
**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, 2015

OR

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

For the transition period from _____ to _____

Commission file number: 001-36510

Zafgen, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

20-3857670
(I.R.S. Employer
Identification No.)

175 Portland Street, 4th Floor
Boston, Massachusetts 02114
(Address of principal executive office) (Zip Code)

Registrant's telephone number, including area code: (617) 622-4003

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

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

As of April 30, 2015, there were 26,894,157 shares of the registrant’s Common Stock, \$0.001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- our plans to develop and commercialize beloranib as a treatment for obesity that is a co-morbidity of an underlying rare condition such as Prader Willi syndrome; or hypothalamic injury-associated obesity, including craniopharyngioma-associated obesity; or severe obesity in the general population, or at all;
- our ability to advance beloranib into pivotal trials, and successfully complete such clinical trials;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party manufacturers and clinical research organizations;
- our ability to obtain and maintain intellectual property protection for our proprietary assets;
- the size of the potential markets for beloranib and our ability to serve those markets;
- the rate and degree of market acceptance of beloranib for any indication once approved;
- our ability to obtain additional financing;
- the success of competing products that are or become available for the indications that we are pursuing;
- the loss of key scientific or management personnel; and
- other risks and uncertainties, including those listed under Part II, Item 1A. Risk Factors.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. Risk Factors and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

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Zafgen, Inc.

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(In thousands, except share and per share data)
(Unaudited)

	<u>March 31,</u> <u>2015</u>	<u>December 31,</u> <u>2014</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 106,934	\$ 58,103
Marketable securities	127,267	57,359
Tax incentive receivable	391	391
Prepaid expenses and other current assets	1,734	1,345
Total current assets	236,326	117,198
Property and equipment, net	101	79
Tax incentive receivable	205	—
Other assets	89	242
Total assets	<u>\$ 236,721</u>	<u>\$ 117,519</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,404	\$ 2,348
Accrued expenses	4,034	3,172
Notes payable, current	2,093	1,381
Total current liabilities	9,531	6,901
Notes payable, net of discount, long-term	5,521	6,177
Total liabilities	<u>15,052</u>	<u>13,078</u>
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock; \$0.001 par value; 5,000,000 shares authorized at March 31, 2015 and December 31, 2014; no shares issued and outstanding at March 31, 2015 and December 31, 2014	—	—
Common stock, \$0.001 par value; 115,000,000 shares authorized at March 31, 2015 and December 31, 2014; 26,856,329 and 22,879,160 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	27	23
Additional paid-in capital	340,538	209,838
Accumulated deficit	(118,857)	(105,385)
Accumulated other comprehensive loss	(39)	(35)
Total stockholders' equity	221,669	104,441
Total liabilities and stockholders' equity	<u>\$ 236,721</u>	<u>\$ 117,519</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

Zafgen, Inc.**Condensed Consolidated Statements of Operations and Comprehensive Loss**
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	10,215	3,275
General and administrative	3,025	1,246
Total operating expenses	13,240	4,521
Loss from operations	(13,240)	(4,521)
Other income (expense):		
Interest income	39	—
Interest expense	(213)	(2)
Foreign currency transaction gains (losses), net	(58)	65
Total other income (expense), net	(232)	63
Net loss	(13,472)	(4,458)
Accretion of redeemable convertible preferred stock to redemption value	—	(49)
Net loss attributable to common stockholders	\$ (13,472)	\$ (4,507)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.53)	\$ (6.18)
Weighted average common shares outstanding, basic and diluted	25,615,282	729,391
Comprehensive loss:		
Net loss	\$ (13,472)	\$ (4,458)
Other comprehensive loss:		
Unrealized loss on marketable securities	(4)	—
Total other comprehensive loss	(4)	—
Total comprehensive loss	\$ (13,476)	\$ (4,458)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Zafgen, Inc.

Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$ (13,472)	\$ (4,458)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	1,057	176
Non-cash interest expense	16	—
Depreciation expense	5	3
Unrealized foreign currency transaction (gains) losses	24	(42)
Premium on purchases of marketable securities	(341)	—
Amortization of premium on marketable securities	131	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(389)	(44)
Tax incentive receivable	(229)	506
Accounts payable	1,121	(511)
Accrued expenses	990	350
Net cash used in operating activities	<u>(11,087)</u>	<u>(4,020)</u>
Cash flows from investing activities:		
Purchase of marketable securities	(98,952)	—
Proceeds from maturities of marketable securities	29,250	—
Purchases of property and equipment	(27)	(5)
Net cash used in investing activities	<u>(69,729)</u>	<u>(5)</u>
Cash flows from financing activities:		
Proceeds from issuance of redeemable convertible preferred stock	—	442
Proceeds from issuance of notes payable, net of issuance costs	—	7,376
Proceeds from exercise of common stock options and issuance of common stock pursuant to employee stock purchase plan	76	—
Proceeds from public offering, net	129,571	—
Payments of deferred offering costs	—	(827)
Net cash provided by financing activities	<u>129,647</u>	<u>6,991</u>
Net increase in cash and cash equivalents	48,831	2,966
Cash and cash equivalents at beginning of period	<u>58,103</u>	<u>35,517</u>
Cash and cash equivalents at end of period	<u>\$ 106,934</u>	<u>\$ 38,483</u>
Supplemental disclosure of non-cash investing and financing activities:		
Accretion of redeemable convertible preferred stock to redemption values	\$ —	\$ 49
Deferred offering costs included in accounts payable and accrued expenses	\$ —	\$ 362

The accompanying notes are an integral part of these condensed consolidated financial statements.

Zafgen, Inc.

**Notes to the Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)**

1. Nature of the Business and Basis of Presentation

Zafgen, Inc. (the “Company”) was incorporated on November 22, 2005 under the laws of the State of Delaware. The Company is a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by obesity and complex metabolic disorders. Zafgen is focused on developing novel therapeutics that treat the underlying biological mechanisms through the Methionine Aminopeptidase 2 (“MetAP2”) pathway. Beloranib, the Company’s lead product candidate, is a novel, first-in-class, twice-weekly subcutaneous injection being developed for the treatment of multiple indications, including severe obesity in two rare diseases, Prader-Willi syndrome and obesity caused by hypothalamic injury, including craniopharyngioma-associated obesity; and severe obesity in the general population. Zafgen is also developing ZGN-839, a liver-targeted MetAP2 inhibitor, for the treatment of nonalcoholic steatohepatitis (“NASH”) and abdominal obesity. Since its inception, the Company has devoted substantially all of its efforts to research and development, recruiting management, acquiring operating assets and raising capital.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance-reporting capabilities.

The Company’s product candidates are all in the development stage. There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries Zafgen Securities Corporation, Zafgen Australia Pty Limited, and Zafgen Animal Health, LLC. All significant intercompany balances and transactions have been eliminated.

The accompanying condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”).

On June 24, 2014, the Company completed an initial public offering (“IPO”) of its common stock, which resulted in the sale of 6,900,000 shares at a price of \$16.00 per share. The Company received net proceeds from the IPO of approximately \$102,672 based upon the price of \$16.00 per share and after deducting underwriting discounts and commissions paid by the Company. The Company also incurred offering costs of \$2,508 related to the IPO.

On January 28, 2015, the Company completed a follow-on offering of its common stock, which resulted in the sale of 3,942,200 shares at a price of \$35.00 per share. The Company received net proceeds from the follow-on offering of \$129,571 based upon the price of \$35.00 per share after deducting underwriting discounts and commissions, and offering expenses of \$473.

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Unaudited Interim Financial Information

The condensed consolidated balance sheet at December 31, 2014 was derived from audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited condensed consolidated financial statements as of March 31, 2015 and for the three months ended March 31, 2015 and 2014, have been prepared by the Company, pursuant to the rules and regulations of the SEC for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2014, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, on file with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair presentation of the Company's condensed consolidated financial position as of March 31, 2015 and condensed consolidated results of operations and cash flows for the three months ended March 31, 2015 and 2014 have been made. The results of operations for the three months ended March 31, 2015 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2015.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates, assumptions and judgments reflected in these condensed consolidated financial statements include, but are not limited to, the accrual of research and development expenses, the valuation of common stock prior to the IPO and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Fair Value Measurements

The following tables present information about the Company's financial assets that have been measured at fair value at March 31, 2015 and December 31, 2014, and indicate the fair value of the hierarchy of the valuation inputs utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair value determined by Level 2 inputs utilize observable inputs other than Level 1 prices, such as quoted prices, for similar assets or liabilities, quoted market 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 related assets or liabilities. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and includes situations where there is little, if any, market activity for the asset or liability.

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The following tables summarize the Company's cash equivalents and marketable securities as of March 31, 2015 and December 31, 2014:

	March 31, 2015			
	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	\$ 4,179	\$ 4,179	\$ —	\$ —
U.S. government securities	4,700	—	4,700	—
Corporate bonds	3,503	—	3,503	—
Total cash equivalents	<u>12,382</u>	<u>4,179</u>	<u>8,203</u>	<u>—</u>
Marketable securities:				
U.S. government securities	80,085	—	80,085	—
Corporate bonds	40,187	—	40,187	—
Commercial paper	6,995	—	6,995	—
Total marketable securities	<u>127,267</u>	<u>—</u>	<u>127,267</u>	<u>—</u>
Total cash equivalents and marketable securities	<u>\$139,649</u>	<u>\$ 4,179</u>	<u>\$ 135,470</u>	<u>\$ —</u>

	December 31, 2014			
	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	\$ 14,742	\$14,742	\$ —	\$ —
U.S. government securities	27,767	—	27,767	—
Total cash equivalents	<u>42,509</u>	<u>14,742</u>	<u>27,767</u>	<u>—</u>
Marketable securities:				
U.S. government securities	34,191	—	34,191	—
Corporate bonds	22,168	—	22,168	—
Commercial paper	1,000	—	1,000	—
Total marketable securities	<u>57,359</u>	<u>—</u>	<u>57,359</u>	<u>—</u>
Total cash equivalents and marketable securities	<u>\$ 99,868</u>	<u>\$14,742</u>	<u>\$ 85,126</u>	<u>\$ —</u>

During the three months ended March 31, 2015, there were no transfers between Level 1 and Level 2 financial assets. The carrying amounts reflected in the condensed consolidated balance sheets for tax incentive receivable, accounts payable, and accrued expenses approximate fair value due to their short-term maturities. The carrying value of the Company's outstanding notes payable approximates fair value (a Level 2 fair value measurement), reflecting discount rates currently available to the Company.

Marketable Securities

The following table summarizes the Company's marketable securities as of March 31, 2015 and December 31, 2014:

	March 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Assets:				
U.S. government securities (due within 1 year)	\$ 80,098	\$ —	\$ (13)	\$ 80,085
Corporate bonds (due within 1 year)	37,752	—	(22)	37,730
Corporate bonds (due after 1 year through 2 years)	2,460	—	(3)	2,457
Commercial paper (due within 1 year)	6,996	—	(1)	6,995
	<u>\$127,306</u>	<u>\$ —</u>	<u>\$ (39)</u>	<u>\$127,267</u>

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	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Assets:				
U.S. government securities (due within 1 year)	\$ 34,200	\$ —	\$ (9)	\$ 34,191
Corporate bonds (due within 1 year)	18,716	—	(18)	18,698
Corporate bonds (due after 1 year through 2 years)	3,478	—	(8)	3,470
Commercial paper (due within 1 year)	1,000	—	—	1,000
	<u>\$ 57,394</u>	<u>\$ —</u>	<u>\$ (35)</u>	<u>\$ 57,359</u>

[Table of Contents](#)**Income (Loss) Per Share**

Upon the closing of the Company's IPO in June 2014, all of the Company's outstanding redeemable convertible preferred shares were converted into shares of common stock. Prior to this conversion, the Company followed the two-class method when computing net income (loss) per share as the Company had issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The Company's redeemable convertible preferred shares contractually entitled the holders of such shares to participate in dividends, but did not contractually require the holders of such shares to participate in losses of the Company. Accordingly, the two-class method did not apply for periods in which the Company reported a net loss or a net loss attributable to common stockholders resulting from dividends or accretion related to its redeemable convertible preferred shares.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of common shares, including potential dilutive common shares assuming the dilutive effect of outstanding stock options and unvested restricted common shares, as determined using the treasury stock method. For periods in which the Company has reported net losses, diluted net loss per common share attributable to common stockholders is the same as basic net loss per common share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is antidilutive.

The Company reported a net loss attributable to common stockholders for the three months ended March 31, 2015 and 2014.

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	<u>Three Months Ended March 31,</u>	
	<u>2015</u>	<u>2014</u>
Basic and diluted net loss per share attributable to common stockholders:		
Numerator:		
Net loss	\$ (13,472)	\$ (4,458)
Accretion of redeemable convertible preferred stock to redemption value	—	(49)
Net loss attributable to common stockholders	<u>\$ (13,472)</u>	<u>\$ (4,507)</u>
Denominator:		
Weighted average common shares outstanding, basic and diluted	<u>25,615,282</u>	<u>729,391</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.53)</u>	<u>\$ (6.18)</u>

The following common stock equivalents outstanding (prior to consideration of the treasury stock method) as of March 31, 2015 and 2014, were excluded from the computation of diluted net loss per share for the three months ended March 31, 2015 and 2014, because they had an anti-dilutive impact:

	<u>As of March 31,</u>	
	<u>2015</u>	<u>2014</u>
Options to purchase common stock	<u>2,589,767</u>	<u>1,513,353</u>
Unvested restricted common stock	<u>3,870</u>	<u>—</u>
	<u>2,593,637</u>	<u>1,513,353</u>

Recently Issued and Adopted Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board issued Accounting Standards Update No. 2014-15, Presentation of Financial Statements — Going Concern (Subtopic 205-40). The new guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the effect that this guidance will have on its consolidated financial statements.

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3. Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2015	December 31, 2014
Accrued payroll and related expenses	\$ 543	\$ 1,239
Accrued research and development expenses	2,828	1,180
Accrued professional fees	371	585
Accrued other	292	168
	<u>\$ 4,034</u>	<u>\$ 3,172</u>

4. Notes Payable

The Company has outstanding amounts due under a loan and security agreement with Oxford Finance LLC and Midcap Financial (the “Credit Facility”) entered into in March 2014. All promissory notes issued under the Credit Facility are collateralized by substantially all of the Company’s personal property, other than intellectual property. There are no financial covenants associated with the debt facility; however, there are negative covenants restricting the Company’s activities, including limitations on dispositions, mergers or acquisitions; encumbering or granting a security interest in the Company’s intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and certain other business transactions. As of March 31, 2015 and December 31, 2014, notes payable consist of the following:

	March 31, 2015	December 31, 2014
Notes payable	\$ 7,500	\$ 7,500
Less: current portion	(2,093)	(1,381)
Notes payable, net of current portion	5,407	6,119
Debt discount, net of accretion	(67)	(79)
Accretion related to final payment	181	137
Notes payable, net of discount, long term	<u>\$ 5,521</u>	<u>\$ 6,177</u>

As of March 31, 2015, estimated future principal payments due are as follows:

<u>Years Ending December 31,</u>	
2015	\$1,381
2016	2,936
2017	<u>3,183</u>
	<u>\$7,500</u>

During the three months ended March 31, 2015 and 2014, the Company recognized \$213 and \$2, respectively, of interest expense related to the Credit Facility. The effective annual interest rate of the outstanding debt under the Credit Facility is approximately 14%.

5. Stockholders’ Equity

In January 2015, the Company completed a follow-on offering resulting in the sale of 3,942,200 common shares at \$35.00 per share, including 504,200 shares related to the exercise of the over-allotment option by the underwriters. Net proceeds were \$129,571 after deducting underwriting discounts and commissions, and offering expenses of \$473.

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6. Stock-Based Awards

The Company grants equity awards under its 2014 Stock Option and Incentive Plan and is authorized to issue common stock under its 2014 Employee Stock Purchase Plan. The Company also has outstanding stock-based awards under its Amended and Restated 2006 Stock Option Plan but is no longer granting awards under this plan. As of March 31, 2015, 1,970,599 shares are available for grant under the 2014 Stock Option and Incentive Plan, including 915,166 shares automatically added to the 2014 Stock Option and Incentive Plan on January 1, 2015 as a result of a provision in the plan, and 262,136 shares are available for issuance to participating employees under the 2014 Employee Stock Purchase Plan. The Company recorded stock-based compensation expense related to stock options and restricted common stock in the following expense categories of its statements of operations:

	Three Months Ended March 31,	
	2015	2014
Research and development	\$ 404	\$ 69
General and administrative	653	107
	<u>\$ 1,057</u>	<u>\$ 176</u>

As of March 31, 2015, the Company had an aggregate of \$26,317 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 3.7 years. As of March 31, 2015, there were outstanding unvested service-based stock options held by nonemployees for the purchase of 10,683 shares of common stock.

7. Commitments and Contingencies

Leases

The Company has a lease for office space in Boston, Massachusetts, effective as of July 28, 2014, with a term expiring July 31, 2017 and an option to extend the lease for three additional years.

