

	March 31, 2011	Proforma March 31, 2011
Cash and cash equivalents	$ 12,479	$ 65,861
Deferred IPO Fees	1,550	—
Preferred stock warrant liability	76	—
Convertible preferred stock	1	—
Common stock	—	—
Additional paid in capital	79,210	131,043
Accumulated deficit	(87,787)	(87,787)
Total stockholders equity (deficit)	$ (9,209)	$ 42,623

On March 3, 2011 the Company's Board of Directors adopted, and shareholders subsequently approved, the 2011 Stock Option Plan, (the "2011 Plan") which authorized the issuance of up to 2,627,945 shares of common stock under the plan. The plan became effective on April 1, 2011.

On April 19, 2011 the Company's Board of directors authorized the issuance of 1,148,030 common stock options from the 2011 Plan to employees and directors of the company at an exercise price of $4.00 per share.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included in our final prospectus dated April 4, 2011 filed with the Securities and Exchange Commission in connection with an initial public offering, as well as the information relating to such audited financial statements contained under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the final prospectus, which includes annual financial statements as of and for the year ended December 31, 2010. In addition to historical information, some of the information contained in this discussion and analysis or set forth elsewhere in this document, including information with respect to our plans and strategy for our clinical programs, business and related financing, contains forward-looking statements that involve risks, uncertainties and assumptions. All statements that express expectations, estimates, forecasts or projections are forward-looking statements. Words such as "expects", "anticipates", "intends", "plans", "believes", "seeks", "estimates", "projects", "forecasts", "may", "should", variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future results and our actual results may differ materially from those anticipated or implied in these forward-looking statements as a result of important factors described in the cautionary statements included in this document, particularly those discussed under the heading "Risk Factors" in Item 1A of Part II of this Quarterly Report on Form 10-Q. We undertake no obligation to revise or update any forward-looking statements, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing novel, first-in-class small molecule therapeutics for the treatment of acute (hospital-based) and chronic GI motility disorders. Our two most advanced product candidates, *ulimorelin* , which is in Phase 3, and TZP-102, which is entering Phase 2b, are being evaluated for the treatment of predominantly upper GI motility disorders. All of our product candidates have been discovered by our scientists using our proprietary chemistry technology platform, MATCH (Macrocyclic Template Chemistry), which enables us to construct synthetic libraries of drug-like, macrocyclic compounds in a predictable and efficient manner. We not only have first-in-class product candidates and a strong drug discovery platform, but also have pursued a licensing strategy with collaborators whose capabilities complement our own. One such regional partnership for *ulimorelin* enables us to retain significant control over development and commercialization of the product candidate, share the development costs and retain a substantial portion of the future long-term value of our product candidate in the United States and certain other major pharmaceutical markets.

We were incorporated in Delaware on January 12, 1998. On December 17, 2003, we entered into a business combination with Neokimia Inc., a Quebec, Canada based chemistry company which now operates under the name Tranzyme Pharma Inc., or Tranzyme Pharma. Tranzyme Pharma is a wholly-owned subsidiary and owns substantially all of our intellectual property and conducts our preclinical research.

We have devoted substantially all of our resources to our drug discovery efforts which consist of research and development activities, clinical trials for our product candidates, the general and administrative support of these operations and intellectual property protection and maintenance. To date, we have funded our operations principally through private placements of our common stock, preferred stock and convertible debt; bank and other lender financings; and through payments received under collaborative licensing arrangements with Norgine B.V., or Norgine, and Bristol-Myers Squibb Company, or BMS, raising an aggregate of approximately $116.0 million. In April 2011, we completed an intial public offering (IPO) of our common stock pursuant to a Registration Statement raising an aggregate of $51.4 million in net proceeds.

We have incurred significant losses since our inception. As of March 31, 2011, our accumulated deficit was approximately $87.8 million. We expect to incur significant operating losses over the next several years as we complete the development of, and seek regulatory approval for, our product candidates and develop other product candidates.

Strategic Partnerships

Norgine, B.V. In June 2010, we entered into a license agreement with Norgine, a leading, GI-focused European specialty pharmaceutical company, to co-develop and commercialize ulimorelin in licensed territories that include Europe, Australia, New Zealand, Middle East, North Africa and South Africa. Under the terms of the agreement, we received a nonrefundable, upfront license fee of $8.0 million. In addition, Norgine purchased 1,047,120 shares of our Series B convertible preferred stock for $1.91 per share, resulting in total net proceeds of approximately $2.0 million.

The agreement contains potential development, regulatory and commercial milestone payments that, if achieved, could provide us with additional cash payments of up to $32.0 million, including the purchase of $1.0 million of additional shares of our capital stock. Upon the achievement of certain milestones, we will issue shares of our common stock at a price per share equal to $1.0 million divided by 110% of the average of the closing bid price of our common stock over the 30-day period ending three days prior to the issuance of these additional shares. In addition, we may receive sales milestone payments of up to approximately $120.0 million and tiered royalties as a percentage of net sales beginning in the low teens escalating up several tiers to the high twenties on sales of any successfully commercialized products within the licensed territory. These tiers are sales-based milestones. The $8.0 million nonrefundable up-front payment is being deferred and recognized on a straight-line basis over 31 months, the estimated period of time of the core development phase of the collaboration. As of March 31, 2011, we have not received any milestone or royalty payments.

Under the agreement, Norgine will share the cost of our Phase 3 clinical trials and the cost of procuring clinical manufacturing supply for the trials. Each party is solely responsible for managing and covering the cost of regulatory filings in its own territories. In addition, each party is solely responsible for the cost of any special studies required for regulatory approval specific to its own territory. Costs for development services provided under the agreement are expensed as incurred. Reimbursement of expenses under this agreement will be offset against costs as incurred. As of March 31, 2011, we have recognized $1.6 million as a reduction in research and development expenses as a result of reimbursement for cost-sharing activities under this agreement including $1.2 million for the three month period ended March 31, 2011.

Bristol-Myers Squibb Company . In December 2009, we entered into a collaboration agreement with BMS to discover, develop and commercialize additional novel compounds discovered using our MATCH technology platform, other than our product candidates and internal programs, against a limited number of targets of interest to BMS. Under the terms of the agreement, BMS is funding our early lead discovery efforts on these targets and is also primarily responsible for optimizing the identified lead compounds. BMS will be solely responsible for preclinical and clinical development of all product candidates arising from the collaboration and, if successful products are developed, for their commercialization globally. As part of the agreement, we received a $10.0 million nonrefundable upfront license fee, and we may receive up to approximately $80.0 million in additional development milestone payments, and $30.0 million in sales milestone payments, for each target program if development and regulatory milestones, or commercial milestones, respectively, are achieved. In addition, we would receive single-digit percentage royalties and sales milestone payments on sales of successful products. The $10.0 million nonrefundable upfront license fee is being deferred and recognized on a straight-line basis

over thirty months, the estimated initial research and collaboration period of the agreement. As of March 31, 2011, we have not received any milestone or royalty payments, and we are not certain when we will be eligible for such payments in the future.

The agreement with BMS provides for reimbursement of costs of up to $1.5 million in year one and $2.5 million in year two, payable in quarterly installments, to support collaboration related personnel expenses, laboratory supplies and equipment, with additional funding available for certain other research program expenses. The collaboration agreement may be extended by BMS for a one-year period with ninety day notice to us and may be further extended by mutual agreement. As of March 31, 2011, we have recognized $2.9 million of revenue for reimbursement of research costs under this agreement including $442,000 for the three month period ended March 31, 2011.

