
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): August 11, 2015

Zafgen, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-36510
(Commission
File Number)

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

175 Portland Street, 4th Floor
Boston, Massachusetts
(Address of principal executive offices)

02114
(Zip Code)

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

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition.

On August 11, 2015, Zafgen, Inc. announced its financial results for the second quarter of 2015. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K and is incorporated by reference herein.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Zafgen, Inc. on August 11, 2015, furnished herewith.

SIGNATURES

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

Date: August 11, 2015

ZAFGEN, INC.

By: /s/ Thomas E. Hughes
Thomas E. Hughes, Ph.D.
Chief Executive Officer

EXHIBIT INDEX

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Contacts:

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Zafgen Reports Second Quarter 2015 Financial Results

*Quarter Highlighted by Completion of Enrollment in bestPWS Phase 3 Clinical Trial—Six Month
Data on Track for Release in Early Q1 2016*

*On Track to Report Data from Ongoing ZAF-203 Clinical Trial in Severe Obesity Complicated by
Type 2 Diabetes in Late 2015/Very Early 2016*

Ends Quarter with Cash and Marketable Securities of \$220 Million

BOSTON, Mass., August 11, 2015 – Zafgen, Inc. (Nasdaq: ZFGN), a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by obesity and complex metabolic disorders, today announced its second quarter 2015 financial results.

Zafgen Q2 2015 Business Highlights

- Announced completion of enrollment in the bestPWS (Beloranib Efficacy, Safety and Tolerability in Prader-Willi syndrome) Phase 3 clinical trial in patients with a rare genetic disorder, Prader-Willi syndrome (PWS) and has exceeded the original patient recruitment target of 102 patients, having enrolled 108 PWS patients in the trial across 15 sites in the United States. The objective of the study is to evaluate the efficacy and safety of beloranib in PWS patients over six months of randomized treatment, followed by a six-month open label extension. Release of six-month randomized top-line results is expected to occur early in the first quarter of 2016.
- The Company has enrolled greater than 95% of its enrollment target of 150 patients in the Phase 2b clinical trial (ZAF-203) to establish the long-term weight loss benefits of MetAP2 inhibitor treatment with beloranib in patients with severe obesity complicated by type 2 diabetes. The Company began randomized treatment in December 2014 and expects to complete enrollment in August 2015. The Company remains on track to release six-month interim data in a subset of 95 patients in late 2015 or very early 2016.

“We are very pleased with our accomplishments for the second quarter of 2015. We are executing very well on two important clinical trials, the bestPWS Phase 3 clinical trial in PWS and the ZAF-203 Phase 2b clinical trial in patients with severe obesity complicated by type 2 diabetes,” said Dr.

Thomas Hughes, Chief Executive Officer of Zafgen. “We are also growing our company and continuing to attract very high caliber employees as we head towards commercialization.”

“With enrollment completed in our bestPWS Phase 3 trial this past quarter and enrollment now greater than 95% in our Phase 2b trial (ZAF-203) in patients with severe obesity complicated by type 2 diabetes, we remain on track to release data in late 2015 or very early 2016 for both of these clinical trials,” said Dr. Dennis Kim, Chief Medical Officer of Zafgen. “The bestPWS trial is the first Phase 3 trial conducted for a potential treatment of hyperphagia and weight loss in this hard to treat patient population. We are also extremely excited to see the six-month interim data from the ZAF-203 clinical trial which will provide our first look at the effects of beloranib treatment on both body weight and glycemic control chronically in the setting of type 2 diabetes, an important and vexing co-morbidity of obesity.”

“We are pleased to have a strong cash position that is enabling us to meet our 2015 goals, ending the current quarter with a total cash position of approximately \$220 million,” said Patricia Allen, Chief Financial Officer of Zafgen. “This is an incredibly productive and exciting time for Zafgen and we are investing this capital in the development of beloranib in multiple indications, along with advancing our ZGN-839 program in nonalcoholic steatohepatitis, or NASH, and our second-generation MetAP2 inhibitors for obesity. We are also expanding our organization to deliver on our multiple development programs and establish our commercial operations in anticipation of approval of beloranib in PWS.”

Second Quarter 2015 Financial Results

Cash and Cash Equivalents and Marketable Securities

As of June 30, 2015, the Company had cash and cash equivalents and marketable securities totaling \$220.1 million.

Net Loss

The Company reported a net loss for the second quarter of 2015 of \$17.8 million, or \$0.66 per share, compared to a \$6.4 million net loss, or \$2.96 per share, for the second quarter of 2014, which was the quarter that the Company completed its initial public offering. The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 27,011,960 for the second quarter of 2015, compared to 2,178,465 for the second quarter of 2014.