Future minimum lease payments for its operating lease as of March 31, 2015 are as follows:

Years Ending December 31,	
2015	\$172
2016	235
2017	139
	<u>\$546</u>

In March 2015, the Company entered into an operating lease for additional office space in Boston, Massachusetts, effective as of April 15, 2015, with a term expiring on July 31, 2017, and two options to extend the lease for three additional years each. As a result payments under operating lease will increase by \$70 in 2015, \$100 in 2016 and \$60 in 2017.

During the three months ended March 31, 2015 and 2014, the Company recognized \$58 and \$25, respectively, of rental expense related to office space.

Intellectual Property Licenses

The Company has acquired exclusive rights to develop patented compounds and related know-how for beloranib under licensing agreements with two third parties in the course of its research and development activities. The licensing rights obligate the Company to make payments to the licensors for license fees, milestones, license maintenance fees and royalties. The Company is also responsible for patent prosecution costs.

As of March 31, 2015, the Company is obligated to make milestone payments of up to \$12,250 upon reaching certain pre-commercialization milestones, such as clinical trials and government approvals, and up to \$12,500 upon reaching certain product commercialization milestones. Under one of the license agreements, the Company is also obligated to pay up to \$1,250 with respect to each subsequent licensed product, if any, that is a new chemical entity. In addition, the Company will owe single-digit royalties on sales of commercial products developed using these licensed technologies, if any. The Company is also obligated to pay to the licensors a percentage of fees received if and when the Company sublicenses the technology. As of March 31, 2015, the Company has not yet developed a commercial product using the licensed technologies and it has not entered into any sublicense agreements for the technologies.

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Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of March 31, 2015.

8. Retirement Plan

The Company has a Savings Incentive Match Plan for employees. Under the terms of the plan, the Company contributes 2% of an employee's annual base salary, up to a maximum of the annual Internal Revenue Service compensation limits, for all full-time employees.

During the three months ended March 31, 2015 and 2014, the Company recognized \$45 and \$13, respectively, of expense related to its contributions to this plan.

9. Australia Research and Development Tax Incentive

The Company's wholly owned subsidiary, Zafgen Australia Pty Limited, which conducts core research and development activities on behalf of the Company is eligible to receive a 45% refundable tax incentive for qualified research and development activities. For the three months ended March 31, 2015 and 2014, \$229 and \$26, respectively, was recorded as a reduction to research and development expenses in the condensed consolidated statements of operations. These amounts represented 45% of the Company's qualified research and development spending in Australia. The refund is denominated in Australian dollars and, therefore, the receivable is re-measured into U.S. dollars as of each reporting date. For the three months ended March 31, 2015 and 2014, the Company recorded in its condensed consolidated statements of operations unrealized foreign currency exchange gains (losses) of \$(24) and \$42, respectively, related to this tax incentive receivable. As of March 31, 2015 and December 31, 2014, the Company's tax incentive receivable from the Australian government was \$596 and \$391, respectively.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2014 included in our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 25, 2015. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described, in or implied, by these forward-looking statements.

Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods.

The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, including those risks identified under the Risk Factors section.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by obesity and complex metabolic disorders. Beloranib, our lead product candidate, is a novel, first-in-class, twice-weekly subcutaneous injection being developed for the treatment of multiple indications, including severe obesity in two rare diseases, Prader-Willi syndrome, or PWS, and hypothalamic injury-associated obesity, or HIAO, including craniopharyngioma-associated obesity; and severe obesity in the general population. We are also developing ZGN-839, a liver-targeted MetAP2 inhibitor, for the treatment of nonalcoholic steatohepatitis, or NASH, and abdominal obesity.

Obesity is a complex medical disorder involving appetite dysregulation and altered lipid and energy metabolism that results in excessive accumulation of fat tissue. Weight loss and hunger control are urgently needed for certain subpopulations of obese patients, in which obesity is life-threatening and a co-morbidity of an underlying condition such as PWS and HIAO that, while rare, occurs most commonly as a consequence of treatment for craniopharyngioma and other mid-brain tumors. PWS and HIAO are characterized by uncontrollable hunger resulting from damage to or impaired functioning of the hypothalamus, an area of the brain responsible for many functions including the neurophysiological drive to eat.

Since our inception in November 2005, we have devoted substantially all of our resources to developing beloranib and ZGN-839, building our intellectual property portfolio, developing our supply chain, business planning, raising capital, and providing general and administrative support for these operations. Prior to our initial public offering, or IPO, in June 2014, we funded our operations primarily through sales of redeemable convertible preferred stock and, to a lesser extent, through the issuances of convertible promissory notes. From our inception through December 31, 2014, we have received gross proceeds of \$104.0 million from such transactions. During June 2014, we completed our IPO with net proceeds of \$102.7 million after deducting underwriting discounts and commissions paid by us. We also incurred offering costs of \$2.5 million related to the IPO.

On January 28, 2015, we completed a follow-on offering of our common stock, which resulted in the sale of 3,942,200 shares at a price of \$35.00 per share. We received net proceeds from the follow-on offering of \$129.6 million based upon the price of \$35.00 per share and after deducting underwriting discounts and commissions, and offering expenses of \$0.5 million.

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We have never generated any revenue and have incurred net losses in each year since our inception. We have an accumulated deficit of \$118.9 million as of March 31, 2015. Our net loss was \$13.5 million for the three months ended March 31, 2015 and \$36.5 million for the year ended December 31, 2014. These losses have resulted principally from costs incurred in connection with in-licensing our product candidates, research and development activities and general and administrative costs associated with our operations. We expect to incur significant expenses and increasing operating losses for the foreseeable future.

We expect that our expenses will increase substantially in connection with our ongoing activities, as we:

- advance the clinical development of beloranib as a treatment for obesity and hyperphagia in patients with PWS through our Phase 3 clinical trials;
- advance the clinical development of beloranib as a treatment for patients with HIAO;
- initiate Investigational New Drug Application, or IND, enabling studies and clinical development of ZGN-839 and our second-generation Methionine Aminopeptidase 2, or MetAP2, inhibitors;
- advance the clinical development of beloranib as a treatment for severe obesity in the general population through a Phase 2b clinical trial;
- seek to identify additional indications for beloranib;
- seek to obtain regulatory approvals for our product candidates;
- add operational, financial and management information systems;
- add personnel, including personnel to support our product development and future commercialization; and
- maintain, leverage and expand our intellectual property portfolio.

As a result, we will need additional financing to support our continuing operations. Until such time that we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. Arrangements with collaborators or others may require us to relinquish rights to certain of our technologies or product candidates. In addition, we may never successfully complete development of any of our product candidates, obtain adequate patent protection for our technology, obtain necessary regulatory approval for our product candidates or achieve commercial viability for any approved product candidates. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

We expect that our existing cash and cash equivalents and marketable securities as of March 31, 2015 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 18 months. See “—Liquidity and Capital Resources.”

Financial Operations Overview

Revenue

We have not generated any revenue from product sales since our inception, and do not expect to generate any revenue from the sale of products in the near future. If our development efforts result in clinical success and regulatory approval or collaboration agreements with third parties for our product candidates, we may generate revenue from those product candidates.

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Operating Expenses

The majority of our operating expenses since inception have consisted primarily of in-licensing costs of our product candidate beloranib, research and development activities, and general and administrative costs.

Research and Development Expenses

Research and development expenses, which consist primarily of costs associated with our product research and development efforts, are expensed as incurred. Research and development expenses consist primarily of:

- personnel costs, including salaries, related benefits and stock-based compensation for employees engaged in scientific research and development functions;
- third-party contract costs relating to research, formulation, manufacturing, pre-clinical studies and clinical trial activities;
- external costs of outside consultants;
- payments made under our third-party licensing agreements;
- laboratory consumables; and
- allocated facility-related costs.

We have been developing beloranib, ZGN-839, and our second-generation MetAP2 inhibitors, and typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, external consultant costs, payments made under our licensing agreements or other internal costs to specific development programs or product candidates unless the payments are specifically identifiable to a development program or product candidate. We record our research and development expenses net of any research and development tax incentives we are entitled to receive from government authorities.

Research and development activities are central to our business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase in the foreseeable future as we pursue later stages of clinical development of our product candidates.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs, and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing as well as any additional clinical trials and other research and development activities;
- future clinical trial results;
- uncertainties in clinical trial enrollment rate or design;
- significant and changing government regulation;
- the timing and receipt of any regulatory approvals; and
- the FDA's or other regulatory authority's influence on trial design.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, or another 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.

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General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, consisting of salaries, related benefits and stock-based compensation, of our executive, finance, commercial, business and corporate development and other administrative functions. General and administrative expenses also include travel expenses, allocated facility-related costs not otherwise included in research and development expenses, insurance expenses, and professional fees for auditing, tax and legal services, including legal expenses to pursue patent protection of our intellectual property.

We expect that general and administrative expenses will increase in the future as we expand our operating activities and incur additional costs associated with operating as a public company. These public company related increases will likely include additional costs related to personnel; legal, accounting and audit services; directors' and officers' liability insurance premiums; and investor relations. In addition, if we obtain marketing approval for belorانب, we will incur significant sales and marketing expenses.

Other Income (Expense)

Interest income. Interest income consists of interest earned on our cash equivalents and marketable securities. Our interest income has not been significant due to low interest earned on invested balances. We anticipate that our interest income will increase in the future due to increased invested balances from cash proceeds received from our IPO in June 2014 and the follow-on offering that we closed in January 2015.

Interest expense. Interest expense relates to outstanding borrowings under a credit facility that we entered into on March 31, 2014, consisting of the stated interest of 8.1% per year due on outstanding borrowings, a final payment of 6% of amounts drawn down that is being recorded as interest expense over the term through the maturity date using the effective-interest method, the amortization of deferred financing costs, the accretion of debt discount relating to the credit facility, and a fee which was due to the lender upon the completion of our IPO.

Foreign currency transaction gains (losses), net. Foreign currency transaction gains (losses), net consists of the realized and unrealized gains and losses from foreign currency-denominated cash balances, vendor payables and tax-related receivables from the Australian government. We currently do not engage in hedging activities related to our foreign currency-denominated receivables and payables; as such, we cannot predict the impact of future foreign currency transaction gains and losses on our operating results. See “—Quantitative and Qualitative Disclosures about Market Risk.”

Income Taxes

Since our inception in 2005, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2014, we had federal and state net operating loss carryforwards of \$17.0 million and \$9.6 million, respectively. Our federal net operating loss carryforwards begin to expire in 2026 and our state net operating carryforwards begin to expire in 2030. We also had federal and state research and development tax credit carryforwards of \$7.7 million and \$1.9 million, respectively, as of December 31, 2014, which begin to expire in 2026 and 2021, respectively.

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Results of Operations

Comparison of Three Months Ended March 31, 2015 and 2014

The following table summarizes our results of operations for the three months ended March 31, 2015 and 2014:

	Three Months Ended March 31,		Change
	2015	2014	
	(in thousands)		
Statement of Operations Data:			
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	10,215	3,275	6,940
General and administrative	3,025	1,246	1,779
Total operating expenses	<u>13,240</u>	<u>4,521</u>	<u>8,719</u>
Loss from operations	<u>(13,240)</u>	<u>(4,521)</u>	<u>(8,719)</u>
Other income (expense):			
Interest income	39	—	39
Interest expense	(213)	(2)	(211)
Foreign currency transaction gains (losses), net	(58)	65	(123)
Total other income (expense), net	<u>(232)</u>	<u>63</u>	<u>(295)</u>
Net loss	<u>\$ (13,472)</u>	<u>\$ (4,458)</u>	<u>\$ (9,014)</u>

Research and development expenses

	Three Months Ended March 31,		Change
	2015	2014	
	(in thousands)		
Direct research and development expenses by program:			
Beloranib:			
Pre-clinical and manufacturing	\$ 2,530	\$ 1,357	\$1,173
Clinical trials	3,265	294	2,971
Subtotal	<u>5,795</u>	<u>1,651</u>	<u>4,144</u>
ZGN-839 and other early stage development activities	1,983	220	1,763
Subtotal	<u>7,778</u>	<u>1,871</u>	<u>5,907</u>
Unallocated expenses:			
Personnel related	1,596	581	1,015
Consultants	579	729	(150)
Other	262	94	168
Subtotal	<u>2,437</u>	<u>1,404</u>	<u>1,033</u>
Total research and development expenses	<u>\$ 10,215</u>	<u>\$ 3,275</u>	<u>\$6,940</u>

Research and development expenses for the three months ended March 31, 2015 increased \$6.9 million compared to the three months ended March 31, 2014. The increase was primarily due to increased costs of \$4.1 million associated with our beloranib program, \$1.8 million associated with ZGN-839 and other early-stage development programs (consisting of our second-generation MetAP2 inhibitors), and \$1.0 million in our unallocated expenses. Of the increase in our beloranib program, pre-clinical and manufacturing costs increased by \$1.2 million over the prior period primarily as a result of increased costs for toxicology studies required for our Planned New Drug Application, or NDA, submission. Additionally, clinical trial expenses for beloranib increased by \$3.0 million period over period as a result of timing of our clinical trials in 2015 and 2014. As of March 31, 2015, we had two ongoing clinical trials, our Phase 2 trial in patients with severe obesity complicated by type 2 diabetes and our U.S. Phase 3 trial in patients with PWS. Clinical trial activities undertaken by our Australian subsidiary are recorded net of a 45% research and development tax incentive from the Australian government. In the first quarter of 2014 we did not have any ongoing clinical trials but were preparing for upcoming clinical trials. Costs related to ZGN-839 and other early-stage development programs increased in 2015 as a result of our increased focus on our early-stage programs in 2015. Unallocated expenses increased period over period primarily due to an increase in personnel related costs of \$1.0 million of which salary expense increased \$0.4 million, bonus expense increased \$0.1 million and stock-based compensation expense increased \$0.3 million. These increases resulted primarily from an increase in hiring. Between April 1, 2014 and March 31, 2015, we hired 10 new employees in research and development.

[Table of Contents](#)**General and administrative expenses**

	Three Months Ended March 31,		Change
	2015	2014	
	(in thousands)		
Personnel related	\$ 1,475	\$ 534	\$ 941
Professional fees	1,064	585	479
Travel and other	486	127	359
Total general and administrative expenses	<u>\$ 3,025</u>	<u>\$ 1,246</u>	<u>\$1,779</u>

General and administrative expenses for the three months ended March 31, 2015 increased \$1.8 million compared to the three months ended March 31, 2014. The increase was primarily due to increased personnel related costs of \$0.9 million, increased professional fees of \$0.5 million and increased travel and other related costs of \$0.4 million period over period. Personnel related costs increased period over period primarily due to hiring additional employees and granting stock-based awards to our new hires and existing employees. Of the increase in personnel related costs, salary expense increased \$0.2 million and stock-based compensation expense increased \$0.5 million. The increase in stock-based compensation was due to granting additional stock-based awards as well as an increase in the value of the awards. Professional fees increased primarily due to increased accounting and legal fees to support our operating as a public company and costs incurred for market research studies. Travel and other costs increased \$0.4 million primarily due to increased insurance expense, travel, and information technology-related expenses to support our operating as a public company.

Other income (expense), net

Interest expense. Interest expense for the three months ended March 31, 2015 and 2014 was related to interest expense on our outstanding borrowings under the credit facility that we entered into on March 31, 2014, consisting of the stated interest of 8.1% per year due on outstanding borrowings of \$0.2 million, a final payment of 6% of amounts drawn down that is being recorded as interest expense over the term through the maturity date using the effective-interest method and the amortization of deferred financing costs and debt discount relating to the credit facility.

Foreign currency transaction gains (losses), net. We had a small amount of foreign currency transaction losses for the three months ended March 31, 2015 compared to a small amount of foreign currency transaction gains for the three months end March 31, 2014. Foreign currency transactions gains and losses consisted of the realized and unrealized gains and losses from foreign currency-denominated cash balances, vendor payables and tax-related receivables from the Australian government, generally reflecting the movements of the Australian dollar relative to the U.S. dollar.

Liquidity and Capital Resources

As of March 31, 2015, we had cash and cash equivalents and marketable securities totaling \$234.2 million. We invest our cash in money market funds, U.S. government securities, corporate bonds, and commercial paper, with the primary objectives to preserve principal, provide liquidity and maximize income without significantly increasing risk. Since our inception in November 2005, we have not generated any revenue and have incurred recurring net losses. As of March 31, 2015, we had an accumulated deficit of \$118.9 million. From inception to our IPO, we funded our operations primarily through sales of redeemable convertible preferred stock and, to a lesser extent, through the issuances of convertible promissory notes. In June 2014, we completed an IPO of common stock with net proceeds of \$100.2 million, after deducting underwriting discounts and commissions, and offering expenses. On January 28, 2015, we completed a follow-on offering of our common stock, which resulted in the sale of 3,942,200 shares at a price of \$35.00 per share. We received net proceeds from the follow-on offering of \$129.6 million based upon the price of \$35.00 per share and after deducting underwriting discounts and commissions, and offering expenses.