Open Biosystems, Inc . In October 2005, we entered into a license and marketing agreement whereby Open Biosystems, Inc. acquired a worldwide royalty-bearing license to certain of our intellectual property unrelated to our product candidates and MATCH drug discovery technology. The agreement provides for royalty revenue on annual net sales at rates ranging from mid-single digits to 20 percent based on sales by licensed product category or, through 2010, minimum annual royalties if greater than earned, until the expiration date of the last-to-expire licensed patent or 12 years, whichever occurs last. We have recognized $1.4 million of royalty revenue from this agreement through March 31, 2011, including $64,000 for the three month period ended March 31, 2011.

Financial Operations Overview

Revenues

Our revenue consists primarily of licensing and royalty revenue as well as research revenue, which consists of fees for research services from license or collaboration agreements. The upfront licensing fees received pursuant to our license agreements are deferred and are being recognized in licensing and royalty revenue on a straight-line basis over a period which represents the estimated period of time over which our involvement in the collaboration represents a substantive performance obligation. These fees under our collaboration agreement with BMS and license agreement with Norgine are being recognized over 30 and 31 month periods, respectively. Revenue for research services provided under our collaboration agreement with BMS is recognized in research revenue as such services are performed. Royalty revenue from our agreement with Open Biosystems, Inc. is recognized in licensing and royalty revenue as applicable products are sold.

We expect our future revenues to increase from historical levels as a result of the deferral and subsequent amortization of the upfront payments received under the collaboration agreement with BMS and the Norgine license agreement and research service revenue being recognized for the collaboration agreement with BMS. In addition, our revenue will increase if we achieve development, regulatory and commercial milestones as specified in these agreements.

In the future, we may generate revenue from product sales, upfront licensing fees and milestone payments from collaborations, and royalties from the sale of products commercialized under licenses of our intellectual property. We do not expect to generate any significant revenue unless or until we commercialize our product candidates or reach milestones contained in our collaboration agreements. We expect that our revenue will fluctuate from quarter to quarter as a result of the timing and amount of licensing and milestone payments received, research and development reimbursements for collaborative agreements, and other payments received from partnerships. If we or our strategic partners fail to complete the development of our drug candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue from product sales and milestones payments or royalties from product sales may adversely affect our results of operations and financial position.

Research and Development

We expense research and development costs as they are incurred. Research and development expenses consist of expenses incurred in the discovery and development of our product candidates, and primarily include:

- expenses, including salaries, benefits and non-cash share-based compensation expenses for research and development personnel;
- expenses incurred under third party agreements with contract research organizations, or CROs, investigative sites and consultants in conducting clinical trials;
- costs of acquiring and manufacturing clinical trial supplies;
- costs associated with our discovery efforts and preclinical activities;
- costs associated with non-clinical activities and regulatory approvals; and
- costs associated with the maintenance and protection of our intellectual property.

Direct development expenses and certain indirect overhead expenses associated with our research and development activities are allocated to our product candidates. The allocation of indirect overhead is based on management's estimate of the use of such resources on a program-by-program basis. Indirect costs related to our research and development activities that are not allocated to a product candidate, including salaries and benefits for our clinical development personnel, and costs associated with the development of our preclinical product candidates are included in "Other research and development" in the table below.

The following table presents our research and development expenses for the periods indicated (in thousands):

	Three Months Ending March 31,	
	2011	2010
ulimorelin	$ 2,330	$ 100
TZP-102	587	1,387
Other research and development expenses	1,584	1,459
	$ 4,501	$ 2,946

We expect our research and development expenses to increase as we advance into later-stage development of our product candidates. We expect to fund our research and development expenses from our current cash and cash equivalents, a portion of the net proceeds from our initial public offering, milestones and cost-sharing reimbursement payments received from collaboration agreements, if any, and potentially, additional financing transactions or collaboration arrangements.

At this time, we cannot reasonably estimate or know the nature, specific timing and estimated costs of the efforts that will be necessary to complete the development of our product candidates, or the period, if any, in which material net cash inflows may commence from our product candidates. This is due to the numerous risks and uncertainties associated with developing our product candidates, including:

- the progress, costs, results of and timing of our two Phase 3 clinical trials of *ulimorelin* for the management of postoperative ileus (POI) following partial bowel resection surgery;
- the need for, and the progress, costs and results of, any additional Phase 3 clinical trials of *ulimorelin* we may initiate based on the results of our clinical trials or our discussions with regulatory agencies, including any additional trials the FDA, EMA or other regulatory agencies may require evaluating the safety of *ulimorelin;*
- the initiation, progress, costs, results of and timing of our planned Phase 2b clinical trial of TZP-102 for treatment of diabetic gastroparesis and future clinical trials of TZP-102;
- the costs and timing of obtaining regulatory approval in the United States and abroad for our product candidates;

- the FDA's willingness to review our TZP-102 application under the fast track development program;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights globally;
- the costs and timing of obtaining or maintaining manufacturing for our product candidates, including commercial manufacturing if any of our product candidates is approved;
- the costs and timing of establishing sales and marketing capabilities in selected markets; and
- the terms and timing of establishing collaborations, license agreements and other partnerships on terms favorable to us.

Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements provide a fixed fee or unit price for services performed. Payments under the contracts depend on factors such as the successful enrollment of patients or the achievement of clinical trial milestones. Expenses related to clinical trials generally are accrued based on services performed at contractual amounts and the achievement of milestones such as number of patients enrolled. If timelines or contracts are modified based upon changes to the clinical trial design or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

A change in the outcome of any of these variables with respect to the development of a product candidate could result in a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative

General and administrative expenses consist primarily of compensation for employees in executive and administrative functions including non-cash, share-based compensation expense, costs associated with our corporate infrastructure, and professional fees for business development, market research, accounting and legal services.

We anticipate that our general and administrative expenses will continue to increase primarily for the following reasons:

- increased expenses for sales and marketing activities in preparing for commercial launch of our product candidates prior to regulatory approval;
- increased administrative personnel related expenses required to support our growth as we continue to develop our product candidates; and
- increased costs of operating as a public company including costs associated with regulatory compliance, corporate governance, insurance and consulting fees for our legal, accounting and investor relations activities.

Other Income (Expense), Net

Interest income consists of interest earned on our cash and cash equivalents. We expect our interest income to increase as we invest the net proceeds from our initial public offering pending their use in our operations.

Interest expense to date has consisted primarily of interest expense on convertible shareholder notes payable and long-term debt and the amortization of debt discounts and debt issuance costs. We amortize debt issuance costs over the life of the notes which are reported as interest expense in our statements of operations.

Other income and expense, to date has primarily consisted of costs incurred from extinguishment of debt, changes in the fair value of our warrant liability and gains and losses on foreign currency transactions primarily from purchases made by Tranzyme Pharma.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to preclinical, nonclinical and clinical development costs and drug manufacturing costs. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity within Note 1 to our financial statements in our Registration Statement on Form S-1 (File No. 333-170749). There have been no material changes to our critical accounting policies and estimates as disclosed in our Registration Statement on Form S-1 (File No. 333-170749).

Results of Operations

Comparison of the Three Months Ended March 31, 2011 and 2010

Revenues

The following table summarizes our revenues for the three months ended March 31, 2011 and 2010 (in thousands, except percentages):

	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2011	2010		
Licensing and royalties	$ 1,897	$ 1,047	$ 850	81%
Research revenue	442	375	67	18%
Total	$ 2,339	$ 1,422	$ 917	64%

Total revenues increased for the three months ended March 31, 2011 primarily due to the amortization of deferred revenue from the upfront licensing fee received from our collaboration agreement with Norgine, which totaled $823,000 for the three month period ended March 31, 2011.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2011 and 2010 (in thousands, except percentages):

	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2011	2010		
Research and development expenses	$ 4,501	$ 2,946	$ 1,555	53%

During the three months ended March 31, 2011, our research and development costs related primarily to the initiation of our Phase 3 clinical trials for *ulimorelin* for which the first patients were dosed in February of 2011. Costs related to these *ulimorelin* activities resulted in an increase in clinical trial expenses of approximately $2.2 million. This increase was offset by a decrease of approximately $800,000 in Phase 2 clinical trial costs for TZP-102 which completed enrollment in April 2010.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2011 and 2010 (in thousands, except percentages):

	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2011	2010		
General and administrative	$ 971	$ 847	$ 124	15%

The increase in general and administrative expenses was due primarily to the timing of expenses incurred for our year-end financial audit and other consulting fees related to our corporate governance activities.

Other Income, (Expense) Net

The following table summarizes our other income (expense) for the three months ended March 31, 2011 and 2010 (in thousands, except percentages):

	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2011	2010		
Interest income	$ 5	$ 11	$ (6)	(55)%
Interest expense	(425)	(390)	(35)	9%
Other income	188	41	147	359%
Total	$ (232)	$ (338)	$ 106	(31)%

The increase in interest expense for the period was primarily due to an increase in interest expense for our notes payable. The increase in other income for the period was primarily due to a $195,000 decrease in the fair value of our warrant liability which was recognized as other income for the three month period ended March 31, 2011.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses since our inception and we anticipate that we will continue to incur losses for at least the next several years. Historically, we have financed our operations primarily through private placements of common stock and convertible preferred stock, issuance of convertible promissory notes to our shareholders, upfront payments from strategic partnerships, bank and other lender financing and development grants from governmental authorities. As of March 31, 2011, we had $12.5 million in cash and cash equivalents. Cash in excess of immediate requirements is invested in accordance with our investment policy primarily with a view to liquidity and capital preservation. As of March 31, 2011 our cash and cash equivalents funds are invested in money market funds which are currently providing only a minimal return.

On April 6, 2011, the Company completed its IPO of common stock pursuant to a Registration Statement that was declared effective on April 1, 2011. The Company sold 13,500,000 shares of its

common stock, at a price to the public of $4.00 per share. The underwriters had 30 days to exercise their option to purchase up to an additional 1,481,250 shares at the initial public offering price per share pursuant to an over-allotment option granted to the underwriters. On April 29, 2011, the underwriters partially exercised their over-allotment option and purchased an additional 850,000 shares of our common stock for an aggregate gross proceeds of $3,400,000.

We raised approximately $51.4 million in net proceeds from the IPO after deducting underwriting discounts and commissions of $4.0 million and estimated offering expenses of $2.0 million after giving effect to the partial exercise of the underwriters' over-allotment option.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods presented:

	Three Months Ended March 31,		Increase (Decrease)
	2011	2010	
Cash Flow from Continuing Operations **:**			
Net cash used in operating activities	$ (4,414)	$ (4,157)	$ 257
Net cash used in investing activities	(11)	(253)	(242)
Net cash used in financing activities	(483)	(587)	(104)
Effect of exchange rate changes on cash	14	344	330
Net (decrease) in cash an cash equivalents	$ (4,894)	$ (4,653)	$ 241

During the three months ended March 31, 2011 and 2010 our operating activities used cash of $4.4 million and $4.2 million, respectively, primarily reflected our net losses and changes in working capital, partially offset by non-cash charges including depreciation expense, share-based compensation expense and the amortization of deferred revenue from our licensing agreements. The increase in cash used in operations during the three months ended March 31, 2011 as compared to the three months ended March 31, 2010 was primarily due to Phase 3 clinical trial activities for *ulimorelin* which was partially offset by a decrease in Phase 2 clinical trial activities for TZP-102.

During the three months ended March 31, 2011 and 2010, our investing activities used cash to purchase laboratory and other equipment to support our research and development activities. During the three months ended March 31, 2011, financing activities used cash of $483,000 which was primarily related to expenses incurred for our initial public offering. During the three months ended March 31, 2010, financing activities used cash of $587,000 which was primarily related to principal payments on our notes payable.

Credit Facilities

On September 30, 2010, we entered into a term loan and security agreement with Oxford Finance Corporation and Compass Horizon Funding Company for $13.0 million. The loan bears interest at an annual interest rate of 10.75% and is secured by our assets, excluding our intellectual property. The loan matures on January 1, 2014 and requires interest only payments for the first nine months and principal and interest payments for the following 30 months. Upon payment of the final monthly installment of the loan, or the remaining balance in the case of a prepayment, we will also pay an end-of-term fee of approximately $520,000. In addition, in the event of prepayment we will pay a prepayment fee ranging from 6% to 1%, based on time to maturity, of the principal amount of the loan at the time of repayment. As of March 31, 2011, $13.0 million of principal remains outstanding on the loan.

The loan and security agreement also contains certain covenants, including limitations on our ability to transfer assets, engage in any change of control transaction, incur additional indebtedness, pay dividends, make investments and engage in transactions with affiliates. Upon an event of default, the lenders may declare the unpaid principal amount of all outstanding loans and interest accrued under the loan and security agreement to be immediately due and payable, and

exercise their security interests and other rights under the credit agreement. As of March 31, 2011, we were in compliance with the covenants under our loan and security agreement.

Capital Resources and Funding Requirements

We expect to continue to incur substantial operating losses in the future and that our operating expenses will increase as we continue developing our product candidates and begin to operate as a public company. We will require substantial amounts of capital in the future for clinical trials and regulatory and commercialization activities for our products.

Our IPO of common stock was effected through a Registration Statement on Form S-1 (File No. 333-170749) that was declared effective by the SEC on April 1, 2011, which registered an aggregate of 13,500,000 shares of our common stock at an aggregate gross offering price to the public of $54,000,000. All of the 13,500,000 shares of common stock registered under the Registration Statement were sold at a price to the public of $4.00 per share. The offering closed on April 6, 2011. The underwriters partially exercised their over-allotment option on April 29, 2011, and purchased an additional 850,000 shares of our common stock for aggregate gross proceeds of $3,400,000.

Net proceeds received were approximately $51.4 million, after underwriting fees and estimated offering expenses of approximately $6.0 million. Costs directly associated with our IPO were capitalized and recorded as deferred IPO costs prior to the closing of the IPO. These costs will be recorded as a reduction of the proceeds received in arriving at the amount to be recorded in additional paid-in capital.