On March 31, 2014, we entered into a loan and security agreement, or the 2014 Credit Facility, which provided for initial borrowings of \$7.5 million and additional borrowings of up to \$12.5 million. On that same date, we received proceeds of \$7.5 million from the issuance of promissory notes under a term loan as part of the 2014 Credit Facility. Of the additional \$12.5 million of borrowings that was available to us, \$7.5 million was available to be drawn down until September 30, 2014 and \$5.0 million was available to be drawn down for a 30-day period upon the completion of our IPO that occurred in June 2014. We elected not to draw down the \$7.5 million or the \$5.0 million and these amounts are no longer available to us. All promissory notes issued under the 2014 Credit Facility are collateralized by substantially all of our personal property, other than our intellectual property. There are no financial covenants associated with the debt facility; however, there are negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions; encumbering or granting a security interest in our intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and certain other business transactions.

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Upon entering into this 2014 Credit Facility, we were obligated to make monthly, interest-only payments on any term loans funded under the 2014 Credit Facility until December 1, 2014 and, thereafter, to pay 36 consecutive, equal monthly installments of principal and interest from January 1, 2015 through December 1, 2017. As per the terms of the agreement, in June 2014, upon the completion of our IPO, the term of monthly, interest-only payments was extended until June 1, 2015. Outstanding term loans under the 2014 Credit Facility bear interest at an annual rate of 8.1%. In addition, a final payment equal to 6.0% of any amounts drawn under the facility is due upon the earlier of the maturity date, acceleration of the term loans or prepayment of all or part of the term loans. We were also obligated to pay a separate fee upon any initial public offering; a sale of substantially all of our assets; or a merger, reorganization or sale of our voting equity securities where existing voting stockholders hold less than 50% of voting equity securities after such transaction. During the year ended December 31, 2014, we recorded interest expense of \$0.2 million relating to the fee paid to the lender upon completion of our IPO.

The following table summarizes our sources and uses of cash for each of the periods presented below:

	Three Months Ended March 31,	
	2015	2014
	(in thousands)	
Cash used in operating activities	\$ (11,087)	\$ (4,020)
Cash used in investing activities	(69,729)	(5)
Cash provided by financing activities	129,647	6,991
Net increase in cash and cash equivalents	<u>\$ 48,831</u>	<u>\$ 2,966</u>

Net cash used in operating activities

During the three months ended March 31, 2015, operating activities used \$11.1 million of cash, primarily resulting from our net loss of \$13.5 million, partially offset by cash provided by changes in our operating assets and liabilities of \$1.5 million and non-cash charges of \$1.2 million. Net cash provided by changes in our operating assets and liabilities during the three months ended March 31, 2015 consisted primarily of a \$2.1 million increase in accounts payable and accrued expenses, partially offset by an increase of \$0.4 million in prepaid expenses and other current assets and a \$0.2 million increase in our research and development tax incentive receivable from the Australian government. Our net non-cash charges during the three months ended March 31, 2015 consisted primarily of stock-based compensation expense of \$1.1 million.

During the three months ended March 31, 2014, operating activities used \$4.0 million of cash, primarily resulting from our net loss of \$4.5 million, partially offset by cash provided by changes in our operating assets and liabilities of \$0.3 million and non-cash charges of \$0.1 million. Net cash provided by changes in our operating assets and liabilities during the three months ended March 31, 2014 consisted primarily of a \$0.5 million decrease in our research and development tax incentive receivable from the Australian government and a \$0.3 million increase in accrued expenses, partially offset by a \$0.5 million decrease in accounts payable. In the three months ended March 31, 2014, we collected the \$0.6 million tax incentive receivable recorded as of December 31, 2012. Our net non-cash charges during the three months ended March 31, 2014 consisted primarily of stock-based compensation expense of \$0.2 million, partially offset by unrealized foreign currency transaction gains.

Our cash provided by operating activities is generally affected by the amount of our net loss, changes in operating asset accounts and add-backs of non-cash expense items such as stock-based compensation expense and unrealized foreign currency gains and losses. Our net losses were primarily attributed to research and development activities related to our beloranib and ZGN-839 programs and our general and administrative expenses, as we had no revenue in the periods. Changes in our operating asset accounts are generally driven by the level of operating activity and timing of payments to our vendors.

Net cash used in investing activities

During the three months ended March 31, 2015 and 2014, net cash used in investing activities was \$69.7 million and \$5,000, respectively. During the three months ended March 31, 2015, we used \$99.0 million to purchase marketable securities, which was partially offset by proceeds from the maturities of marketable securities of \$29.3 million. During the three months ended March 31, 2015 and 2014, we used a small amount of cash for the purchases of property and equipment.

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Net cash provided by financing activities

During the three months ended March 31, 2015, net cash provided by financing activities was \$129.6 million primarily as a result of proceeds of \$129.6 million from our IPO, net of underwriting discounts and commissions and offering costs.

During the three months ended March 31, 2014, net cash provided by financing activities was \$7.0 million as a result of net proceeds of \$7.4 million from the issuance of debt and \$0.4 million from issuances of our Series E redeemable convertible preferred stock, both partially offset by payments of \$0.8 million of deferred offering costs in anticipation of our planned initial public offering that we completed in June 2014.

Operating Capital Requirements

Beloranib is still in clinical development and ZGN-839 and our second-generation MetAP2 inhibitors are in pre-clinical development. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- advance the clinical development of beloranib as a treatment for obesity and hyperphagia in patients with PWS through Phase 3 clinical trials;
- advance the clinical development of beloranib as a treatment for patients with HIAO;
- initiate IND-enabling studies and clinical development of ZGN-839 and our second-generation MetAP2 inhibitors through the initiation of Phase 1 clinical development;
- advance the clinical development of beloranib as a treatment for severe obesity in the general population through a Phase 2b clinical trial;
- seek to identify additional indications for beloranib;
- seek to obtain regulatory approvals for our product candidates;
- add operational, financial and management information systems;
- add personnel, including personnel to support our product development and future commercialization; and
- maintain, leverage and expand our intellectual property portfolio.

We expect that our existing cash and cash equivalents and marketable securities as of March 31, 2015 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 18 months. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of beloranib, ZGN-839 and our second-generation MetAP2 inhibitors and because the extent to which we may enter into collaborations with third parties for development of these product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements for beloranib, ZGN-839 and our second-generation MetAP2 inhibitors will depend on many factors, including:

- the costs, timing and outcome of regulatory review;
- the costs of future research and development activities, including clinical trials;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other products and technologies; and
- our ability to establish any future collaboration arrangements on favorable terms, if at all.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute the ownership interest of our common stockholders. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs of beloranib, ZGN-839 or our second-generation MetAP2 inhibitors or grant

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licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market beloranib, ZGN-839 or our second-generation MetAP2 inhibitors that we would otherwise prefer to develop and market ourselves.

Since our inception in 2005, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2014, we had federal and state net operating loss carryforwards of \$17.0 million and \$9.6 million, respectively. Our federal net operating loss carryforwards begin to expire in 2026 and our state net operating loss carryforwards begin to expire in 2030. As of December 31, 2014, we also had federal and state research and development tax credit carryforwards of \$7.7 million and \$1.9 million, respectively, which begin to expire in 2026 and 2021, respectively. We have not completed a study to assess whether an ownership change, generally defined as a greater than 50% change (by value) in the equity ownership of our corporate entity over a three-year period, has occurred or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such studies. Accordingly, our ability to utilize our tax carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes.

Contractual Obligations and Commitments

During the three months ended March 31, 2015, there have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments” in our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 25, 2015.

In March 2015, we entered into an operating lease for additional office space in Boston, Massachusetts, effective as of April 15, 2015, with a term expiring on July 31, 2017, and two options to extend the lease for three additional years each. As a result payments under operating lease will increase by \$0.1 million in each of 2015, 2016 and 2017.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Application of Critical Accounting Policies

Our condensed consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. We believe that of our critical accounting policies which are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Significant Judgments and Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 25, 2015, the following accounting policies involve the most judgment and complexity:

- accrued research and development costs; and
- stock-based compensation.

Accordingly, we believe the policies set forth above are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected. There have been no material changes to our critical accounting policies during the three months ended March 31, 2015.

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Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board issued Accounting Standards Update, Presentation of Financial Statements — Going Concern (Subtopic 205-40). The new guidance addresses management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. Management’s evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. We are evaluating the effect that this guidance will have on our consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Interest Rate Fluctuation Risk

Our cash and cash equivalents as of March 31, 2015 consisted of cash, government securities, corporate bonds, commercial paper, and money market accounts. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the 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 operation.

Foreign Currency Exchange Risk

Foreign currency transaction exposure results primarily from transactions with our contract research organizations and other providers related to our clinical trials that are denominated in currencies other than the functional currency of the legal entity in which the transaction is recorded by us, primarily the Australian dollar. Any transaction gains or losses resulting from currency fluctuations is recorded on a separate line in our consolidated statements of operations. Net foreign currency transaction losses of \$0.1 million were recorded for the three months ended March 31, 2015.

Currently, our largest foreign currency exposures are those with respect to the Australian dollar. Relative to foreign currency exposures existing as of March 31, 2015, a 10% unfavorable movement in foreign currency exchange rates would expose us to losses in earnings. For the three months ended March 31, 2015, we estimated that a 10% unfavorable movement in foreign currency exchange rates would have increased our net loss by less than \$0.1 million. This amount is based on a sensitivity analysis performed on our financial position as of March 31, 2015. We have experienced and we will continue to experience fluctuations in our net income (loss) as a result of revaluing our assets and liabilities that are not denominated in the functional currency of the entity that recorded the asset or liability. At this time, we do not hedge our foreign currency risk.

Item 4. Management’s Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Based on this evaluation, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of March 31, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

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Changes in Internal Control Over Financial Reporting

During the three months ended March 31, 2015, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, 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

As of the date of this filing, we were not party to any legal matters or claims. In the future, we may become party to legal matters and claims arising in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q and in our other public filings before making an investment decision. Our business, prospects, financial condition, or operating results could be harmed by any of these risks, as well as other risks not currently known to us or that we currently consider immaterial. If any such risks or uncertainties actually occur, our business, financial condition or operating results could differ materially from the plans, projections and other forward-looking statements included in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report and in our other public filings. The trading price of our common stock could decline due to any of these risks, and as a result, you may lose all or part of your investment.

Risks Related to Product Development, Regulatory Approval and Commercialization

We depend almost entirely on the success of one product candidate, beloranib, which is in Phase 3 clinical development for our lead indication of the treatment of obesity and hyperphagia in patients with PWS and Phase 2 clinical development for HIAO and severe obesity in the general population. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, beloranib.

We currently have only one product candidate, beloranib, in clinical development, and our business depends almost entirely on its successful clinical development, regulatory approval and commercialization. We currently have no drug products for sale and may never be able to develop marketable drug products. Beloranib, which is currently in Phase 3 clinical development as a treatment for obesity and hyperphagia in Prader-Willi syndrome, or PWS, Phase 2 clinical development for hypothalamic injury-associated obesity, or HIAO, and Phase 2b clinical development for severe obesity in the general population, will require substantial additional clinical development, testing and regulatory approval before we are permitted to commence its commercialization. Our other product candidates, including ZGN-839, are still in pre-clinical development stages. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through pre-clinical testing and clinical trials that the product candidate is safe and effective for use in each target indication. This process can take many years and may include post-marketing studies and surveillance, which will require the expenditure of substantial resources beyond the proceeds we currently have on hand. Of the large number of drugs in development in the United States, only a small percentage will successfully complete the U.S. Food and Drug Administration, or FDA, regulatory approval process and be commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and clinical trials, we cannot assure you that beloranib or any other of our product candidates will be successfully developed or commercialized.

We are not permitted to market beloranib in the United States until we receive approval of a New Drug Application, or an NDA, from the FDA, or in any foreign countries until we receive the requisite approval from such countries. We recently completed three Phase 2 clinical trials of beloranib, one in patients with PWS, one in patients with HIAO and one in severely obese patients. We expect that the FDA will require us to conduct at least one pivotal trial in order to submit an NDA for beloranib as a treatment for patients with PWS and HIAO. However, meeting the requirements of the FDA or certain European regulatory authorities may require that we conduct additional pivotal trials. We expect that the FDA will also require us to complete our ongoing Phase 2b clinical trial and at least two Phase 3 clinical trials to submit an NDA for beloranib as a treatment for severe obesity in the general population, and may require that we conduct a cardiovascular outcomes trial. Pursuant to the FDA’s February 2007 draft guidance to industry on the development of weight management drugs, in order to reasonably estimate the safety of a weight-management drug, Phase 3 clinical trials must randomize approximately 3,000 subjects to active doses of the product and 1,500 subjects to placebo in clinical trials for a one-year duration.

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We initiated our Phase 3 clinical program, which is planned to consist of two Phase 3 clinical trials, of beloranib in patients with PWS, with the first Phase 3 trial in the United States, also referred to as the bestPWS clinical trial, having started in September 2014. We achieved our patient enrollment target of 102 patients in our first Phase 3 trial in May 2015. We plan to initiate our second Phase 3 clinical trial of beloranib in patients with PWS in the European Union in the middle of 2015. We continue to engage in discussions with applicable regulatory authorities to determine if our proposed Phase 3 clinical trials will be sufficient to support an NDA submission to the FDA and a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, and other regulatory agencies seeking approval of beloranib for the treatment of obesity and hyperphagia in patients with PWS. Prior to initiation of our Phase 3 clinical program for beloranib in patients with PWS, we submitted pre-clinical animal studies and clinical trial results for the FDA's review, and have several additional studies to complete or that need further evaluation, including a human factors study to demonstrate patients' ability to correctly use the syringe device for dispensing beloranib, an abuse potential study and rat and mouse carcinogenicity studies. However, the FDA may require additional pre-clinical animal studies or clinical studies. We also initiated a Phase 2b clinical trial of beloranib as a treatment for severe obesity in the general population in patients who also have type 2 diabetes.

We are also evaluating additional proprietary methionine aminopeptidase 2, or MetAP2, inhibitors beyond beloranib as potential development candidates that would provide increased patient convenience in the form of oral dosing, or an otherwise improved clinical profile. A decision on whether to subsequently advance beloranib into pivotal trials for severe obesity or to leverage the opportunity to advance another MetAP2 inhibitor into early development for severe obesity is anticipated to be made on the basis of results obtained from our Phase 3 clinical trial in the United States of beloranib in patients with PWS and discussions with regulatory authorities.

Accordingly, obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process, and the FDA and certain European regulatory authorities may delay, limit or deny approval of beloranib for many reasons, including, among others:

- we may not be able to demonstrate that beloranib is safe and effective in treating obesity and hyperphagia in patients with PWS, obesity in patients with HIAO or severe obesity in the general population, to the satisfaction of the FDA and certain European regulatory authorities;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA and certain European regulatory authorities for marketing approval;
- the FDA and certain European regulatory authorities may disagree with the number, design, size, duration, conduct or implementation of our clinical trials;
- the FDA and certain European regulatory authorities may require that we conduct additional clinical trials or pre-clinical studies;
- the FDA and certain European regulatory authorities may not approve the formulation, labeling or specifications of beloranib;
- the contract research organizations, or CROs, that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA and certain European regulatory authorities may find the data from pre-clinical studies and clinical trials insufficient to demonstrate that beloranib's clinical and other benefits outweigh its safety risks;
- the FDA and certain European regulatory authorities may disagree with our interpretation of data from our pre-clinical studies and clinical trials;
- the FDA and certain European regulatory authorities may not accept data generated at our clinical trial sites;
- if and when our NDA is submitted and reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- the FDA and certain European regulatory authorities may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the FDA and certain European regulatory authorities may change their approval policies or adopt new regulations.

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Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market beloranib. Moreover, because our business is almost entirely dependent upon this one product candidate, any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

Positive results from early clinical trials of beloranib are not necessarily predictive of the results of later clinical trials of beloranib. If we cannot replicate the positive results from our earlier clinical trials of beloranib in our later-stage clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize beloranib. It may further be necessary to validate different or additional instruments for measuring subjective endpoints, and to show that beloranib has a clinically meaningful impact on those endpoints in order to obtain regulatory approval.