We believe that our existing cash and cash equivalents, together with the net proceeds received from our IPO, will be sufficient to fund our anticipated operating requirements for at least the next 24 months. We have based this estimate on assumptions that may prove to be wrong resulting in the use of our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, including our ability to enter into collaborations with third parties to participate in development and commercialization of our product candidates, we are unable to estimate the amount of increased capital required to become profitable. Our future funding requirements will depend on many factors, including:

- the scope, progress and results of our clinical trials for *ulimorelin* and TZP-102;
- the costs and timing involved in obtaining regulatory approvals for our product candidates;
- the market acceptance of our product candidates, if approved, and related success in commercializing and generating sales from our product candidates if approved by the regulatory authorities;
- the costs of developing manufacturing capabilities to support our commercialization activities;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the number and characteristics of product candidates that we pursue;
- the timing and amount of payments received under new or existing strategic collaboration agreements, if any, including upfront payments, milestone payments and royalties;
- the amount of cost sharing under new or existing strategic collaboration agreements, if any;
- our ability to hire qualified employees at salary levels consistent with our estimates to support our growth and development, including additional general and administrative personnel as a result of becoming a public company; and
- the costs of developing our anticipated internal sales, marketing and distribution capabilities.

Until we obtain regulatory approval to market our product candidates, if ever, we cannot generate revenues from sales of our products. Even if we are able to sell our products, we may not generate a sufficient amount of product revenues to finance our cash requirements. Accordingly, we may need to obtain additional financing in the future which may include public or private debt and equity financings, entering into product and technology collaboration agreements or licenses and asset sales. There can be no assurance that additional capital will be available when needed on acceptable terms, or at all. The issuance of equity securities may result in dilution to stockholders. If we raise additional funds through the issuance of debt securities, these securities may have rights, preferences and privileges senior to those of our common stock and the terms of the debt securities could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities, which would have a material adverse impact on our business prospects and results of operations.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

Occasionally, new accounting standards are issued or proposed by the Financial Accounting Standards Board, or FASB, or other standards-setting bodies that we adopt by the effective date specified within the standard. Unless otherwise discussed, standards that do not require adoption until a future date are not expected to have a material impact on our financial statements upon adoption.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Foreign Currency Risk

We incur a substantial amount of our research and development expenses through our Canadian subsidiary. In addition, we contract with third-party providers to manufacture product and to conduct clinical trials and perform other research and development activities in Europe. Accordingly, we are exposed to fluctuations in foreign currency exchange rates in connection with the liabilities incurred by us in these relationships. Pursuant to the terms of a strategic collaboration agreement we entered into in June 2010 with Norgine, the calculation of certain milestone payments and royalty payments, when earned, may be impacted by fluctuations in foreign exchange rates thereby impacting the amount of revenue we ultimately recognize from these payments. In addition, product revenues, if any, are expected to be generated from worldwide sales in various currencies. We do not currently hedge our exposures to foreign currency fluctuations.

Market Risk

Our cash and cash equivalents as of March 31, 2011 consisted primarily of cash and money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of United States interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations.

Interest Risk

The interest rates on our notes payable are fixed. Therefore, we are not exposed to market risk from changes in interest rates as it relates to these interest-bearing obligations.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, including our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes to Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) under the Exchange Act) during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

The following risks and uncertainties, together with all other information in this Quarterly Report on Form 10-Q, including our consolidated financial statements and related notes, should be considered carefully. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations, and could cause the market price of our common stock to fluctuate or decline.

Risks Related to the Development, Regulatory Approval and Commercialization of our Product Candidates

Our near-term success is largely dependent on the success of our clinical stage product candidates, ulimorelin, for which we have initiated two Phase 3 clinical trials and TZP-102, which is entering Phase 2b clinical development. Our other product candidates are in the preclinical research stage. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, any of our product candidates.

We have invested, and expect to continue to invest, a significant portion of our time and financial resources in the development of our clinical stage product candidates, *ulimorelin* for the management of postoperative ileus, or POI, and TZP-102 for the treatment of diabetic gastroparesis. We have also invested a significant amount of time and financial resources in the development of our other drug candidates, TZP-201 and TZP-301. We anticipate that our success will depend largely on the receipt of regulatory approval and successful commercialization of these product candidates, particularly our clinical stage product candidates *ulimorelin* and TZP-102. The future regulatory and commercial success of these product candidates is subject to a number of risks, including the following:

- we may not be able to provide acceptable evidence of their safety and efficacy;
- the results of our ongoing and planned clinical trials may not confirm the positive results of earlier clinical trials;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA, EMA or other regulatory agencies for marketing approval;

- the dosing of our product candidate in a particular clinical trial may not be at an optimal level;
- our ability to demonstrate clinically meaningful results for *ulimorelin* in our Phase 3 trials may be more difficult now than when we conducted our Phase 2 trials in 2007 and 2008 due to better placebo performance, which may be attributable to improvements in the overall care of patients in acute care settings;
- patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- competing products may be approved for marketing by the FDA and EMA and any other similar foreign regulatory authorities;
- we may not be able to obtain, maintain and enforce our patents and other intellectual property rights; and
- we may not be able to obtain and maintain commercial manufacturing arrangements with third-party manufacturers or establish commercial-scale manufacturing capabilities.

Of the large number of drugs in development, only a small percentage result in the submission of a new drug application, or NDA, to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market a commercial product, any such approval may be subject to limitations on the indicated uses for which we may market the product.

Favorable results in our Phase 2 clinical trial of ulimorelin for the management of POI may not be predictive of the safety and efficacy results in our Phase 3 clinical trials of ulimorelin for the management of POI following partial bowel resection surgery.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in earlier-stage development. Our Phase 2 clinical trial of *ulimorelin* for the management of POI showed statistically significant results against clinically meaningful endpoints; however, we will not have the same primary endpoints in our Phase 3 clinical trials. In our Phase 2 trial, the primary endpoint was time to recovery of gastrointestinal, or GI, function based on first bowel movement, or BM, but the primary endpoint for our Phase 3 trials is GI2, which is the later of time to BM and tolerance of solid food. Although we observed statistically significant improvement in GI2 in our Phase 2 trial, we cannot assure you that our Phase 3 trials will achieve positive results. A number of factors could contribute to a lack of favorable safety and efficacy results in our Phase 3 trials. For example:

- a multinational, multicenter trial could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique;
- a multinational, multicenter trial could result in increased variability due to varying patient characteristics including demographic factors and health status; and
- mix of surgery types may be different from the prior clinical trial.

Favorable results in our Phase 2 clinical trial of TZP-102 for the treatment of diabetic gastroparesis may not be predictive of the safety and efficacy results in our planned Phase 2b clinical trial of TZP-102 for the treatment of diabetic gastroparesis.

Although our proof of concept Phase 2 clinical trial of TZP-102 for the treatment of diabetic gastroparesis showed statistically significant results against clinically meaningful endpoints, we will not have the same primary endpoints or reporting instrument in our planned Phase 2b clinical trial. The primary endpoint for our Phase 2 trial was the change from baseline in gastric emptying time; however, the primary endpoint for our Phase 2b trial will be, based upon our meeting with the FDA in November 2010, a composite of clinically relevant, patient-reported symptoms measured by a reporting instrument with a shorter recall period. While we observed statistically significant improvements in these clinically relevant symptoms in our Phase 2 trial, we cannot assure you that our Phase 2b trial will achieve positive results. A

number of factors could contribute to a lack of favorable safety and efficacy results in our planned Phase 2b clinical trial. For example:

- a multinational, multicenter trial could result in increased variability due to varying patient characteristics including demographic factors, health status, underlying reason for disease state and concomitant medications; and
- an extended length of treatment period could results in changes in safety and efficacy results.

Our ability to demonstrate clinically meaningful results for ulimorelin in our Phase 3 trials may be more difficult now than when we conducted our Phase 2 trials in 2007 and 2008 due to better placebo performance, which may be attributable to improvements in the overall care of patients in acute care settings.

Over the past several years, postoperative measures such as early mobilization, early feeding and removal of the nasogastric tube, without any additional pharmacological interventions, have contributed to improved recovery of GI motility in patients that undergo bowel resection surgery. Our Phase 2 trial of *ulimorelin* in POI incorporated these enhanced recovery measures. Although the protocols for our Phase 3 trials of *ulimorelin* also incorporate these enhanced recovery measures, additional measures may be implemented by some of the investigational sites that could further accelerate GI recovery in the placebo treated group. If we are unable to demonstrate clinically meaningful results, we may have difficulty receiving the regulatory approval necessary to commercialize *ulimorelin* .

If we are not able to obtain required regulatory approvals for ulimorelin, TZP-102 or our other product candidates, we will not be able to commercialize them and our ability to generate revenue will be limited.

We have not submitted an NDA or received regulatory approval to market any of our product candidates in any jurisdiction. We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party contract research organizations to assist us in this process. Securing FDA approval requires the submission of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish each product candidate's safety and efficacy. Our product candidates, and any future product candidates, may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. We are not permitted to market *ulimorelin* , TZP-102, TZP-201 or TZP-301 in the United States until we receive approval of an NDA for the product candidate in a particular indication from the FDA. Failure to obtain regulatory marketing approval for a product candidate will prevent us from commercializing the product candidate, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application, may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval.

We have completed three Phase 2 trials for *ulimorelin* : two in patients with diabetic gastroparesis and one in patients undergoing partial bowel resection. We have begun dosing in two Phase 3 trials in patients undergoing partial bowel resection. We recently completed a Phase 2, double-blind, placebo-controlled trial in 92 subjects which evaluated TZP-102 in diabetic patients with gastroparesis over a 28-day period. We are currently planning to initiate a Phase 2b trial in diabetic gastroparesis patients in 2011. We cannot guarantee that our future trials will be successful or that regulators will agree with our assessment of the preclinical studies and clinical trials we have conducted to date. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or preclinical or other studies. In

addition, varying interpretation of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable.

Even if we receive regulatory approval for one of our product candidates, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, will be limited.

The commercial success of any product candidate for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of such product by the medical community, including physicians, patients and health care payors. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy compared to other products;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse effects;
- limitations or warnings contained in a product's FDA-approved labeling;
- availability of alternative treatments, including, *metoclopramide* , *erythromycin* , *domperidone* and *alvimopan* and any new products that may in the future become available to treat indications for which *ulimorelin* or TZP-102 may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. In addition, our ability to successfully commercialize our product candidates will depend on our ability to manufacture our products, differentiate our products from competing products and defend the intellectual property of our products.

It will be difficult for us to profitably sell any of our product candidates if reimbursement is limited.

Market acceptance and sales of our product candidates will depend on reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors have been challenging the prices charged for products. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted marketing approval. This trend may impact the reimbursement for treatments for GI disorders especially, as physicians typically focus on symptoms rather than underlying conditions when treating patients with these disorders and drugs are often prescribed for uses outside of their approved indications. In instances where alternative products are available, it may be required that those alternative treatment

options are tried before reimbursement is available for our products. We cannot be sure that reimbursement will be available for our product candidates and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. In addition, in certain foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize our product candidates.

We have no sales, marketing or distribution experience and we will have to invest significant resources to develop those capabilities.

We have no sales, marketing or distribution experience. To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that *ulimorelin* , TZP-102 or any other of our product candidates will be approved. For product candidates where we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- we may not be able to attract and build an effective marketing or sales force;
- the cost of establishing a marketing or sales force may exceed the revenues generated by any products; and
- our direct sales and marketing efforts may not be successful.

We have entered into an agreement with Norgine B.V., or Norgine, to assist in the development and commercialization of *ulimorelin* outside the United States, if approved, and may elect to seek other strategic partners for our products. We may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties.

Recent federal legislation and actions by state and local governments may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results and our overall financial condition.

We may face competition in the United States for our product candidates, if approved, from lower priced products from foreign countries that have placed price controls on pharmaceutical products. This risk may be particularly applicable to drugs such as TZP-102 that are formulated for oral delivery and expected to command a premium price. The U.S. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, contains provisions that may change U.S. importation laws and expand pharmacists' and wholesalers' ability to import lower priced versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. The Secretary of Health and Human Services has not yet announced any plans to make this required certification.

A number of federal legislative proposals have been made to implement the changes to the U.S. importation laws without any certification, and to broaden permissible imports in other ways. Even if the changes do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, U.S. Customs and Border Protection and other government agencies. For example, the Department of Homeland Security Appropriations Act, 2010, expressly prohibits U.S. Customs and Border Protection from using funds to prevent individuals from importing from Canada less than a 90-day supply of a prescription drug for personal use, when the drug otherwise complies with the Federal Food, Drug, and Cosmetic Act, or FDCA. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts.

The importation of foreign products that compete with any of our product candidates for which we obtain marketing approval could negatively impact our revenue and profitability, possibly materially.

We rely and will continue to rely on outsourcing arrangements for certain of our activities, including clinical research of our product candidates and manufacturing of the compounds and product candidates.

We rely on outsourcing arrangements for some of our activities, including manufacturing, preclinical and clinical research, data collection and analysis. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We do not own or operate manufacturing facilities for the production of any of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, drug substance and drug product for our preclinical research and clinical trials.

We do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates and the current manufacturer of *ulimorelin* , our most advanced product candidate, may not have the capacity to serve commercial demand. If any of our product candidates are approved for sale by any regulatory agency, we intend to enter into agreements with third-party contract manufacturers for the commercial production of those products. The number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture bulk drug substance on a commercial scale is limited.

In addition, our reliance on third party contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, entails further risks including, but not limited to:

- non-compliance by third parties with regulatory and quality control standards;
- breach by third parties of our agreements with them;
- termination or non-renewal of an agreement with third parties; and
- sanctions imposed by regulatory authorities if compounds supplied or manufactured by a third party supplier or manufacturer fail to comply with applicable regulatory standards.

If any of our current strategic partners fails to perform its obligations or terminates its agreement with us, the development and commercialization of the product candidates under such agreement could be delayed or terminated and our business could be substantially harmed.