Positive results from our Phase 1 and Phase 2 clinical trials of beloranib may not necessarily be predictive of the results from required later-stage clinical trials. Similarly, even if we are able to complete our Phase 2b or Phase 3 clinical trials of beloranib according to our current development timeline, the positive results from our Phase 1 and Phase 2a clinical trials of beloranib may not be replicated in our Phase 2b or Phase 3 clinical trial results. The design of our Phase 3 clinical program of beloranib as a treatment for obesity and hyperphagia in patients with PWS differs in several aspects from our recently completed Phase 2a clinical trial for PWS. For example, patients with PWS will not be limited to living in closely-controlled PWS-specific group homes like they were in our Phase 2a clinical trial but will be predominantly living in family homes. In addition, patients with PWS will be treated with beloranib for substantially longer than four weeks and our U.S. Phase 3 extension trial, European Phase 3 trial for PWS and all subsequent Phase 2 and 3 studies will test a pre-filled diluent syringe instead of single use glass vials, which were used in our Phase 2a and U.S. Phase 3 clinical trials. One of the Phase 3 clinical trials will be conducted in Europe, where we have not previously conducted clinical trials. Based on an ongoing dialogue with the FDA, we have recently finalized our plan regarding the statistical analysis of primary efficacy endpoints for the best PWS clinical trial. Both hyperphagia-related behaviors and body weight will be the co-primary efficacy endpoints and will be evaluated at a significance level of p-value less than 0.05. In our Phase 2a clinical trial for PWS we saw statistically significant improvements in body mass and fat mass; body weight was also reduced, but not to a statistically significant level. Later-stage clinical trials will utilize highly rigorous statistical analyses. For example, the results of our Phase 2a clinical trial for severe obesity were based on a per protocol analysis of patients who completed the 12-week dosing in the clinical trial. Later-stage clinical trials will be evaluated based on an intent-to-treat analysis that includes all patients randomized in the clinical trial, regardless of whether they complete treatment, which may lead to different results. Moreover, if we fail to validate a caregiver-administered PWS-specific hyperphagia-related behaviors questionnaire, or PWS-HQ, in time for it to be an effective tool to support the data from our Phase 3 clinical trials, our Phase 3 clinical program and, in turn, our regulatory filing may be delayed until we validate the tool or develop and test a new one. This can be a lengthy process.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, pre-clinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials nonetheless failed to obtain FDA approval. If we fail to produce positive results in our Phase 2b or Phase 3 clinical trials of beloranib, the development timeline and regulatory approval and commercialization prospects for our leading product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Failures or delays in the commencement or completion of our planned clinical trials of beloranib could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.

We initiated our Phase 3 clinical trial of beloranib as a treatment for obesity and hyperphagia in patients with PWS in the United States in September 2014. We plan to initiate our second Phase 3 trial in the European Union in patients with PWS in the middle of 2015. We also initiated a Phase 2b clinical trial of beloranib as a treatment for severe obesity in the general population in patients who also have type 2 diabetes in December 2014. Despite the guidance received from, and to be received from, these regulatory authorities, both the FDA and the European regulatory authorities can change their positions on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or impose stricter approval conditions than we currently expect. Successful completion of such clinical trials is a prerequisite to submitting an NDA to the FDA and, consequently, the ultimate approval and commercial marketing of beloranib. We do not know whether any of these Phase 2b or Phase 3 clinical trials will begin or be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA or European regulatory authorities may place an ongoing clinical trial on hold or may deny permission to pursue other clinical trials we want to initiate;
- delays in regulatory filing or receiving regulatory approvals or additional investigational new drug applications, or INDs, that may be required;

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- negative results from our ongoing pre-clinical studies, or the FDA or European regulatory authorities may require additional pre-clinical studies;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining Institutional Review Board, or IRB, approval to conduct a clinical trial at a prospective site or sites;
- challenges in recruiting and enrolling patients to participate in clinical trials, including the size and nature of the patient population, the proximity of patients to trial sites, eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- severe or unexpected drug-related side effects experienced by patients in a clinical trial, including side effects previously identified in our completed clinical trials;
- delays in validating the PWS-HQ or any other self-reported measures of hunger and related endpoints utilized in a clinical trial, including delays caused as a result of the need to translate the PWS-HQ or other self-reported measures of hunger into European languages other than English;
- the FDA or European regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials;
- reports from pre-clinical or clinical testing of other weight loss therapies that raise safety or efficacy concerns; and
- difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical trials, lack of efficacy, side effects, personal issues or loss of interest.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, other regulatory authorities, the IRBs, at the sites where the IRBs are overseeing a clinical trial, a data and safety monitoring board, or DSMB, overseeing the clinical trial at issue or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;
- unforeseen safety issues, including any that could be identified in our ongoing pre-clinical studies, adverse side effects or lack of effectiveness;
- changes in government regulations or administrative actions;
- problems with clinical supply materials; and
- lack of adequate funding to continue the clinical trial.

Changes in regulatory requirements, FDA guidance or guidance from certain European regulatory authorities or unanticipated events during our clinical trials of beloranib may occur, which may result in changes to clinical trial protocols or additional clinical trial requirements, which could result in increased costs to us and could delay our development timeline.

Changes in regulatory requirements, FDA guidance or guidance from certain European regulatory authorities or unanticipated events during our clinical trials may force us to adjust our clinical program or the FDA or certain European regulatory authorities may impose additional clinical trial requirements. For instance, the FDA issued draft guidance on developing products for weight management in February 2007, but this guidance may be revised in the near future. In March 2012, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee met to discuss possible changes to how the FDA evaluates the cardiovascular safety of weight-management drugs. Amendments to our clinical trial protocols would require resubmission to the FDA or certain European regulatory authorities and IRBs for review and approval, which may adversely impact the cost, timing or successful completion of a clinical trial. If we experience delays completing, or if we terminate, any of our clinical trials, or if we are required to conduct additional clinical trials, the commercial prospects for beloranib may be harmed and our ability to generate product revenue will be delayed.

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We rely, and expect that we will continue to rely, on third parties to conduct any future clinical trials for beloranib. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize beloranib and our business could be substantially harmed.

We enter into agreements with third-party CROs to provide monitors for and to manage data for our ongoing clinical trials. We rely heavily on these parties for execution of clinical trials for beloranib and control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through the clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with current Good Clinical Practices, or cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with product produced under current Good Manufacturing Practices, or cGMPs, regulations and will require a large number of test subjects. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we do design our clinical trials for beloranib, CROs conduct all of the clinical trials. As a result, many important aspects of our drug development programs are outside of our direct control. In addition, the CROs may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements, but we remain responsible and are subject to enforcement action that may include civil penalties up to and including criminal prosecution for any violations of FDA laws and regulations during the conduct of our clinical trials. If the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of beloranib may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs devote to our program or beloranib. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs in a timely manner, or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize beloranib. As a result, our financial results and the commercial prospects for beloranib in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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The number of patients suffering from each of PWS and HIAO is small and has not been established with precision. If the actual number of patients with either of these conditions is smaller than we estimate or if any approval that we obtain is based on a narrower definition of these patient populations, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

There is no current comprehensive patient registry or other method of establishing with precision the actual number of patients with PWS or HIAO in any geography. Published population studies estimate that the prevalence of PWS in the United States and in the European Union ranges from 1 in 8,000 to 1 in 50,000. Published population studies estimate that the incidence of craniopharyngioma, the leading cause of HIAO, is 0.13 to 0.17 per 100,000 per year, or approximately 400 to 500 cases per year in the United States and 650 to 850 cases per year in the European Union. The total addressable market opportunity for beloranib for the treatment of patients with PWS or HIAO will ultimately depend upon, among other things, the diagnosis criteria included in the final label for beloranib, if approved for sale for these indications, acceptance by the medical community and patient access, product pricing and reimbursement. If the actual number of patients with PWS or HIAO is lower than we believe or if any approval that we obtain is based on a narrower definition of these patient populations, then the potential markets for beloranib for these indications will be smaller than we anticipate.

In addition, we plan to seek approval of beloranib initially for the treatment of adolescent and adult patients, 12 years of age and older, with PWS and adolescent and adult patients with HIAO. We believe that approximately 40-50% of patients with PWS are 12 years of age or older. We are currently engaged in early discussions with the FDA and EMA regarding plans for development of beloranib for the treatment of pediatric patients under the age of 12. To support approval for pediatric patients (younger than 12 years of age) we will need to conduct pediatric clinical trials of beloranib for the treatment of these patients with PWS, but we do not yet have plans regarding when these trials will commence. As a result, any FDA approval would likely, at least initially, be limited to use for treating adolescent and adult patients with PWS or adolescent and adult patients with HIAO. This would limit our initial product revenue and may make it more difficult for us to achieve or maintain profitability.

We rely completely on third-party suppliers to manufacture our clinical drug supplies for beloranib, and we intend to rely on third parties to produce commercial supplies of beloranib and pre-clinical, clinical and commercial supplies of any future product candidate.

We do not currently have, nor do we currently plan to acquire, the infrastructure or capability to internally manufacture our clinical drug supply of beloranib, or any future product candidates, for use in the conduct of our pre-clinical studies and clinical trials, and we lack the internal resources and the capability to manufacture any product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers, or CMOs, to manufacture the active drug substance, sterile drug substance and final drug product must be approved by the FDA and other comparable foreign regulatory agencies pursuant to inspections that would be conducted after we submit our NDA or relevant foreign regulatory submission to the applicable regulatory agency.

We do not control the manufacturing process of, and are completely dependent on, our CMOs to comply with cGMPs for manufacture of active drug substance, sterile drug substance and finished drug products. If our CMOs cannot successfully manufacture material that conforms to our specifications and the regulatory requirements of the FDA or applicable foreign regulatory agencies, the CMOs will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. While we manage our quality expectations through a regular audit program for our vendors and suppliers, we have no direct control over our CMOs' ability to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, our CMOs are engaged with third party vendors to supply and/or manufacture starting materials or components for them, which exposes our CMOs to regulatory risks for the production of such materials and components. As a result, failure to satisfy the regulatory requirements for the production of those materials and components may affect the regulatory clearance of our CMOs' facilities generally. If the FDA or an applicable foreign regulatory agency does not approve these facilities for the manufacture of our product candidates or if it withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would adversely impact our ability to develop, obtain regulatory approval for or market our product candidates.

We control our clinical trial supply chain by periodically meeting to assess clinical trial material needs and status of supply. Clinical trial materials are forecasted on a six month rolling basis taking into account enrollment rates, number of sites, component inventory and clinical kit shelf-life. The clinical supply forecast is maintained internally and used to aid in decision making for cGMP manufacturing as well as clinical kit packaging and labeling. In addition, the CRO we employ maintains an inventory of all clinical kits that are allocated for a clinical trial as well as all components needed for the clinical kits. Our cross-functional internal working group discusses inventory on a regular basis. Distribution of kits to clinical sites is controlled via a validated system thus helping to manage inventory at the CRO. Resupply of finished drug product is in progress at our drug product CMO. The manufacturing process is under active development and is not yet validated. Any delays encountered with manufacturing activities, CMO scheduling, or raw material supply could delay the manufacturing of finished drug product.

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We do not have long-term supply agreements in place with our CMOs, and each batch of beloranib is individually contracted under a quality and supply agreement. CMOs are currently supporting clinical activities, however CMOs that will manufacture commercial cGMP batches for beloranib will need to be approved by the FDA and other applicable foreign regulatory agencies, prior to commercialization. We plan to continue to rely upon CMOs and, potentially, collaboration partners to manufacture commercial quantities of beloranib, if approved. Our current scale of manufacturing is adequate to support all of our needs for clinical trial supplies and launch for orphan markets. For peak usage in orphan markets and for indications with larger populations of affected patients, we will need to identify CMOs or partners to produce beloranib on a larger scale.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell beloranib, we may not be able to generate any revenue.

We do not currently have an infrastructure for the sales, marketing and distribution of pharmaceutical products. In order to market beloranib, if approved by the FDA or any other regulatory body, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected.

Even if we receive marketing approval for beloranib in the United States, we may never receive regulatory approval to market beloranib outside of the United States.

We intend to pursue marketing approval of beloranib in the European Union and in other countries worldwide. In order to market any product outside of the United States, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other countries, including potential additional clinical trials or pre-clinical studies. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. The marketing approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process or commercial activities in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to market beloranib in such foreign markets. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

Even if we receive marketing approval for beloranib, it may not achieve broad market acceptance, which would limit the revenue that we generate from its sales.

The commercial success of beloranib, if approved by the FDA or EMA or other applicable regulatory authorities, will depend upon the awareness and acceptance of beloranib among the medical community, including physicians, patients and healthcare payors. Market acceptance of beloranib, if approved, will depend on a number of factors, including, among others:

- beloranib's demonstrated ability to treat obesity and hyperphagia in patients with PWS, obesity in patients with HIAO, or patients with severe obesity in the general population and, if required by any applicable regulatory authority in connection with the approval for these indications, to provide patients with incremental health benefits, as compared with other available weight loss therapies, devices or surgeries;
- the relative convenience and ease of subcutaneous injections as the necessary method of administration of beloranib, including as compared with other treatments for severely obese patients;
- the prevalence and severity of any adverse side effects associated with beloranib, such as nausea, vomiting, headaches and difficulty sleeping or falling asleep;
- limitations or warnings contained in the labeling approved for beloranib by the FDA, EMA, or other regulatory authorities, such as a Category X limitation;
- availability of alternative treatments, including a number of competitive obesity therapies already approved or expected to be commercially launched in the near future;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;

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- publicity concerning our products or competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of beloranib through marketing efforts;
- our ability to obtain sufficient third-party coverage or reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If beloranib is approved but does not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from beloranib to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that, in addition to treating obesity in patients, beloranib also provides incremental health benefits to patients. Our efforts to educate the medical community and third-party payors about the benefits of beloranib may require significant resources and may never be successful.

Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. In our recently completed Phase 2 clinical trials of beloranib, the main adverse events, or AEs, including those leading to premature treatment discontinuation, in patients dosed with beloranib, have been dizziness, sleep disturbances, principally manifested as delayed onset of sleep, as well as nausea and vomiting.

The safety data we have disclosed to date represents our interpretation of the data at the time of disclosure and it is subject to our further review and analysis. There have been no serious adverse events, or SAEs, attributed to beloranib in our completed clinical trials. However, SAEs that are not characterized by clinical investigators as possibly related to beloranib or SAEs that occur in small numbers may not be disclosed to the public until such time the various documents submitted to the FDA as part of the approval process are made public. We are unable to determine if the subsequent disclosure of SAEs will have an adverse effect on our stock price. In addition, our interpretation of the safety data from our clinical trials is contingent upon the review and ultimate approval of the FDA or other regulatory authorities. The FDA or other regulatory authorities may not agree with our methods of analysis or our interpretation of the results.

Further, if beloranib receives marketing approval and we or others identify undesirable side effects caused by the product (or any other similar product) after the approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to change the way the product is distributed or administered, conduct additional clinical trials or change the labeling of the product;
- we may decide to remove the products from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

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Even if we receive marketing approval for beloranib, we may still face future development and regulatory difficulties.

Even if we receive marketing approval for beloranib, regulatory authorities may still impose significant restrictions on beloranib's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Beloranib will also be subject to ongoing FDA and EMA requirements governing the labeling, packaging, storage and promotion of the product and recordkeeping and submission of safety and other post-market information. The FDA has significant post-market authority, including, for example, the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate serious safety risks related to the use of a drug. The FDA also has the authority to require, as part of an NDA or post-approval, the submission of a REMS. Any REMS required by the FDA may lead to increased costs to assure compliance with new post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue.

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 cGMPs and other regulations. If we or a regulatory agency discover problems with beloranib, such as adverse events of unanticipated severity or frequency, or problems with the facility where beloranib is manufactured, a regulatory agency may impose restrictions on beloranib, the manufacturer or us, including requiring withdrawal of beloranib from the market or suspension of manufacturing. If we or the manufacturing facilities for beloranib fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted 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 products, or request that we initiate a product recall.

Competing technologies could emerge, including devices and surgical procedures, adversely affecting our opportunity to generate revenue from the sale of beloranib.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Established competitors may invest heavily to quickly discover and develop novel compounds that could make beloranib obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to beloranib. 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.

There are no current pharmacological treatments for regulating hunger and hyperphagia-related behaviors of patients with PWS or hunger of patients with HIAO, and bariatric surgery is contraindicated in patients with PWS and is not frequently employed in patients with HIAO. We are aware of a clinical trial that was recently completed by Ferring Pharmaceuticals, Inc. to evaluate the use of carbetocin, an analogue of a brain peptide hormone oxytocin hypothesized to increase trust, reduce anxiety and improve behavior in patients with PWS. We also are aware of a clinical trial being conducted by Essentialis, Inc. to evaluate the safety and tolerability of controlled-release diazoxide in patients with PWS and to explore the effects of diazoxide on hyperphagia-related behaviors and energy expenditure. We are aware of a Phase 2 trial in its early phase of execution, by Rhythm Pharmaceuticals, Inc. to evaluate the effect of treatment with RM-493, a melanocortin receptor agonist, in patients with PWS. In addition, any of our competitors may develop a drug to treat patients with PWS at any time. We are not aware of any clinical trials of drugs specifically targeting patients with HIAO. Also, Alize Pharma recently started a Phase 2 clinical trial in PWS of AZP-531, its uncyclated ghrelin analog.