We currently have strategic partnerships in place relating to certain of our product candidates and technologies. We entered into a license agreement with Norgine regarding the development and commercialization of *ulimorelin* for the potential management of POI and other diseases and disorders in Europe, Australia, New Zealand, Middle East, North Africa and South Africa. We entered into a strategic collaboration with Bristol-Myers Squibb Company, or BMS, primarily focused on the identification and optimization of novel drug compounds for certain targets of interest to BMS. These strategic partnerships may not be scientifically or commercially successful due to a number of important factors, including the following:

- BMS and Norgine have significant discretion in determining the efforts and resources that each will apply to their strategic relationship with us. The timing and amount of any cash payments, milestones and royalties that we may receive under such agreements will depend on, among other things, the efforts, allocation of resources and successful development and commercialization of our product candidates by BMS and Norgine under their respective agreements.
- Our agreement with BMS provides it with wide discretion in deciding which novel compounds to advance through the clinical development process. It is possible for BMS to reject certain compounds at any point in the research, development and clinical trial process without triggering a termination of their agreement with us. In the event of any such decision, our business and prospects may be adversely affected due to our inability to progress such compounds ourselves.
- BMS or Norgine may develop and commercialize, either alone or with others, or be acquired by

a company that has, products that are similar to or competitive with the product candidates that they license from us.

- BMS or Norgine may change the focus of their development and commercialization efforts or pursue higher-priority programs.

- BMS or Norgine may, under specified circumstances, terminate their strategic partnership with us on short notice and for circumstances outside of our control, which could make it difficult for us to attract new strategic partners or adversely affect how we are perceived in the scientific and financial communities.

- BMS and Norgine have, under certain circumstances, the first right to maintain or defend our intellectual property rights licensed to them, and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our strategic partners do not, our ability to do so may be compromised by our strategic partners' acts or omissions.

- BMS or Norgine may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability.

- BMS or Norgine may not comply with all applicable regulatory requirements, or fail to report safety data in accordance with all applicable regulatory requirements.

If either BMS or Norgine fails to develop or effectively commercialize novel compounds or *ulimorelin* , respectively, for any of the foregoing reasons, we may not be able to replace the strategic partner with another partner. We may also be unable to obtain, on terms acceptable to us, a license from such strategic partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize a product candidate. Any of these events could have a material adverse effect on our business, results of operations and our ability to achieve future profitability, and could cause our stock price to decline.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

A variety of risks associated with our planned international business relationships could materially adversely affect our business.

We have entered into an agreement with Norgine for the development of *ulimorelin* , and we may enter into agreements with other third parties for the development and commercialization of *ulimorelin* or our other product candidates, in international markets. International business relationships subject us to additional risks, including:

- differing regulatory requirements for drug approvals in foreign countries;

- potentially reduced protection for intellectual property rights;

- potential third party patent rights in foreign countries;

- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market, with low or lower

prices, rather than buying them locally;

- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks of international business relationships may materially adversely affect our ability to attain or sustain profitable operations.

We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.

Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of product candidates. Our objective is to design, develop and commercialize new products with superior efficacy, convenience, tolerability or safety. We expect any product candidate that we commercialize with our strategic partners or on our own will compete with existing, market-leading products. For example, we anticipate that *ulimorelin* , if approved for the management of POI, and TZP-102, if approved for the treatment of diabetic gastroparesis, would compete directly with *metoclopramide* , *erythromycin* , *domperidone* and *alvimopan* , each of which is available under various trade names sold by several major pharmaceutical companies.

Many of our potential competitors have substantially greater financial, technical and personnel resources than we have. In addition, many of these competitors have significantly greater commercial infrastructures than we have. We will not be able to compete successfully unless we successfully:

- design and develop products that are superior to other products in the market;
- attract qualified scientific, medical, sales and marketing and commercial personnel;
- obtain patent and/or other proprietary protection for our processes and product candidates;
- obtain required regulatory approvals; and
- collaborate with others in the design, development and commercialization of new products.

Established competitors may invest heavily to quickly discover and develop novel compounds that could make our product candidates obsolete. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials 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 are highly dependent upon our senior management, as well as other senior scientists and members of our management team. The loss of services of any of these individuals or one or more of our other members of senior management could delay or prevent the successful development of our product pipeline, completion of our ongoing or planned clinical trials or the commercialization of our product candidates. We do not have employment agreements with any members of our senior management other than Vipin Garg, our President and Chief Executive Officer. We carry "key person" insurance only on our President and Chief Executive Officer.

We need to hire and retain qualified personnel for the development, manufacture and commercialization of drugs. We could experience problems in the future attracting and retaining qualified employees. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. 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 who have the expertise we need to sustain and grow our business.

If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time we have considered, and we will continue to consider in the future, strategic business initiatives intended to further the development of our business. These initiatives may include acquiring businesses, technologies or products or entering into a business combination with another company. If we do pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources in integrating new businesses, technologies and products;
- assume substantial actual or contingent liabilities;
- reprioritize our development programs and even cease development and commercialization of our product candidates; or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company or a combination of both on terms that certain of our stockholders may not deem desirable.

Although we intend to evaluate and consider acquisitions, reorganizations and business combinations in the future, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

Risks Related to Marketing Approval and Other Government Regulations

The FDA may impose requirements on our clinical trials that are difficult to comply with, which could harm our business.

The requirements that the FDA may impose on clinical trials for our product candidates are uncertain. As a result, we cannot assure you that we will be able to comply with such requirements. For example, the FDA may require endpoints in our late-stage clinical trials that are different from or in addition to the endpoints in our early-stage clinical trials or the endpoints which we may propose. The endpoints or other trial elements, including sample size, dose selection and level at which clinical meaningfulness is achieved, that the FDA requires may make it less likely that our Phase 3 clinical trials are successful or may delay completion of the trials. If we are unable to comply with the FDA's requirements, we will not be able to get approval for our product candidates and our business will suffer.

Any termination or suspension of, or delays in the commencement or completion of, clinical testing of our product candidates could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical trials will begin on time or planned or ongoing trials will be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA failing to grant permission to proceed and placing the clinical trial on hold;
- the FDA's willingness to review our TZP-102 application under the fast track development program;
- subjects failing to enroll or remain in our trials at the rate we expect;
- a facility manufacturing our product candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of current Good Manufacturing Practices, or cGMP, or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing our product candidates, or participating in competing clinical trials;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports from preclinical or clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, Good Clinical Practice and regulatory requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or institutional review boards, or IRBs, finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire trial, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications; or
- one or more IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial.

Product development costs will increase if we have delays in testing or approval of our product candidates or if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical trial sites suspend or terminate any of our clinical trials, the commercial prospects for our product candidate may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Also if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced.

Final marketing approval of our product candidates by the FDA or other regulatory authorities for commercial use may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

After the completion of our clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates and we cannot, therefore, predict the timing of any future revenue from these product candidates. *Ulimorelin* and TZP-102 are ghrelin receptor agonists. There are no FDA-approved ghrelin receptor agonists and the adverse effects from long-term exposure to this drug class are unknown.

We cannot commercialize any of our product candidates until the appropriate regulatory authorities have reviewed and approved the applications for the product candidates. We cannot assure you that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for any product candidate we develop. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

If marketing approval for our product candidates is delayed, limited or denied, our ability to market products, and our ability to generate product sales, would be adversely affected.

Any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance or clinical trials. Our product candidates will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements or applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of product, or request us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

The FDA has the authority to require a risk evaluation and mitigation strategy plan as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry.

In addition, if any of our product candidates are approved, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for our product candidates, physicians may nevertheless prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any of our product candidates for which we obtain marketing approval.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the MMA changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

More recently, in March 2010, President Obama signed into law the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. We will not

know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we are subject to additional regulatory burdens and other risks and uncertainties. However, we have limited experience marketing and servicing our products outside North America.