Other potential competitors in the severe obesity market include bariatric service providers, and other potential approaches which utilize various implantable devices or surgical tools that have been approved by the FDA, such as EnteroMedics Inc.'s recently FDA-approved (January 2015) VBlock Therapy, or that are in development by companies such as Allergan, Inc., Boston Scientific Corporation, Covidien Ltd., GI Dynamics, Inc., Johnson & Johnson and Medtronic, Inc. In addition, beloranib will compete with orlistat, phentermine/topiramate and lorcaserin, approved and currently marketed pharmaceutical products in the United States for the treatment of obesity, and several older agents, indicated for short-term administration, including phentermine, phendimetrazine,

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benzphetamine and diethylpropion. Orlistat is marketed in the United States by the Roche Group under the brand name Xenical and over-the-counter in the United States at half the prescribed dose by GlaxoSmithKline under the brand name alli. In June 2013, Arena Pharmaceuticals, Inc. launched its lorcaserin product, which is marketed in the United States under the name Belviq and in September 2012, Vivus, Inc. commercially launched its combination product, phentermine/topiramate, under the trade name Qsymia. In October 2014, Takeda Pharmaceuticals U.S.A., Inc. and Orexigen Therapeutics, Inc. launched Contrave (naltrexone HCl and bupropion HCl) extended-release tablets for chronic weight management in obese adults. In December 2014, the FDA approved Novo Nordisk A/S's Saxenda for weight management in obese and overweight patients in the presence of at least one related co-morbid condition and in April 2015, Novo Nordisk launched Saxenda. Neurosearch A/S is also pursuing pharmaceutical treatments for obesity.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize beloranib in foreign markets for which we may rely on collaborations with third parties. If we commercialize beloranib in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for beloranib in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- 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 beloranib could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

We are subject to healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of beloranib, if approved. Our future arrangements with third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute beloranib, if we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.
- The federal False Claims Act imposes criminal and civil penalties, including those from civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government.
- The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

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- The federal transparency requirements, sometimes referred to as the “Sunshine Act,” under the Patient Protection and Affordable Care Act, require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws and transparency laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines and exclusion from government funded healthcare programs, such as Medicare and Medicaid, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as beloranib, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product’s approved labeling. If we receive marketing approval for beloranib as a treatment for obesity and hyperphagia in patients with PWS or patients with HIAO physicians may nevertheless prescribe beloranib 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 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. If we cannot successfully manage the promotion of beloranib, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Even if approved, reimbursement policies could limit our ability to sell beloranib.

Market acceptance and sales of beloranib 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 for those medications. Cost containment is a primary concern in the U.S. healthcare industry and elsewhere. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for beloranib and, if reimbursement is available, the level of such reimbursement. Reimbursement may impact the demand for, or the price of, beloranib. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize beloranib.

In some foreign countries, particularly in Canada and European countries, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of beloranib with other available therapies. If reimbursement for beloranib is unavailable in any country in which we seek reimbursement, if it is limited in scope or amount, if it is conditioned upon our completion of additional clinical trials, or if pricing is set at unsatisfactory levels, our operating results could be materially adversely affected.

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Even though we have received orphan drug designation for PWS, we may not receive orphan drug exclusivity for beloranib.

As part of our business strategy, we have obtained orphan drug designation in the United States and the European Union for beloranib for the treatment of patients with PWS. In the United States, the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application, including a full NDA to market the same drug for the same orphan indication, except in very limited circumstances, including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines “same drug” as a drug that contains the same active chemical entity and is intended for the same use as the drug in question. To obtain orphan drug exclusivity for a drug that shares the same active chemical entity as an already orphan designated drug, it must be demonstrated to the FDA that the drug is safer or more effective than the approved orphan designated drug, or that it makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition or if another drug with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care.

In the European Union, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers. In addition, ten years of market exclusivity is granted following drug product approval, meaning that another application for marketing authorization of a later similar medicinal product for the same therapeutic indication will generally not be approved in the European Union. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable to not justify maintenance of market exclusivity.

Our product development programs for candidates other than beloranib may require substantial financial resources and may ultimately be unsuccessful.

In addition to the development of beloranib, we may pursue development of our other early-stage development programs. None of our other potential product candidates has commenced any clinical trials, and there are a number of FDA and certain European regulatory requirements that we must satisfy before we can commence clinical trials. Satisfaction of these requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. Any time, effort and financial resources we expend on our other early-stage development programs may adversely affect our ability to continue development and commercialization of beloranib, and we may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. If we do commence clinical trials of our other potential product candidates, such product candidates may never be approved by the FDA or other regulatory authorities.

Risks Relating to Our Intellectual Property Rights

If we are unable to adequately protect our proprietary technology or maintain issued patents which are sufficient to protect beloranib, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.

Our commercial success will depend in part on our success in obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

Our owned and licensed patents and patent applications relate to beloranib compositions of matter, formulations, polymorphs, methods of treating obesity using dosing regimens of beloranib, and methods of treating hypothalamic obesity. The issued U.S. and European patents generally directed to beloranib compositions of matter are exclusively licensed and will each expire in 2019. We own two issued U.S. patents relating to beloranib polymorph compositions of matter that will expire in 2031 and three issued U.S. patents to methods of treating obesity that will expire in 2029. We own pending patent applications in Europe to beloranib polymorph composition of matter and methods of treating obesity that we expect to expire, once issued, in 2031.

As of April 30, 2015, we owned five issued U.S. patents, six pending U.S. patent applications and foreign counterpart applications, and one Patent Cooperation Treaty, or PCT, application that will allow us to seek corresponding protection worldwide, all of which relate to beloranib. We have a license to two U.S. issued patents, one with corresponding issued foreign counterpart patents, that also relate to beloranib. We also co-own one patent application relating to methods of using beloranib.

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As of April 30, 2015, we owned nine pending U.S. patent applications with pending foreign counterpart applications and three PCT patent applications, all of which relate to our internal efforts to discover novel MetAP2 inhibitors. Of these, one pending U.S. patent application with pending foreign counterpart patent applications and one PCT patent application relate to our early-stage product candidate ZGN-839.

As of April 30, 2015, we owned one issued U.S. patent, two pending U.S. patent applications with pending foreign counterpart patent applications, one pending PCT patent application and two U.S. provisional patent applications that relate to our second-generation injectable MetAP2 inhibitor program.

We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect beloranib or our other product candidates. Other parties have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, *ex parte* reexamination, or *inter partes* review proceedings, supplemental examination and challenges in district court. Patents may be subjected to opposition, post-grant review, or comparable proceedings lodged in various foreign, both national and regional, patent offices. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize beloranib.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our sales.

Our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering beloranib are invalidated or found unenforceable, our financial position and results of operations would be materially and adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered beloranib, our financial position and results of operations would also be materially and adversely impacted.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect beloranib or any other products or product candidates;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize beloranib, if approved, before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;

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- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- that our commercial activities or products will not infringe upon the patents of others.

We rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us and have non-compete agreements with some, but not all, of our consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing beloranib, if approved.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products and methods do not or will not infringe the patents or other intellectual property rights of third parties.

The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that beloranib or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing another party's patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license. In addition, if any such claim were successfully asserted against us and we could not obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing beloranib.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing beloranib;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- in the case of trademark claims, redesign, or rename, beloranib to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

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We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

The U.S. Patent and Trademark Office, or U.S. PTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering our product candidate, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the U.S. PTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

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We do not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, an April 2014 report from the Office of the United States Trade Representative identified a number of countries, including India and China, where challenges to the procurement and enforcement of patent rights have been reported. Several countries, including India and China, have been listed in the report every year since 1989. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We are dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing beloranib or our other product candidates, if approved.

We have licensed our rights to beloranib from Chong Kun Dang Pharmaceutical Corp. of South Korea, or CKD. Our license with CKD imposes various obligations on us, including a requirement to use commercially reasonable efforts to develop beloranib and provides CKD the right to terminate the license thereunder in the event of a material breach. For example, CKD may allege that we have breached our license agreement and may accordingly seek to terminate our license with them. Termination of our license from CKD could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize beloranib, if approved, as well as harm our competitive business position and our business prospects. We also have an exclusive license with Children's Medical Center Corporation, or Children's, pursuant to which we exclusively licensed certain patient rights relating to decreasing the growth of fat tissue from Children's on a worldwide basis.

We may enter into additional license(s) to third-party intellectual property that are necessary or useful to our business. Future licensor(s) may also allege that we have breached our license agreement and may accordingly seek to terminate our license with them. In addition, future licensor(s) may decide to terminate our license at will. If successful, this could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects.

We have not yet registered trademarks for a commercial trade name for beloranib and failure to secure such registrations could adversely affect our business.

We have not yet registered trademarks for a commercial trade name for beloranib. Any future trademark applications may be rejected during trademark registration proceedings. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the U.S. PTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

Depending upon the timing, duration and specifics of FDA marketing approval of beloranib, one or more of the U.S. patents we license 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 ability to generate revenues could be materially adversely affected.

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

The United States has recently enacted and is currently implementing the America Invents Act of 2011, which is wide-ranging patent reform legislation. Further, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents or future patents.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Our employees have been previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of our employees. 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 fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize beloranib, which would materially adversely affect our commercial development efforts.

General Company-Related Risks

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of April 30, 2015, we had 26 full-time employees and one part-time employee, and as we advance beloranib into later-stage clinical trials, we expect to increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of beloranib. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize beloranib, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

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Our future success depends on our ability to retain our Chief Executive Officer, and to attract, retain and motivate qualified personnel.

We are highly dependent on Dr. Thomas E. Hughes, our Chief Executive Officer. We have entered into an employment agreement with Dr. Hughes, but he may terminate his employment with us at any time. Although we do not have any reason to believe that we will lose the services of Dr. Hughes in the foreseeable future, the loss of his services might impede the achievement of our research, development and commercialization objectives. We also do not have any key-man life insurance on Dr. Hughes. We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us and may not be subject to our standard non-compete agreements. Recruiting and retaining qualified scientific personnel and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and applicable non-U.S. regulators, provide accurate information to the FDA and applicable non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We face potential product liability exposure, and, if claims are brought against us, we may incur substantial liability.

The use of beloranib in clinical trials and the sale of beloranib, if approved, exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with beloranib. 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, including as a result of interactions with alcohol or other drugs, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we become subject to product liability claims and cannot successfully defend ourselves against them, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things:

- withdrawal of patients from our clinical trials;
- substantial monetary awards to patients or other claimants;
- decreased demand for beloranib or any future product candidates following marketing approval, if obtained;
- damage to our reputation and exposure to adverse publicity;
- increased FDA warnings on product labels;
- litigation costs;
- distraction of management's attention from our primary business;
- loss of revenue; and
- the inability to successfully commercialize beloranib or any future product candidates, if approved.

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We maintain product liability insurance coverage for our clinical trials with a \$10.0 million annual aggregate coverage limit. Nevertheless, our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses, including if insurance coverage becomes increasingly expensive. If and when we obtain marketing approval for beloranib, we intend to expand our insurance coverage to include the sale of commercial products; however, we may not be able to obtain this product liability insurance on commercially reasonable terms. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could cause our stock price to decline and, if we are unsuccessful in defending such a claim or claims and the resulting judgments exceed our insurance coverage, our financial condition, business and prospects could be materially adversely affected.

We must maintain effective internal control over financial reporting, and if we are unable to do so, the accuracy and timeliness of our financial reporting may be adversely affected, which could have a material adverse effect on our business and stock price.

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, as a public company, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires, among other things, that we assess the effectiveness of our disclosure controls and procedures quarterly and the effectiveness of our internal control over financial reporting at the end of each fiscal year. We anticipate being first required to issue management's annual report on internal control over financial reporting, pursuant to Section 404 of the Sarbanes-Oxley Act, in connection with issuing our consolidated financial statements as of and for the year ending December 31, 2015.

The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management's review of internal control over financial reporting. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that will be applicable to us as a public company. If we fail to staff our accounting and finance function adequately or maintain internal control over financial reporting adequate to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, our business and reputation may be harmed and our stock price may decline. Furthermore, investor perceptions of us may be adversely affected, which could cause a decline in the market price of our common stock.

In order to satisfy our obligations as a public company, we will need to hire additional qualified accounting and financial personnel with appropriate public company experience.

As a newly public company, we need to establish and maintain effective disclosure and financial controls and make changes in our corporate governance practices. We will need to hire additional accounting and financial personnel with appropriate public company experience and technical accounting knowledge, and it may be difficult to recruit and maintain such personnel. Even if we are able to hire appropriate personnel, our existing operating expenses and operations will be impacted by the direct costs of their employment and the indirect consequences related to the diversion of management resources from product development efforts.

Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

As of December 31, 2014, we had federal and state net operating loss carryforwards of \$17.0 million and \$9.6 million, respectively. Our federal net operating loss carryforwards begin to expire in 2026 and our state net operating loss carryforwards begin to expire in 2030. As of December 31, 2014, we also had federal and state research and development tax credit carryforwards of \$7.7 million and \$1.9 million, respectively, which begin to expire in 2026 and 2021, respectively. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and research and development tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and research and development tax credit carryforwards before they expire. Our recent follow-on public offering, IPO, private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382. Any such limitation, whether as the result of our recent follow-on public offering, IPO, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years. We have not completed a study to assess whether an ownership change for purposes of Section 382 has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such study.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for beloranib could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of beloranib could be delayed.

We may not be successful in our efforts to identify or discover additional product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our weight loss platform. Although beloranib is currently in clinical development, our research programs may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions or alliances.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate such businesses with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such transaction, we will achieve the expected synergies to justify the transaction.

Risks Related to Our Financial Position and Need for Capital

We have not generated any revenue from product sales. We have incurred significant operating losses since our inception, and anticipate that we will incur continued losses for the foreseeable future.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Our operations to date have been limited primarily to organizing and staffing our company and conducting research and development activities for beloranib and ZGN-839. We have never generated any revenue from product sales. We have not obtained regulatory approvals for any of our product candidates.

Since our inception, we have focused substantially all of our efforts and financial resources on developing beloranib, which is currently in Phase 3 clinical development for our lead indication of the treatment of hyperphagia and obesity in patients with PWS and Phase 2 clinical development for the treatment of obesity in patients with HIAO and the treatment of severe obesity in the general population. We have funded our operations to date through proceeds from sales of redeemable convertible preferred stock, convertible debt and proceeds from our IPO and follow-on public offering, and have incurred losses in each year since our inception. Our net

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losses were \$13.5 million for the three months ended March 31, 2015 and \$36.5 million for the year ended December 31, 2014. As of March 31, 2015, we had a deficit accumulated of \$118.9 million. Substantially all of our operating losses resulted from costs incurred in connection with our development programs for beloranib and ZGN-839, licensing milestone fees and from general and administrative costs associated with our operations. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital. We expect our research and development expenses to significantly increase in connection with our additional clinical trials of beloranib and development of ZGN-839 and of any other product candidates we may choose to pursue. In addition, if we obtain marketing approval for beloranib, we will incur significant sales, marketing and outsourced manufacturing expenses. Now that we are a public company, we will incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our lead product candidate, beloranib, and we do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval of, and begin to sell, beloranib. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- initiate and successfully complete later-stage clinical trials that meet their clinical endpoints;
- initiate and successfully complete all safety studies required to obtain U.S. and foreign marketing approval for beloranib in the indications we are pursuing;
- commercialize beloranib, if approved, by developing a sales force or entering into collaborations with third parties; and
- achieve market acceptance of beloranib in the medical community and with third-party payors.

Absent our entering into a collaboration or partnership agreement, we expect to incur significant sales and marketing costs as we prepare to commercialize beloranib. Even if we initiate and successfully complete our pivotal clinical trials of beloranib, and beloranib is approved for commercial sale, and despite expending these costs, beloranib may not be a commercially successful drug. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient product revenue, we will not become profitable and may be unable to continue operations without continued funding.

We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We are currently advancing beloranib through clinical development. Developing small molecule products is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance beloranib in later-stage, more costly clinical trials. Depending on the status of regulatory approval or, if approved, commercialization of beloranib, as well as the progress we make in selling beloranib, we may require additional capital to fund operating needs thereafter. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for beloranib or otherwise expand more rapidly than we presently anticipate.

As of March 31, 2015, our cash and cash equivalents and marketable securities were \$234.2 million. We expect that our cash and cash equivalents will be sufficient to fund our current operations for at least the next 18 months. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates. Raising funds in the current economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We

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could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidate or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights.

We may seek additional capital through a combination of private and public equity offerings, debt financings, collaborations and strategic and licensing arrangements. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, a stockholder's ownership interest in our company will be diluted. In addition, the terms of any such securities may include liquidation or other preferences that materially adversely affect the rights of our stockholders. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic partnerships and licensing arrangements with third parties, we may have to relinquish valuable rights to beloranib, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us.

Risks Related to Our Common Stock

We expect that our stock price may fluctuate significantly.

Our IPO was completed on June 24, 2014 at a price of \$16.00 per share and our follow-on public offering was completed on January 28, 2015 at a price of \$35.00 per share. A public market for our common stock has only been in existence for a short period of time. An active public market for our common stock may not be sustained.

In addition, the market price of shares of our common stock, similar to the market price of shares of common stock of other biopharmaceutical companies, is subject to wide fluctuations, and will continue to be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- plans for, progress of or results from pre-clinical studies and clinical trials of beloranib;
- the failure of the FDA or the EMA to approve beloranib;
- announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;
- the success or failure of other weight loss therapies;
- regulatory or legal developments in the United States and other countries;
- failure of beloranib, if approved, to achieve commercial success;
- fluctuations in stock market prices and trading volumes of similar companies;
- general market conditions and overall fluctuations in U.S. equity markets;
- variations in our quarterly operating results;
- changes in our financial guidance or securities analysts' estimates of our financial performance;
- changes in accounting principles;
- our ability to raise additional capital and the terms on which we can raise it;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- additions or departures of key personnel;
- discussion of us or our stock price by the press and by online investor communities; and
- other risks and uncertainties described in these risk factors.

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These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and NASDAQ listed and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

Our executive officers, directors, and principal stockholders exercise significant control over our company.

As of April 30, 2015, the existing holdings of our executive officers, directors, principal stockholders and their affiliates, including investment funds affiliated with Atlas Ventures, or Atlas, investment funds affiliated with Third Rock Ventures, or TRV, investment funds affiliated with Alta Partners, or Alta, and entities affiliated with Fidelity Investment, or Fidelity, represent beneficial ownership, in the aggregate, of approximately 53% of our common stock. As a result, these stockholders, if they act together, are able to influence our management and affairs and control the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. The concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- 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 us.

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

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

We have broad discretion in how we use the proceeds of our IPO and our follow-on public offering. We may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We have considerable discretion in the application of the net proceeds of our IPO and our follow-on public offering. We intend to use the net proceeds to advance the clinical development of beloranib as a treatment for obesity and hyperphagia in patients with PWS patients and obesity in patients with HIAO, or patients with severe obesity in the general population and to develop multiple back-up molecules of beloranib as a treatment for severe obesity in the general population, to continue the development and initiate clinical development of ZGN-839, to develop a pen-injector system for eventual commercial use in PWS, HIAO and severe obesity in the general population and to fund new and ongoing research and development activities, working capital and other general corporate purposes, which may include funding for the hiring of additional personnel, capital expenditures, early commercialization activities and the costs of operating as a public company. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of the net proceeds. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds in a manner that does not produce income or that loses value.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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We are an “emerging growth company” and have availed ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act, and we have taken advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are electing not to take advantage of such extended transition period, and as a result we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to not take advantage of the extended transition period for complying with new or revised accounting standards is irrevocable. We cannot predict if investors will find our common stock less attractive because we may rely on any of the exemptions available under the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.0 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; and (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We have never paid dividends on our common stock and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have not paid dividends on any of our common stock to date and we currently intend to retain all of our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gains for our common stockholders for the foreseeable future. Consequently, in the foreseeable future, our common stockholders will likely only experience a gain from their investment in our common stock if the price of our common stock increases.

If equity research analysts do not continue to publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity analysts downgrade our common stock or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Anti-takeover provisions contained in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions which could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our board of directors. Our corporate governance documents include provisions:

- creating a classified board of directors whose members serve staggered three-year terms;
- authorizing “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock;
- limiting the liability of, and providing indemnification to, our directors and officers;
- limiting the ability of our stockholders to call and bring business before special meetings;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our board of directors;
- controlling the procedures for the conduct and scheduling of board of directors and stockholder meetings; and
- providing our board of directors with the express power to postpone previously scheduled annual meetings and to cancel previously scheduled special meetings.

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These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents some stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

Unregistered Sales of Equity Securities

Upon the closing of our IPO, all of the outstanding shares of our redeemable convertible preferred stock were converted into 15,077,621 shares of common stock. The shares of common stock issued pursuant to such conversion were issued in reliance on the exemption from registration provided by Section 3(a)(9) of the Securities Act, which exemption is available for transactions involving securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange.

No underwriters were used in the foregoing transactions.

Use of Proceeds from IPO

On June 24, 2014, we closed the sale of 6,900,000 shares of common stock to the public (inclusive of 900,000 shares of common stock sold by us pursuant to the full exercise of an over-allotment option granted to the underwriters) at a price of \$16.00 per share, before underwriting discounts. The offer and sale of the shares in our IPO was registered under the Securities Act pursuant to registration statements on Form S-1, which was filed with the SEC on January 31, 2014 (File No. 377-00464) and amended subsequently and declared effective by the SEC on June 18, 2014 (File No. 333-195391), and Form S-1MEF, which was filed with the SEC on June 18, 2014 (File No. 333-196891) and automatically effective upon filing. There has been no change in the use of proceeds from our IPO.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

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.

ZAFGEN, INC.

May 14, 2015

By: /s/ Thomas E. Hughes
Thomas E. Hughes
Chief Executive Officer
(Principal Executive Officer)

May 14, 2015

By: /s/ Patricia L. Allen
Patricia L. Allen
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
10.1*	Commercial Lease by and between the Company and Contour LLC, dated March 30, 2015.
31.1*	Certification of Principal Executive Officer pursuant to Exchange Act rules 13a-14 or 15d-14.
31.2*	Certification of Principal Financial Officer pursuant to Exchange Act rules 13a-14 or 15d-14.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Link Document.

* Filed herewith.

COMMERCIAL LEASE**ARTICLE I (Parties)**

Contour LLC, a Massachusetts limited liability company with a principal address of 1601 Beacon Street, #301, Brookline, MA 02446, hereinafter referred to as “LESSOR”, which expression shall include LESSOR’S successors, executors, administrators, and assigns where the context so admits, does hereby lease to **Zafgen, Inc.**, a Delaware corporation with a principal address of 175 Portland Street, Boston, MA 02114, hereinafter referred to as “LESSEE”, which expression shall include LESSEE’S successors, executors, administrators, and assigns where the context so admits, the following described premises (the “Lease”).

ARTICLE II (Leased Premises)

A. **Leased Premises:** LESSOR hereby leases and demises to LESSEE, subject to and with the benefit of the terms, covenants, conditions and provisions of this Lease, a certain portion of the building located at 173-179 Portland Street, Boston, MA 02114, known as Unit 2 of the 175 Portland Street Condominium (the “Condominium”) at as more particularly described in the Master Deed for the Condominium recorded at the Suffolk County Registry of Deeds, at Book 40836, Page 316 (the “Master Deed”) and the Declaration of Trust for the Condominium recorded with said Deeds at Book 40837, Page 1 (the “Declaration of Trust”), comprised of approximately 2,976 rentable square feet, as shown on the attached **Exhibit A** (collectively, the “Leased Premises”).

B. **Condition of Premises:** LESSEE agrees to accept delivery of the Leased Premises on the Effective Date (as defined in Article III) in its “as is” condition. LESSEE acknowledges that LESSOR is not required to perform any work or improvements to the Leased Premises as a condition to LESSEE’S initial occupancy thereof or the inception of this Lease, other than the LESSOR agrees to deliver the Leased Premises in broom clean condition and free of all furniture. Landlord agrees to remove the stained glass window inserts throughout the Leased Premises and the wooden display in the conference room. Additionally, LESSOR agrees to warrant that the Leased Premises shall be delivered to LESSEE with all base building mechanical, electrical and plumbing systems and HVAC equipment in good working order with a remaining useful life equal or greater than the Term hereof.

In addition, LESSEE shall have access to the Leased Premises at least 15 days prior to the Effective Date for the purpose of installing furniture, fixtures, equipment, wiring and cabling.

ARTICLE III (Term)

The initial term of the Lease shall be for twenty-eight (28) months commencing on the date (the “Effective Date”) that the Leased Premises is delivered in the condition described in Section II(B) and LESSEE may legally occupy the Leased Premises, which date shall be no later than April 15, 2015 or such earlier date that LESSEE and LESSOR mutually agree that LESSEE may occupy for the conduct of its business and ending on July 31, 2017 (the “Initial Term”).

If Lessor has not delivered the Leased Premises to Lessee in the condition required under this Lease on April 15, 2015, Lessee shall be entitled to a credit against the base rent first due under this Lease in an amount equal to one day of base rent for each day after April 15, 2015 that the Leased Premises has not been so delivered.

So long as LESSEE is not in default of any of the terms and conditions of the Lease, beyond applicable notice and cure periods, LESSEE may, at LESSEE'S option, extend the term of this Lease for two (2) additional three (3) year terms (each, an "Option Term" and collectively, the "Option Terms") by serving written notice upon LESSOR at least one hundred eighty (180) days prior to the expiration of the Initial Term or first Option Term, as applicable. If LESSEE timely exercises the option to extend the Initial Term for one (1) or both of the Option Terms, each Option Term shall be upon all of the terms and conditions of this Lease. The Initial Term and Option Terms are sometimes collectively referred to as the "Term."

ARTICLE IV (Rent)

The LESSEE shall, for the Initial Term of this Lease beginning as of April 15, 2015 (the "Rent Commencement Date"), pay to the LESSOR, base rent at the rate of Ninety Eight Thousand Two Hundred Eight and 00/100 Dollars (\$98,208.00) per Lease year. All base rent accruing until the first anniversary of the Effective Date shall be payable on the first day of each month, in advance, in monthly installments of Eight Thousand One Hundred Eighty Four and 00/100 Dollars (\$8,184.00). Beginning on the first anniversary of the Rent Commencement Date, base rent shall be payable at the rate of One Hundred One Thousand One Hundred Eighty Four and 00/100 Dollars (\$101,184.00) per Lease year in monthly installments of Eight Thousand Four Hundred Thirty Two and 00/100 Dollars (\$8,432.00). Beginning on the second anniversary of the Rent Commencement Date, base rent shall be payable at the rate of One Hundred Four Thousand One Hundred Sixty and 00/100 Dollars (\$104,160.00) per Lease year in monthly installments of Eight Thousand Six Hundred Eighty and 00/100 Dollars (\$8,680.00). All base rent during the Option Term shall be set as ninety-five percent (95%) of the Current Market Rent Rate (as defined below). Any and all base rent due to LESSOR during the Term is hereinafter referred to as the "Base Rent." All payments of Base Rent shall be made by wire transfer of funds or ACH Transfers to accounts as may be designated in writing from time to time by LESSOR. Base Rent, additional rent and any other charges due from Tenant hereunder shall be appropriately pro-rated and paid by Tenant for any partial month or other applicable period at the beginning or end of the Term.

Provided Tenant shall not be in default under this Lease beyond applicable notice and cure periods, LESSEE shall have two (2) three (3) year options to extend the Term of this Lease at ninety-five percent (95%) of the Current Market Rent Rate (defined below) with the base rent increased by One Dollar (\$1.00) per square foot each year for years 2 and 3 of the applicable extended Term. LESSEE shall give LESSOR written notice of its intent to extend the Term of this Lease no less than six (6) months prior to the expiration of the applicable Term of this Lease, as the same may be extended. The term "Current Market Rent Rate" for purposes of this Lease shall mean the annual amount per rentable square foot that a willing, comparable, new, non-renewal, non-equity, non-expansion tenant of credit quality similar to LESSEE would pay,

and a willing, comparable landlord of the Building or a comparable office building in the immediate vicinity of the Building would accept, at arms length, giving appropriate consideration to annual rental rates per rentable square foot, escalation clauses (including type, gross or net, and if gross, whether base year or expense stop), and abatement provisions reflecting free rent, length of lease term, size and location of premises being leased, improvement allowances (if any), brokerage commissions (if any), and any other concessions which would be granted by LESSOR or a comparable landlord and other generally applicable terms and conditions, but at no time less than the base rent payable during the third year of the Initial Term.

If LESSEE exercises an extension option, LESSOR and LESSEE shall attempt to agree upon the Current Market Rental Rate using their best good-faith efforts. If LESSOR and LESSEE fail to reach an agreement within thirty (30) days following LESSEE's exercise of such extension option (the "Outside Agreement Date"), then each party shall make a separate determination of the Current Market Rental Rate which shall be submitted to each other and to arbitration in accordance with the following items (i) through (vii):

(i) LESSOR and LESSEE shall each appoint, within ten (10) business days of the Outside Agreement Date, one arbitrator who shall by profession be a current real estate broker or appraiser of comparable properties in the immediate vicinity of the Building, and who has been active in such field over the last five (5) years. The determination of the arbitrators shall be limited solely to the issue of whether LESSOR's or LESSEE's submitted Current Market Rental Rate is the closest to the actual Current Market Rental Rate as determined by the arbitrators.

(ii) The two arbitrators so appointed shall within five (5) business days of the date of the appointment of the last appointed arbitrator agree upon and appoint a third arbitrator who shall be qualified under the same criteria set forth hereinabove for qualification of the initial two arbitrators.

(iii) The three arbitrators shall within fifteen (15) days of the appointment of the third arbitrator reach a decision as to whether the parties shall use LESSOR's or LESSEE's submitted Current Market Rent Rate, and shall notify LESSOR and LESSEE thereof.

(iv) The decision of the majority of the three arbitrators shall be binding upon LESSOR and LESSEE.

(v) If either LESSOR or LESSEE fails to appoint an arbitrator within ten (10) business days after the applicable Outside Agreement Date, the arbitrator appointed by one of them shall reach a decision, notify LESSOR and LESSEE thereof, and such arbitrator's decision shall be binding upon LESSOR and LESSEE.

(vi) If the two arbitrators fail to agree upon and appoint a third arbitrator, or both parties fail to appoint an arbitrator, then the appointment of the third arbitrator or any arbitrator shall be dismissed and the matter to be decided shall be forthwith submitted to arbitration under the provisions of REBA Dispute Resolution, Inc., but subject to the instruction set forth in this Article IV.

(vii) The cost of arbitration shall be paid by LESSOR and LESSEE equally.

ARTICLE V (Intentionally Deleted)

ARTICLE VI (Taxes and Condominium Fees)

LESSOR shall pay any municipal real property taxes assessed against the Leased Premises and the Property and sewerage taxes, betterments, and any and all other taxes (collectively, the "Taxes") due and payable beginning with the Effective Date and continuing until the end of Fiscal Year 2016 (June 30, 2016). LESSOR warrants and represents that as of and through the date of the execution of this Lease, all outstanding municipal real property taxes attributable to the Leased Premises and the Property have been paid in full. Beginning with Fiscal Year 2017, LESSEE shall pay any increases in Taxes over Taxes due for the Fiscal Year 2016. Such amounts shall be paid to LESSOR within thirty (30) days after receipt of an invoice from LESSOR, accompanied by a copy of the applicable tax bill.

LESSOR shall pay all Condominium fees and assessments assessed against the Leased Premises due and payable beginning with the Effective Date and continuing until the end of calendar year 2015. LESSOR warrants and represents that as of and through the date of the execution of this Lease, all outstanding Condominium fees and assessments attributable to the Leased Premises have been paid in full. Beginning with calendar year 2016, LESSEE shall pay any increases in the Condominium fees assessed to the Leased Premises over Condominium fees due for the calendar year 2015. Such amounts shall be paid to LESSOR within thirty (30) days after receipt of an invoice from LESSOR, accompanied by a copy of the applicable Condominium fee invoice. In no event shall LESSEE be responsible for the payment of special assessments assessed to the Leased Premises by the Condominium, nor shall the special assessments be included in the calculation for determining increases in Condominium fees as of calendar year 2016, unless such special assessment is required solely as a result of LESSEE's negligence or willful misconduct.

ARTICLE VII (Utilities)

LESSEE shall pay for separately metered utilities, to include gas and electric, for Unit 2 without exception; and further, LESSOR agrees to furnish reasonable heat and air conditioning to the Leased Premises during the appropriate seasons of each year, all subject to interruption due to any accident, to the making of repairs, alterations or improvements, to labor difficulties, to trouble in obtaining fuel, electricity, service or supplies from the source from which they are usually obtained for said Leased Premises, or to any cause beyond the LESSOR's control. No plumbing, construction or electrical work of any type shall be done without LESSOR's prior written approval, which approval shall not be unreasonably withheld, conditioned or delayed, and appropriate permits. LESSEE shall contact gas and electric utilities on or before April 15, 2015 and place the utility bills in LESSEE's name, which shall continue throughout the Initial Term and any subsequent Option Terms under this Lease.

ARTICLE VIII (Use of Leased Premises)

LESSEE shall use the Leased Premises only for general office use. LESSEE shall have unlimited, 24 hour-a-day non-exclusive access to the Leased Premises and/or on the Property so that LESSEE may conduct its business in an efficient manner.

ARTICLE IX (Compliance with Laws)

The LESSEE acknowledges that no trade or occupation shall be conducted in the Leased Premises or use made thereof which will be unlawful, improper, noisy or offensive, or contrary to any law or any municipal by-law or ordinance in force in the City of Boston.

ARTICLE X (Insurance)

LESSEE shall obtain and keep in full force during the Term the following coverage: (a) policy of commercial general liability insurance (including personal injury, broad form contractual liability, broad form property damage, and products liability), naming LESSOR as an additional insured, with minimum limits per occurrence of not less than Four Million Dollars (\$4,000,000), combined single limit and aggregate on an occurrence form, (b) "all risks" or special form of coverage, including vandalism and malicious mischief theft and water damage in an amount equal to the full replacement value, new without deduction for depreciation, of LESSEE's furniture, fixtures, equipment and other personal property in the Leased Premises, and (c) worker's compensation insurance as required by applicable federal or state law.