Our future profitability will depend, in part, on our ability to grow and ultimately maintain our sales in foreign markets. We rely on third parties, such as Norgine, to support our foreign operations.

Our foreign operations and any foreign operations we establish in the future subject us to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for procedures using our products in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties who may not put the same priority on our products as we would;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our products could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs and difficulties in staffing and managing foreign operations.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include false claims statutes and anti-kickback statutes. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item

or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

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

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 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 product candidates. Even 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 product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical trials in the amount of $5 million in the aggregate. 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. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may 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.

Risks Relating to Our Intellectual Property

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

We place considerable importance on obtaining patent protection for new technologies, products and processes because our commercial success will depend, in part, on obtaining patent protection for new technologies, products and processes, successfully defending these patents against third-party challenges and successfully enforcing our patents against third party competitors. To that end, we file applications for patents covering compositions of matter or uses of our product candidates or our proprietary processes as well as other intellectual property important to our business. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal, scientific and factual questions. Accordingly, our patent applications may never be approved by U.S. or foreign patent offices and the patents and patent applications relating to our products, product candidates and technologies may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours, or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before U.S. or foreign patent offices.

We also rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information. Our research collaborators and scientific advisors have rights to publish data and information in which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborators and advisors, our ability to receive patent protection or protect our proprietary information may be imperiled.

Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

The biotechnology industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Because patent applications are maintained in secrecy until the application is published, we may be unaware of third party patents that may be infringed by commercialization of our product candidates. In addition, identification of third party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could likely:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause product candidate development delays;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology; or

- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent-related legal action against our collaborators or us claiming damages and seeking to enjoin commercial activities relating to our product candidates and processes could subject us to potential liability for damages and require our collaborators or us to obtain a license to continue to manufacture or market the affected products and processes. We cannot predict whether our collaborators or we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing at least some of our product candidates, which could harm our business, financial condition and operating results.

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success also depends on avoiding infringement of the proprietary technologies of others. In particular, there may be certain issued patents and patent applications claiming subject matter that our collaborators or we may be required to license in order to research, develop or commercialize at least some of our product candidates, including *ulimorelin* and TZP-102 and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all.

A number of companies, including several major pharmaceutical companies, have conducted research on pharmaceutical uses of growth hormone secretagogues, including ghrelin and ghrelin analogs, which resulted in the filing of many patent applications related to this research. We are aware of third party United States patents, and corresponding foreign counterparts, that contain broad claims related to methods of using these general types of compounds, which may be construed to include *ulimorelin* and TZP-102, for stimulation of gastrointestinal motility or treatment of neuropathy associated with diabetes. If we were to challenge the validity of these or any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we were to challenge the enforceability of these or any issued United States patent in court, we would need to meet the burden of showing that the patent is unenforceable. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity or enforceability.

In addition, third parties may assert infringement or other intellectual property claims against us based on patents or other intellectual property rights. An adverse outcome in these proceedings could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease or modify our use of the technology. If we are required to license such technology, we cannot assure you that a license under such patents and patent applications will be available on acceptable terms or at all. Further, we may incur substantial costs defending ourselves in lawsuits against charges of patent infringement or other unlawful use of another's proprietary technology.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation by extending the patent terms and obtaining data exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of *ulimorelin*, TZP-102 and our other products, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks Related to Our Financial Position and Need for Capital

[Rider 6 to come]

We have incurred significant operating losses since inception, and we expect to incur losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.

We have incurred significant operating losses since we were founded in 1998 and expect to incur significant losses for the next several years as we begin our Phase 3 trials for *ulimorelin* and Phase 2b trial for TZP-102. As of March 31, 2011, we had an accumulated deficit of $87.8 million. Losses have resulted principally from costs incurred in our clinical trials, research and development programs and from our general and administrative expenses. In the future, we intend to continue to conduct research and development, clinical testing, regulatory compliance activities and, if any of our product candidates is approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in our incurring further significant losses for the next several years.

We currently generate no revenue from sales, and we may never be able to develop marketable drugs. As a result, there can be no assurance that we will ever generate revenues or achieve profitability, which could impair our ability to sustain operations or obtain any required additional funding. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize our most advanced product candidates.

We will require substantial future capital in order to complete clinical development and commercialize our most advanced product candidate, *ulimorelin* , and to conduct the research and development and clinical and regulatory activities necessary to bring other product candidates to market, including TZP-102. The amount and timing of any expenditure needed to implement our development and commercialization programs will depend on numerous factors, including:

- the progress, costs, results of and timing of our two Phase 3 clinical trials of *ulimorelin* for the management of POI following partial bowel resection surgery;
- the need for, and the progress, costs and results of, any additional Phase 3 clinical trials of *ulimorelin* we may initiate based on the results of our clinical trials or our discussions with regulatory agencies, including any additional trials the FDA, EMA or other regulatory agencies may require evaluating the safety of *ulimorelin* ;
- the initiation, progress, costs, results of and timing of our planned Phase 2b clinical trial of TZP-102 for treatment of diabetic gastroparesis and future clinical trials of TZP-102;
- the costs and timing of obtaining regulatory approval in the United States and abroad for our product candidates;
- the FDA’s willingness to review our TZP-102 application under the fast track development program;

- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights globally;
- the costs and timing of obtaining or maintaining manufacturing for our product candidates, including commercial manufacturing if any of our product candidates is approved;
- the costs and timing of establishing sales and marketing capabilities in selected markets; and
- the terms and timing of establishing collaborations, license agreements and other partnerships on terms favorable to us.

Some of these factors are outside of our control. Based upon our currently expected level of operating expenditures, we should be able to fund our operations for at least the next 24 months. However, we do not expect our existing capital resources to be sufficient to enable us to fund the completion of any of our development programs through commercial introduction. We expect that we will need to raise additional funds in the future.

We may seek additional funding through collaboration agreements and public or private financings. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code, and may be subject to further limitation as a result of the recent public offering of our stock.

Section 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long term tax exempt rate and the value of the company's stock immediately before the ownership change. We may be unable to offset future taxable income, if any, with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability.

In addition, it is possible that the recent public offering of our stock, either on a standalone basis or when combined with future transactions, will cause us to undergo one or more additional ownership changes. In that event, we generally would not be able to use our pre-change loss or credit carryovers or certain built-in losses prior to such ownership change to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383 and those attributes already subject to limitations as a result of our prior ownership changes may be subject to more stringent limitations. As of December 31, 2010, we have estimated approximately $2.9 million of U.S. federal net operating loss carryforwards are at risk of loss due to prior ownership changes, as well as approximately $20.6 million of U.S. federal and state net operating loss carryforwards at risk of limitation in the event of a future ownership change.

Risks Related to our Common Stock

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including:

- our ability to enroll patients in our clinical trials;
- results of clinical trials of our product candidates, those of our competitors or those of other companies in our market sector;
- regulatory developments in the United States and foreign countries;
- 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, especially in light of current reforms to the U.S. healthcare system;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts' reports or recommendations;
- sales of our stock by insiders and 5% stockholders;
- 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 relationships with our collaborators; and
- the other factors described in this "Risk Factors" section.