Policy Standards. All policies of insurance required to be maintained under this Article X shall: (i) be written as primary policy coverage or umbrella coverage and not contributory with any other applicable insurance; (ii) be with carriers licensed to do business in the state where the Facility is located, with an A.M. Best rating of not less than A-VIII; and (iii) contain a clause that neither the insured nor the insurance carrier may cancel nor change to the other party's material detriment the insurance coverage required herein without first giving the other party at least thirty (30) days' prior written notice thereof. LESSOR and LESSEE shall deliver to each other certificates of insurance evidencing the maintenance of the insurance required herein within ten (10) days prior to the Effective Date and at such future times as requested by the other party in writing. If occurrence coverages are not available on commercially reasonable terms then the applicable policy may be on a claims made form with appropriate endorsements for "tail" coverages all to be reasonably satisfactory to the other party.

The parties hereto shall each procure an appropriate clause in, or endorsement on, any property insurance policy on the Leased Premises or any personal property, fixtures or equipment located thereon or therein, pursuant to which the insurer waives subrogation or consents to a waiver of right of recovery in favor of either party, its respective agents or employees. Each party hereby agrees that it will not make any claim against or seek to recover from the other or its agents or employees for any loss or damage to its property or the property of others resulting from fire or other perils covered by such property insurance regardless of the cause or origin of such loss or damage, including, but not limited to, the negligence of such other party or its agents or employees.

ARTICLE XI (Maintenance of Leased Premises)

The LESSEE agrees to maintain the Leased Premises including all plumbing, electrical, heating, cooling and ventilation systems within or serving exclusively the Leased Premises, in the same condition as they are at the Effective Date or as they may be put in during the Term of this Lease, reasonable wear and tear, damage by fire and other casualty excepted. LESSEE shall maintain and keep in force, at LESSEE's sole expense, all licenses, inspections and permits required by any governmental authority in connection with the occupation or use of the Leased Premises (other than a certificate of occupancy for the Premises). The LESSEE shall not knowingly permit the Leased Premises to be overloaded, damaged, stripped, or defaced, nor suffer any waste. LESSEE shall be solely responsible for the maintenance and upkeep of the interior of the Leased Premises, including within LESSEE's responsibilities, cleanliness, safety, timely removal of all trash and debris, and overall neatness and shall hire its own daily cleaning service.

ARTICLE XII (Alterations, Improvements and Trade Fixtures)

LESSEE shall not make any alterations, installations, changes, additions or improvements in or to the Leased Premises, except as expressly provided for in this Article. All such alterations and other improvements shall be made at LESSEE's sole expense and shall become the property of the LESSOR and be surrendered with the Leased Premises upon the expiration of this Lease, unless and to the extent that LESSOR shall specify to the contrary at the time that LESSOR consents thereto. LESSEE hereby agrees to indemnify and hold LESSOR harmless from any and all claims, costs, demands and expenses resulting from such work performed in the Leased Premises by LESSEE.

LESSEE's furniture, equipment and supplies shall remain the property of LESSEE, even if affixed to the Leased Premises, such furniture, equipment and supplies may be removed by LESSEE (and shall be so removed by LESSEE if so directed by LESSOR) at or prior to the expiration or prior termination of this Lease and LESSEE shall repair any damage to the Leased Premises resulting from such removal. All alterations, installations, changes, replacements, additions to or improvements upon the Leased Premises made without LESSOR's consent shall likewise at the election of LESSOR remain upon the Leased Premises and be surrendered, or removed, as aforesaid.

If LESSEE shall fail to remove any property or other items as aforesaid after five (5) days following the expiration or termination of this Lease then, at the election of LESSOR, LESSOR shall remove and store said property in a public storage warehouse or elsewhere at the LESSEE's risk and expense and in the name of the LESSEE. If LESSEE shall fail to remove any property or other items as aforesaid after five (5) days from the expiration or termination of this Lease, and if LESSEE shall be in default of the provisions of this Lease then, at the election of the LESSOR and after thirty (30) days written notice to LESSEE, LESSOR may sell at public or private sale any or all of such property, and shall apply the net proceeds of such sale to the payment of any sums due hereunder and the LESSOR shall not be liable to the LESSEE or any other person in any manner whatsoever by reason of such removal or sale.

LESSEE may, from time to time, at its sole cost and expense, pursuant to plans approved in advance in writing by LESSOR, which approval will not be unreasonably withheld, conditioned

or delayed, redecorate the Leased Premises and make non-structural alterations to the Leased Premises, provided that such alteration shall not impair the safety of the structure of the Leased Premises and shall be done in conformity with applicable government regulations. LESSEE shall not make any other alteration, improvement or addition to the Leased Premises, including, without limitation, any structural change in the Leased Premises, without first having obtained LESSOR's written consent thereto, which consent may not be unreasonably withheld, conditioned or delayed. All such work shall be done by a contractor approved by LESSOR, which approval will not be unreasonably withheld, conditioned or delayed, in accordance with all applicable laws and ordinances and the requirements of LESSOR's insurers. Any salvage from any such work shall belong to LESSEE, but all such installations, erections, alterations and changes, except for trade fixtures and equipment, shall belong to LESSOR and become part of the realty.

LESSOR, upon request of LESSEE, and at the expense of LESSEE, after LESSOR shall have given approval to any such plans, alterations, installations, erections or changes, shall execute and deliver such instruments as may be necessary to obtain any permit or license for same. LESSEE agrees to obtain and pay for any such required permit or license.

LESSEE shall not permit any mechanics' liens, or similar liens, to remain upon the Leased Premises for labor and material furnished to LESSEE in connection with work of any character performed or claimed to have been performed at the direction of LESSEE and shall cause any such lien to be released of record forthwith without cost to LESSOR. In the event LESSEE fails to cause any such lien to be released of record, LESSEE shall be deemed to be in default of this Lease.

ARTICLE XIII (Assignment-Subleasing)

Except as set forth herein, this Lease may only be assigned by LESSEE upon the prior written consent of LESSOR, which shall not be unreasonably withheld, delayed or conditioned. LESSEE shall have the right without LESSOR approval to sublet or assign the Leased Premises or any portion thereof to: (1) any successor of LESSEE resulting from a merger, consolidation, or other form of corporate reorganization of LESSEE or sale of all or substantially all of the assets of LESSEE; and (2) any entity controlled by, controlling or under common control with LESSEE. LESSEE shall not otherwise sublease the Leased Premises or assign this Lease without the prior consent of LESSOR, which consent may not be unreasonably withheld, conditioned or delayed, but in any such event LESSEE shall remain liable for all obligations of LESSEE hereunder and all other provisions of this Lease shall apply including but not limited to Article VIII. Any net profits, less any reasonable costs related to the subleasing of the Leased Premises, including but not limited to LESSEE's unamortized leasehold improvement expenses, attorney's fees, brokerage commissions and rent concessions, resulting from a sublease that requires LESSOR's consent shall be split evenly between LESSOR and LESSEE. LESSEE shall pay for the reasonable legal fees of LESSOR incurred in connection with the review of any request for and assignment or sublease, regardless of whether consent is granted.

ARTICLE XIV (Subordination and Non Disturbance)

This Lease shall be subject and subordinate to any mortgages, deeds of trust and other instruments in the nature of a mortgage on the Leased Premises, provided and on the condition that LESSEE and such mortgagee shall execute in recordable form a subordination, nondisturbance and attornment agreement in a form customary in commercial real estate lending, by which the LESSEE subordinates this lease to the lien of the mortgagee and such mortgagee agrees that in the event of foreclosure of such mortgage, LESSEE shall remain undisturbed under this Lease so long as LESSEE is not in default, beyond applicable notice and cure periods, of the terms and conditions hereunder.

ARTICLE XV (Underlying Condominium)

LESSOR represents and warrants that the Lease Premises hereunder comprise unit 2 of the Condominium which arises from the Master Deed referred to in Article II. All of the activities of the Condominium as such term is defined in the Master Deed and all of the rights and power in, to and with respect to the common areas and facilities of the Condominium are governed by the Declaration of Trust referred to in Article II. LESSEE acknowledges having received and reviewed a copy of the Master Deed and Declaration of Trust. LESSOR represents and warrants that the copy of the Master Deed and Declaration of Trust referenced in Article II and provided to LESSEE are true, correct and complete copies and the Master Deed and Declaration of Trust have not been amended or modified.

This Lease is subject to, and LESSEE accepts this Lease subject to all of the terms, covenants, provisions, conditions and agreements contained in the Master Deed and the matters to which the Master Deed is now or may hereafter be subject and subordinate. This Lease shall also be subject to, and LESSEE accepts this Lease also subject to any future amendments and supplements to the Master Deed hereafter made, provided that any such future amendment or supplement does not prevent or adversely affect the use of the Leased Premises or the common areas, in accordance with the terms of this Lease, increases the obligations of LESSEE or decrease its rights under this Lease or shorten the Term of this Lease and provided LESSEE has prior notice of any such amendment or supplement.

This Lease is subject to, and LESSEE accepts this Lease subject to all of the terms, covenants, provisions, conditions and agreements contained in the Declaration of Trust and the matters to which the Declaration of Trust is now or may hereafter be subject and subordinate. This Lease shall also be subject to, and LESSEE accepts this Lease also subject to any future amendments and supplements to the Declaration of Trust hereafter made, provided that any such future amendment or supplement does not prevent or adversely affect the use of the Leased Premises or the common areas, in accordance with the terms of this Lease, increase the obligations of LESSEE or decrease its rights under this Lease or shorten the Term of this Lease and provided LESSEE has prior notice of any such amendment or supplement.

Subject to the provisions hereof, LESSEE covenants and agrees, except as otherwise provided in this Lease, (a) not to do or suffer or permit any act or thing to be done or suffered which would or might cause the Master Deed and the rights of LESSOR thereunder to be cancelled, terminated or forfeited or cause LESSOR to become liable for any damages, claims or

penalties, or cause LESSOR to be or become in default of any of LESSOR's obligations thereunder; and (b) to defend LESSOR with counsel reasonably acceptable to LESSOR and to indemnify and hold LESSOR harmless from and against any and all liability, loss, damage, suits, penalties, claims and demands of every kind or nature (including, without being limited thereto, reasonable attorneys' fees and expenses by reason thereof) which LESSOR may incur or suffer, arising from the use, occupancy or management of the Leased Premises or of any business conducted therein, or from any work or thing whatsoever done or any condition created by or any other act or omission of LESSEE, its assignees or subtenants, or their respective employees, agents, contractors, visitors or licensees, in or about the Leased Premises or any other part of the Building or from a failure of LESSEE to observe the provisions of this Lease, the Master Deed of the Declaration of Trust. LESSOR shall provide to LESSEE a copy of any notice to LESSOR given by the Trustees, with respect to any act or omission of LESSEE which would give rise to any obligation or liability on LESSEE's part pursuant to the provisions hereof. Any such notice shall be sent to LESSEE immediately after receipt thereof by LESSOR, in order to give LESSEE an opportunity to cure any default caused by LESSEE under the Master Deed or Declaration of Trust. The covenants and obligations of this Article shall survive the termination or expiration of this Lease.

Subject to the provisions hereof, LESSOR covenants and agrees, except as otherwise provided in this Lease, (a) not to do or suffer or permit any act or thing to be done or suffered which would or might cause the Master Deed and the rights of LESSOR thereunder to be cancelled, terminated or forfeited or cause LESSEE to become liable for any damages, claims or penalties; and (b) to defend LESSEE with counsel reasonably acceptable to LESSEE and to indemnify and hold LESSEE harmless from and against any and all liability, loss, damage, suits, penalties, claims and demands of every kind or nature (including, without being limited thereto, reasonable attorneys' fees and expenses by reason thereof) which LESSEE may incur or suffer, arising from a failure of LESSOR to observe the provisions of this Lease, the Master Deed of the Declaration of Trust. LESSEE shall provide to LESSOR a copy of any notice to LESSEE given by the Trustees, with respect to any act or omission of LESSOR which would give rise to any obligation or liability on LESSEE's part pursuant to the provisions hereof. Any such notice shall be sent to LESSOR immediately after receipt thereof by LESSEE, in order to give LESSOR an opportunity to cure any default, caused by LESSOR under the Master Deed or Declaration of Trust. The covenants and obligations of this Article shall survive the termination or expiration of this Lease.

Notwithstanding anything contained in this Lease to the contrary, LESSEE agrees and understands that LESSOR shall have no obligation or responsibility whatsoever pursuant to this Lease or otherwise to provide or perform any service, repair, alteration or other obligation which is the obligation of Trustees to provide or perform pursuant to the provisions and terms of the Master Deed or Declaration of Trust. However, if LESSEE shall notify LESSOR that the Trustees are not supplying services to the Leased Premises as required under the Master Deed or Declaration of Trust, LESSOR, at LESSOR's sole cost and expense, will request Trustees to perform such services. LESSOR shall in no event be liable to LESSEE nor shall LESSEE's obligation under this Lease be impaired or reduced or the performance thereof excused because of any failure or delay on the part of Trustees in providing any services or in making any repairs or alterations, or in performing or observing any obligation of Trustees under the Master Deed or

Declaration of Trust whether or not LESSOR has a similar obligation under this Lease (but if LESSOR has a similar obligation, the foregoing shall not be deemed to release LESSOR from such obligation). If Trustees shall default in any of its obligations to LESSOR with respect to the Leased Premises, LESSOR shall, at LESSOR's sole cost and expense, enforce LESSOR's rights against Trustees (including, where appropriate pursuant to the terms of the Master Deed or Declaration of Trust, by arbitration or otherwise) with respect to the Leased Premises, in LESSOR's name; provided that LESSOR may not take any action which might, in the reasonable opinion of LESSOR, cause a forfeiture of LESSOR's interest in the Leased Premises. LESSOR agrees to cooperate with LESSEE in such action. In the event that LESSOR has not taken action to enforce such rights of LESSOR under the Master Deed or Declaration of Trust within ten (10) business days after written notice from LESSEE, LESSOR shall permit LESSEE to enforce LESSOR's rights against Trustees (including, where appropriate pursuant to the terms of the Master Deed or Declaration of Trust, by arbitration or otherwise) with respect to the Leased Premises, in LESSOR's name; provided that LESSEE may not take any action which might, in the reasonable opinion of LESSOR, cause a forfeiture of LESSOR's interest in the Leased Premises. LESSOR shall reimburse LESSEE for fifty percent (50%) of the out of pocket costs incurred by LESSEE with respect to such enforcement. LESSOR agrees to cooperate with LESSEE in such action, at LESSOR'S sole cost and expense. If Trustees shall default in the performance or observance of any of its agreements or obligations under the Master Deed or Declaration of Trust (including any obligation for the payment of money), LESSOR shall have no liability therefor to LESSEE unless LESSOR has a similar obligation pursuant to this Lease.

LESSEE acknowledges that LESSOR has an interest in the Leased Premises following the Term of this Lease, and as a result thereof, wishes the Leased Premises restored wherever possible if the Master Deed and Declaration of Trust is not effectively and fully cancelled, in the event of a fire, condemnation or other casualty. LESSEE therefore agrees that all rights in the Master Deed and Declaration of Trust to cancel the Master Deed and Declaration of Trust or to nullify a cancellation as therein provided, whether on behalf of Trustees, the LESSOR or the LESSEE, shall be solely vested in LESSOR whether such nullification rights exists by virtue of rebuilding the Leased Premises by the LESSOR and accepting an assignment of any insurance, condemnation or other casualty proceeds from Trustees.

If as a result of condemnation, fire or other casualty the Master Deed and Declaration of Trust is terminated, then this Lease shall simultaneously terminate and in the event any insurance or other casualty proceeds thereafter or thereupon are available to LESSOR pursuant to the Master Deed and Declaration of Trust, LESSEE shall have no right or claim whatsoever to such funds or any portion thereof it being understood that such funds shall belong solely to LESSOR, except to the extent specifically set forth herein.

ARTICLE XVI (Access)

The LESSOR or agents of the LESSOR may, at reasonable times with twenty-four (24) hours notice, except in cases of emergency, enter to inspect or make repairs and alterations as LESSOR should elect to do and may show the Leased Premises to others, and at any time within six (6) months before the expiration of the Term, may affix to any suitable part of the Leased Premises a notice for letting or selling Leased Premises and keep the same so affixed without hindrance or molestation. LESSEE agrees that said third parties shall be granted access to the Leased Premises upon reasonable notice to inspect such wells.

ARTICLE XVII (Compliance with Laws)

LESSEE shall make all non-structural repairs, alterations, additions or replacements to the Leased Premises required by any law or ordinance or any order or regulation of any public authority; keep the Leased Premises equipped with all safety equipment so required; pay all municipal, county, or state taxes assessed against personal property of any kind of the LESSEE; and comply with the orders, regulations, variances, licenses and permits of or granted by governmental authorities with respect to zoning, building, fire, health and other codes, regulations, ordinances or laws applicable to the Leased Premises, and the condition, use or occupancy thereof, except that LESSEE may defer compliance so long as the validity of any such order, regulation, code, ordinance or law shall be contested by LESSEE in good faith and by appropriate legal proceedings, provided LESSEE first gives LESSOR appropriate assurance reasonable satisfactory to LESSOR against any loss, cost or expense on account thereof and either a cash deposit or a bond equal to any potential loss, cost or expense to LESSOR, and provided such contest shall not subject LESSOR to criminal penalties or civil sanctions, loss of property or material civil liability.

ARTICLE XVIII (Indemnification and Liability)

Indemnification by LESSEE. Upon notice and demand by LESSOR, LESSEE agrees to indemnify, defend and hold LESSOR and its shareholders, directors, managers, members, officers, employees, other agents and affiliates (“LESSOR Indemnitees”) harmless from and against any and all losses, injuries, claims, demands, liabilities, obligations, suits, penalties, forfeitures, costs and expenses of every type or kind, including reasonable attorneys’ fees actually incurred, disbursements and costs of investigation which are imposed upon, incurred by or asserted against LESSOR Indemnitees to the extent resulting from (i) the negligent act or omission or willful misconduct of LESSEE or any officer, employee or agent under the control or supervision of LESSEE, (ii) any injury to any party occurring at the Leased Premises, (iii) the violation of any applicable law, regulation or rule by LESSEE or any officer, employee or agent under the control or supervision of LESSEE or (iv) the violation by LESSEE of any provision of this Lease, except to the extent such claims, demands, causes of action, suits, proceedings or liabilities are attributable to the negligence or willful misconduct of any of the LESSOR Indemnitees.

Indemnification by LESSOR. Upon notice and demand by LESSEE, LESSOR agrees to indemnify, defend and hold LESSEE and its shareholders, directors, officers, employees, other agents and affiliates (“LESSEE Indemnitees”) harmless from and against any and all losses, injuries, claims, demands, liabilities, obligations, suits, penalties, forfeitures, costs or expenses of every type or kind, including reasonable attorneys’ fees actually incurred, disbursements and costs of investigation which are imposed upon, incurred by or asserted against LESSEE Indemnitees to the extent resulting from (i) the negligent act or omission or willful misconduct of LESSOR or any officer, employee or agent under the control or supervision of LESSOR, (ii) the violation of any law, regulation or rule by LESSOR or any officer, employee or agent under the control or supervision of LESSOR, except to the extent such claims, demands, causes of action, suits, proceedings or liabilities are attributable to the negligence or willful misconduct of any of the LESSEE Indemnitees.

Any party seeking indemnification shall give prompt written notice to the other of such claim, but the failure to give such notice shall not affect the right to indemnification except to the extent there is actual prejudice from such delay. The indemnifying party shall be entitled to assume the defense with counsel of its selection, and any further costs of legal defense of the indemnified party shall be borne by the indemnified party. The indemnified party shall cooperate fully with the indemnifying party in the defense of the Claim. The indemnifying party may settle any such indemnified Claim on terms satisfactory to the indemnifying party provided that such settlement does not include restrictions upon the business or operations of the indemnified party.

Survival. The provisions of this Article XVIII shall survive the expiration or earlier termination of this Agreement.

ARTICLE XIX [Reserved]

ARTICLE XX (Casualty and Taking)

Should a substantial portion of the Leased Premises be substantially damaged by fire or other casualty, or be taken by eminent domain, the LESSEE may elect to terminate this lease by giving written notice of that effect to LESSOR within thirty (30) days after such occurrence. Any apportionment or adjustment of Rent shall be as of the time of termination. As used in this Article, the word "substantial" shall mean twenty-five percent (25%) or more of the Leased Premises. When such fire, casualty, or taking renders any portion of the Leased Premises unsuitable for their intended use, a just and proportionate abatement of Rent shall be made and the LESSOR shall, forthwith and diligently, restore the Leased Premises to its prior condition, suitable for its intended use as contemplated under the Lease.

Without limitation, in no event, however, need LESSOR restore any portion of the Condominium which is not necessary to access the Leased Premises and not necessary for the use and enjoyment of the Leased Premises by the LESSEE.

ARTICLE XXI (Eminent Domain)

If the whole or any part of the Leased Premises shall be taken or condemned for public or quasi-public use or purpose by any competent authority, or conveyed in lieu thereof (a "Taking"), LESSEE shall have no claim against LESSOR and shall not have any claim or right to any portion of any amount that may be awarded as damages or paid as a result of such taking; and all rights of the LESSEE to damages therefor, if any, are hereby assigned by the LESSEE to the LESSOR. Upon such taking, if the Term of this Lease shall terminate, LESSEE shall have no claims against the LESSOR for the value of any unexpired term of this Lease. LESSEE, however, shall be entitled to claim, prove and receive in a condemnation proceeding such awards as may be allowed for damages to or the Taking of fixtures, equipment and other personal property installed by it and which is herein permitted to remove from the Leased Premises at the end of the Term and any moving expenses, but only if such awards shall be separately awarded in addition to (and not out of or in diminution of) the award made to LESSOR.

ARTICLE XXII (Default and Bankruptcy)

In the event that:

- (a) The LESSEE shall fail to pay any installment of Rent, or other sum herein specified, and such default shall continue for five (5) business days after written notice thereof; or
- (b) The LESSEE shall default in the observance or performance of any other of the LESSEE'S covenants, agreements, or obligations hereunder, and such default shall not be corrected within twenty (20) days after written notice thereof, or if such default is of such a nature that it cannot be completely remedied within said period of twenty (20) days if LESSEE shall not within twenty (20) days institute and thereafter diligently prosecute to completion all steps necessary to remedy the same; or
- (c) The LESSEE shall abandon the Leased Premises and cease paying any Rent due under this Lease; or
- (d) The LESSEE shall become insolvent, or shall make a transfer in fraud of creditors, or shall make an assignment for the benefit of creditors; or
- (e) The LESSEE shall file or there shall be filed against LESSEE a petition in bankruptcy or reorganization or for an arrangement for the benefit of creditors under any Article or chapter of the United States bankruptcy laws or under any similar law or statute of any State; or
- (f) A receiver or trustee shall be appointed for all or substantially all of the assets of LESSEE.

Then a default under this Lease shall be deemed to exist and the LESSOR may terminate this Lease by written notice to LESSEE, specifying a date not less than five (5) days after the giving of such notice on which this Lease shall terminate and this Lease shall come to an end on the date specified therein as fully and completely as if such date were the date herein originally fixed for the expiration of the Term of this Lease and LESSEE will then quit and surrender the Leased Premises to LESSOR, but LESSEE shall remain liable as hereinafter provided. In the event LESSEE fails to surrender the Leased Premises, the LESSOR shall re-enter and take complete possession of the Leased Premises, and remove the LESSEE'S effects, without prejudice to any remedies which might be otherwise used for arrears of any Rent or other default.

The LESSEE covenants and agrees, notwithstanding any termination of this Lease as aforesaid or any entry or re-entry by the LESSOR, whether by summary proceedings, termination, or otherwise, to pay and be liable for on the days originally fixed herein for the payment thereof amounts equal to the several installments of rent and other charges reserved as they would, under

the terms of this lease, become due if this lease had not been terminated or if the LESSOR had not entered or re-entered, as aforesaid, and whether the Leased Premises be relet or remain vacant, in whole or in part, or for a period less than the remainder of the term, and for the whole thereof; but in the event the Leased Premises be relet by the LESSOR, the LESSEE shall be entitled to a credit in the net amount of rent received by the LESSOR in reletting, after deduction of all reasonable expenses incurred in reletting the Leased Premises (including, without limitation, commercially reasonable remodeling costs, brokerage fees, and the like), and in collecting the rent in connection therewith. and the LESSEE hereby waives, to the extent permitted by applicable law, any obligation the LESSOR may have to mitigate the LESSOR's damages; provided, however, that after the termination of this lease as a result of an event of default, the LESSOR shall use reasonable efforts to re-let the demised premises. As an alternative, at the election of the LESSOR, the LESSEE will upon such termination pay to the LESSOR, as damages, such a sum as at the time of such termination represents the amount of the excess, if any, of the then value of the total rent and other benefits which would have accrued to the LESSOR under this lease for the remainder of the lease term if the lease terms had been fully complied with by the LESSEE over and above the then cash rental value (in advance) of the premises for the balance of the term. To induce the LESSOR to enter into this lease, each party hereby waives any right to trial by jury in any action, proceeding or counterclaim brought by the other party on any matter whatsoever arising out of or in any way connected with this Lease, the relationship of the LESSOR and the LESSEE and the LESSEE's use and occupancy of the Leased Premises and/or any claim of injury or damage.

Nothing contained in this Lease shall, however, limit or prejudice the right of LESSOR to prove for and obtain in proceeding under any federal or state law relating to bankruptcy or reorganization or arrangement, an amount equal to the maximum allowed by any statute or rule of law in effect at the time when, and governing the proceedings in which, the damages are to be proved, whether or not the amount be greater than the amount of the loss or damages referred to above.

Any and all rights and remedies which LESSOR may have under this Lease, and at law and equity, shall be cumulative and shall not be deemed inconsistent with each other, and any two or more of all such rights and remedies may be exercised at the same time insofar as permitted by law.

Any consent or permission by LESSOR to any act or omission which otherwise would be a breach of any covenant or condition herein, or any waiver by LESSOR of the breach of any covenant or condition herein, shall not in any way be held or construed (unless expressly so declared) to operate so as to impair the continuing obligation of any covenant or condition herein, or except as to the specific instance, operate to permit similar acts or omissions. The failure of LESSOR to seek redress for violation or to insist upon the strict performance of, any covenant or condition of this Lease shall not be deemed a waiver of such violation nor prevent a subsequent act, which would have originally constituted a violation, from having all the force and effect of an original violation. The receipt by LESSOR of Rent with knowledge of the breach of any covenant of this Lease shall not be deemed to have been a waiver of such breach or covenant of this Lease and shall not be deemed to have been a waiver of such breach by LESSOR unless such waiver is in writing signed by the LESSOR. No consent or waiver, express or implied, by LESSOR to or of any breach of any agreement or duty shall be construed as a waiver or consent to or of any other breach of the same or any other agreement or duty.

ARTICLE XXIII (Notice)

Any notice from the LESSOR to the LESSEE relating to the Leased Premises or to the occupancy thereof, shall be deemed duly served as of the date sent, by registered or certified mail, return receipt requested, postage prepaid, or via hand delivery or via a recognized next business day delivery service and addressed as follows:

If to the LESSEE: 175 Portland Street, 4th Floor
 Boston, MA 02114
 Attn: Patricia L. Allen, Chief Financial Officer

with a copy to

If to the LESSOR: _____

with a copy to

ARTICLE XXIV (Surrender)

The LESSEE shall at the expiration or other termination of this Lease remove all LESSEE'S goods and effects from the Leased Premises (including, without hereby limiting the generality of the foregoing, all signs and lettering affixed or painted by the LESSEE, either inside or outside the Leased Premises). LESSEE shall deliver to the LESSOR the Leased Premises and all keys, locks thereto, and other fixtures connected therewith and all alterations and additions made to or upon the Leased Premises, in the same condition as they were at the Effective Date, or as they were put in during the term hereof, reasonable wear and tear and damage by fire or other casualty only excepted. In the event of the LESSEE'S failure to remove any of the LESSEES' property from the Leased Premises, LESSOR is hereby authorized, without liability to LESSEE for loss or damage thereto, and at the sole risk of LESSEE, to remove and store any of the property at LESSEE'S expense, or to retain same under LESSOR'S control or to sell at public or private sale, without notice, any or all of the property not so removed and to apply the net proceeds of such sale to the payment of any sum due thereunder, or to destroy such property.

For each day that is beyond thirty (30) days after the expiration of the Term, or the earlier termination of this Lease, and prior to LESSEE'S performance of its obligations to yield up the Leased Premises under this Article, LESSEE shall pay to LESSOR as Rent an amount equal to one hundred ten percent (110%) of the Base Rent computed on a daily bases, together with all additional rent payable with respect to each such day.

ARTICLE XXV (Intentionally Omitted)

ARTICLE XXVI (Signage)

LESSOR shall provide LESSEE specification for building lobby standard signage. LESSEE shall be responsible for all costs related thereto. LESSOR shall obtain any consents or approvals of the Trustees required for such signage.

ARTICLE XXVII (Brokerage)

Both parties warrant and represent that they have had no dealing with any broker or agent in connection with this Lease other than Colliers International, as Tenant's broker, and Kimball Borgo Real Estate, as Landlord's broker, and each party covenants to defend, hold harmless and indemnify the other party from and against any and all cost, expense or liability for any compensation, commissions and charges claimed by any broker or agent with respect to a party's dealings in connection with this Lease or the negotiation thereof. Colliers International and Kimball Borgo Real Estate shall be paid a commission by LESSOR pursuant to a separate agreement.

ARTICLE XXVIII (Other Provisions)

A. Intentionally Omitted:

B. Lease Not to be Recorded: LESSEE agrees that it will not record this Lease. Both parties shall execute and deliver a Notice of Lease and record same in such form, if any, as may be permitted by applicable statute. If this Lease is terminated before the Term expires, the parties shall execute, deliver and record an instrument acknowledging such fact and the actual date of termination of this Lease.

C. Applicable Law and Construction: This Lease shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts. If any term, covenant, condition or provision of this Lease or the application thereof to any person or circumstances shall be declared invalid, or enforceable by the final ruling of a court of competent jurisdiction having final review, the remaining terms, covenants, conditions and provisions of this Lease and their application to persons or circumstances shall not be affected thereby and shall continue to be enforced and recognized as valid agreements of the parties, and in the place of such invalid or unenforceable provisions, there shall be substituted a like, but valid and enforceable provision which comports to the findings of the aforesaid court and most nearly accomplished the original intention of the parties.

D. No Other Agreements: There are no oral or written agreements between LESSOR and LESSEE affecting this Lease. This Lease may be amended, and the provisions hereof may be waived or modified, only by instruments in writing executed by LESSOR and LESSEE.

E. No Representations by LESSOR: Neither LESSOR nor any agent of LESSOR has made any representations or promises with respect to the Leased Premises except as herein are expressly set forth and no rights, privileges, easements or licenses are granted to LESSEE except as herein expressly set forth.

F. **Headings and Article Numbers:** The headings and article numbers are contained herein are for convenience only and shall not be considered in construing this lease.

G. **“LESSOR” and “LESSEE”:** The words “LESSOR” and “LESSEE” appearing in this Lease shall be construed to mean those named in Article One and their respective heirs, executors, administrators, successors and assigns and those claiming through or under them respectively. If there be more than one LESSEE, the obligations imposed by this Lease upon LESSEE shall be joint and several.

H. **Mortgagee’s Consent:** This Lease is strictly contingent on the approval of LESSOR’s mortgagees. LESSOR agrees to obtain such consent within five business days after receipt of an executed counterpart of this Lease from LESSEE. If LESSOR has not provided a copy of such written consent to LESSEE within such 5 business day period, LESSEE may terminate this Lease by written notice to LESSOR. LESSOR shall use commercially reasonable efforts to provide a so-called subordination and non-disturbance agreement from LESSOR’s mortgagees.

IN WITNESS WHEREOF, the LESSOR and LESSEE have hereunto set their hands and common seals this 30th day of March 2015.

LESSOR:

Contour LLC

By: /s/ Bin Chen

Name: Bin Chen

Title: Director

LESSEE:

Zafgen, Inc.

By: /s/ Patricia L. Allen

Name: Patricia L. Allen

Title: CFO

Exhibit A
(Leased Property Description)

EXHIBIT "A"
DESCRIPTION OF THE LAND

Real property in the City of Boston, County of Suffolk, Commonwealth of Massachusetts, described as follows:

Unit No. 2.

Condominium Name: 175 Portland Street Condominium

A. That unit of the condominium referred to above, submitted to the provisions of Massachusetts General Laws, Chapter 183A, by virtue of Master Deed dated November 29, 2006, and recorded with the Suffolk County Registry of Deeds in Book 40836, Page 316, as amended of record.

B. Together with the undivided percentage interest appurtenant to said unit in the common areas or facilities of said Condominium as set forth in said Master Deed.

C. Easements appurtenant to said Unit:

- (1) for the existence and maintenance of encroachments within the common areas or facilities;
- (2) for the use of utility and other common facilities; and
- (3) for other purposes

TAX PARCEL ID: 0301649004

PROPERTY ADDRESS: 175 Portland Street, Unit 2, Boston, Massachusetts 02114

Certification

I, Thomas E. Hughes, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2015 of Zafgen, 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 my 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 14, 2015

/s/ Thomas E. Hughes
Thomas E. Hughes
Chief Executive Officer
(Principal Executive Officer)

Certification

I, Patricia L. Allen, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2015 of Zafgen, 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 my 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 14, 2015

/s/ Patricia L. Allen
Patricia L. Allen
Chief Financial Officer
(Principal Financial Officer)

**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 on Form 10-Q of Zafgen, Inc. (the "Company") for the period ended March 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to his or her knowledge:

- 1) the Report which this statement accompanies fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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 14, 2015

/s/ Thomas E. Hughes
Thomas E. Hughes
Chief Executive Officer
(Principal Executive Officer)

Date: May 14, 2015

/s/ Patricia L. Allen
Patricia L. Allen
Chief Financial Officer
(Principal Financial Officer)