In addition, in the past, stockholders have initiated class action lawsuits against biotechnology and pharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidates;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and

- the achievement and timing of milestone payments under our existing strategic partnership agreements.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Because a small number of our existing stockholders, prior to our initial public offering, own a majority of our voting stock, your ability to influence corporate matters will be limited.

Immediately following the closing of our initial public offering, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 39.8% of our outstanding common stock. As a result, such persons, acting together, will have the ability to control our management and affairs and substantially all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. These persons will also have the ability to control our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include:

- the prohibition on actions by written consent of our stockholders;

- the limitation on who may call a special meeting of stockholders;

- the establishment of advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;

- the ability of our board of directors to issue preferred stock without stockholder approval, which would increase the number of outstanding shares and could thwart a takeover attempt; and

- the requirement of at least 75% of the outstanding common stock to amend any of the foregoing provisions.

In addition, because we are incorporated in Delaware, we are governed by the 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. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

Future sales of our common stock may cause our stock price to decline.

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market after the 180-day contractual lock-up and other legal restrictions on resale discussed in the registration statement for our IPO lapse, the trading price of our common stock could decline significantly. Citigroup Global Markets Inc., the representative of all underwriters for our initial public offering, may, in its sole discretion, permit our officers, directors, employees and current stockholders to sell shares prior to the expiration of the lock-up agreements. Moreover, a relatively small number of our shareholders own large blocks of shares. We cannot predict the effect, if any, that public sales of these shares or the availability of these shares for sale will have on the market price of our common stock.

After the lock-up agreements pertaining to our initial public offering expire and based on shares outstanding as of March 31, 2011, an additional 10,208,845 shares will be eligible for sale in the public market, subject to any applicable volume limitations under federal securities laws. In addition, as of March 31, 2011, we had outstanding options and warrants to purchase 819,993 shares of common stock that, if exercised, will result in these additional shares becoming available for sale upon expiration of the lock-up agreements, subject in some cases to volume limitations. Shares subject to outstanding options under our equity incentive plans and shares reserved for future issuance under our equity incentive plans will also become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Moreover, 180 days after the completion of our initial public offering, holders of approximately 10,232,336 shares of our common stock will have the right to require us to register these shares under the Securities Act of 1933, as amended, pursuant to a registration rights agreement. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our ability to produce accurate financial statements and on our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we will be required to furnish a report by our management on our internal control over financial reporting beginning with the fiscal year ended December 31, 2012. We have not been subject to these requirements in the past. The internal control report must contain (a) a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting, (b) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting, (c) management's assessment of the effectiveness of our internal control over financial reporting as of the end of our most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective, and (d) a statement that our independent registered public accounting firm has issued an attestation report on internal control over financial reporting.

To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to dedicate internal resources, engage outside consultants and adopt a detailed work plan to (a) assess and document the adequacy of internal control over financial reporting, (b) take steps to improve control processes where appropriate, (c) validate through testing that controls are functioning as documented, and (d) implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, we can provide no assurance as to our, or our independent registered public accounting firm's, conclusions with respect to the effectiveness of our internal control over financial reporting under Section 404. There is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds from Registered Securities

Our IPO of common stock was effected through a Registration Statement on Form S-1 (File No. 333-170749) that was declared effective by the SEC on April 1, 2011, which registered an aggregate of 13,500,000 shares of our common stock at an aggregate gross offering price to the public of $54,000,000. All of the 13,500,000 shares of common stock registered under the Registration Statement were sold at a price to the public of $4.00 per share. The offering closed on April 6, 2011. The underwriters partially exercised their over-allotment option on April 29, 2011, and purchased an additional 850,000 shares of our common stock for an aggregate gross price of $3,400,000. Citigroup Global Markets Inc. acted as sole book-running manager for the offering. BMO Capital Markets Corp., Canaccord Genuity Inc. and Stifel, Nicolaus & Company, Incorporated acted as co-managers. There were no selling stockholders in the offering.

Net proceeds received were approximately $51.4 million, after underwriting fees and estimated offering expenses of approximately $6.0 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. We intend to use the proceeds as follows: (i) approximately $20.5 million to fund the continued clinical development of *ulimorelin* , including our two Phase 3 clinical trials for the management of postoperative ileus following partial bowel resection surgery; (ii) approximately $14.2 million to fund the continued clinical development of TZP-102, including our planned 12-week Phase 2b clinical trial for the treatment of gastroparesis in diabetic patients; and the remainder for general corporate purposes, such as payment of principal and interest under our debt facilities, general and administrative expenses, capital expenditures, working capital, prosecution and maintenance of our intellectual property and the potential investment in technologies or products that complement our business.

There has been no material change in our planned use of proceeds from the IPO from that described in the final prospectus filed with the SEC pursuant to Rule 424(b) on April 4, 2011.

Item 6. Exhibits

(a) Exhibits required by Item 601 of Regulation S-K.

Exhibit Number	Description
3.1	Form of Eighth Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).
3.2	Form of Amended and Restated Bylaws of the Company (Incorporated by reference to Exhibit 3.3 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).
4.2	Fourth Amended and Restated Registration Rights Agreement dated as of May 12, 2005 by and among the Company and the investors listed therein, as amended (Incorporated by reference to Exhibit 4.2 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).
4.3	Warrant to Purchase Stock dated December 3, 2008 issued by the Company to Oxford Finance Corporation (Incorporated by reference to Exhibit 4.3 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).
4.4	Warrant to Purchase Stock dated December 3, 2008 issued by the Company to Silicon Valley Bank (Incorporated by reference to Exhibit 4.4 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).
4.5	Warrant to Purchase Stock dated September 30, 2010 issued by the Company to Compass Horizon Funding Company LLC (Incorporated by reference to Exhibit 4.5 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).
4.6	Warrant to Purchase Stock dated September 30, 2010 issued by the Company to Oxford Finance Corporation (Incorporated by reference to Exhibit 4.6 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).
10.1	2011 Stock Option and Incentive Plan of the Company, together with forms of award agreement (Incorporated by reference to Exhibit 10.10 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).
10.2	Amended and Restated Agreement of Employment dated February 20, 2007 by and between the Company and Vipin K. Garg, as amended (Incorporated by reference to Exhibit 10.13 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).

10.3	Form of Indemnification Agreement (Incorporated by reference to Exhibit 10.18 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

*Filed herewith

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.

TRANZYME, INC.
(Registrant)

Date: May 12, 2011

By: /s/ Vipin K. Garg, Ph.D.
Vipin K. Garg, Ph.D.
President Chief Executive Officer
(Principal Executive Officer)

Date: May 12, 2011

By: /s/ Richard I. Eisenstadt
Richard I. Eisenstadt, VP, Finance and
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Vipin K. Garg, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Tranzyme, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2011

By: /s/ Vipin K. Garg, Ph.D.
Vipin K. Garg, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Richard I. Eisenstadt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Tranzyme, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2011

By: /s/ Richard I. Eisenstadt
Richard I. Eisenstadt, VP, Finance and
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Tranzyme, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2011, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Vipin K. Garg, Ph.D., President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that: (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2011

By: /s/ Vipin K. Garg, Ph.D.
Vipin K. Garg, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Tranzyme, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2011, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Richard I. Eisenstadt, VP, Finance and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that: (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2011

By: /s/ Richard I. Eisenstadt
Richard I. Eisenstadt, VP, Finance and
Chief Financial Officer
(Principal Financial and Accounting Officer)