Research and Development Expenses

Research and development expenses for the second quarter of 2015 were \$12.5 million, compared to \$4.7 million for the second quarter of 2014. The increase in research and development expenses for the quarter ended June 30, 2015 as compared to the second quarter of 2014 was primarily due to increased costs associated with the advancement of the Company’s beloranib program, ZGN-839 and our second-generation MetAP2 inhibitors, as well as personnel related costs.

General and Administrative Expenses

General and administrative expenses for the second quarter of 2015 were \$5.1 million, compared to \$1.3 million for the second quarter of 2014. The increase in general and administrative expenses for the quarter ended June 30, 2015 as compared to the second quarter of 2014 was primarily due to increased personnel related costs, increased public company costs, increased travel and other related costs, and increased professional fees, primarily commercial-readiness activities related to PWS.

2015 Financial Guidance

The Company continues to expect that its cash and cash equivalents and marketable securities balance will be greater than \$145.0 million at December 31, 2015.

Conference Call Information

Zafgen will host an investor conference call today, August 11, 2015 at 4:30 p.m., Eastern Time, to discuss the Company's second quarter 2015 results as well as other forward-looking information about Zafgen's business. Investors and other interested parties may participate by dialing 844-824-7428 in the United States or 973-500-2177 outside the United States. The call will also be webcast live on the Company's website at <http://ir.zafgen.com/events.cfm>. You can access the replay for seven days by dialing 855-859-2056 in the United States or 404-537-3406 outside the United States and referencing conference ID number 3095656.

About Beloranib

Beloranib is a novel, first-in-class injectable small molecule therapy with a unique mechanism of action that reduces hunger while stimulating the use of stored fat as an energy source. Beloranib is a potent inhibitor of MetAP2, an enzyme that modulates the activity of key cellular processes that control metabolism. MetAP2 inhibitors work, at least in part, by directing MetAP2 binding to cellular stress mediators, and, thus, reducing the tone of signals that drive lipid synthesis by the liver and fat storage throughout the body. In this manner, MetAP2 inhibition increases metabolism of fat as an energy source. Zafgen holds exclusive worldwide rights (exclusive of South Korea) for the development and commercialization of beloranib. Zafgen exclusively licensed beloranib from Chong Kun Dang Pharmaceutical Corporation (CKD Pharma) of South Korea.

About Prader-Willi Syndrome (PWS)

Prader-Willi syndrome (PWS), the most common known genetic cause of life-threatening obesity, results in constant and unrelenting hunger that drives patients with PWS to engage in problematic hunger-related behaviors and to gain excessive weight. As a result, many of those affected with PWS become morbidly obese and suffer significant mortality. Currently, there is no cure for this disease. Although the cause of PWS is complex, it results from a deletion or loss of function of a cluster of genes on the 15th chromosome. PWS typically causes low muscle mass and function, short stature, incomplete sexual development, and a chronic feeling of hunger that, when coupled with a metabolism that utilizes drastically fewer calories than normal, can lead to excessive eating and life-threatening obesity. PWS occurs in males and females equally and in all races, with the same incidence around the world. Prevalence estimates have ranged from 1:8,000 to 1:50,000.

About Hypothalamic Injury-Associated Obesity (HIAO)

When the hypothalamus, a small area of the brain responsible for many hormonal and metabolic functions including the desire to eat, is injured, a syndrome of intractable weight gain can ensue, resulting in severe obesity and a poor quality of life. This rare and complicated medical condition occurs in affected individuals most commonly due to a benign central nervous system tumor called craniopharyngioma, which presents as a mass in or near the hypothalamus. When the tumor is treated with surgical resection and radiation therapy, the hypothalamus often becomes severely damaged and/or dysfunctional, which can result in loss of appetite control and reduction in metabolic rate. Craniopharyngioma-associated obesity incidence estimates have ranged from 0.13 to 0.17 per 100,000 per year. Other comparably located tumors such as pituitary macroadenoma, medulloblastoma, and pineal germinoma, affect a smaller number of patients, but patients with these tumors can have a similar clinical presentation with respect to obesity. Rarely, this form of obesity also has been reported in cases of head trauma or stroke leading to injury to the hypothalamus.

About Zafgen

Zafgen (NASDAQ: ZFGN) 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 MetAP2 pathway. Beloranib, Zafgen'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 (PWS), hypothalamic injury-associated obesity (HIAO), 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, or NASH, and abdominal obesity, as well as second-generation MetAP2 inhibitors. Zafgen aspires to improve the lives of patients through targeted treatments and has assembled a team accomplished in bringing therapies to patients with both rare and prevalent metabolic diseases.

Safe Harbor Statement

Various statements in this release concerning Zafgen's future expectations, plans and prospects, including without limitation, Zafgen's expectations regarding beloranib as a treatment for PWS, HIAO and other forms of severe obesity, its expectations with respect to the timing and success of its clinical trials of beloranib and other product candidates, its plans regarding commercialization of beloranib and its expectations relating to available cash and cash equivalents and marketable securities at the end of 2015 may constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements can be identified by terminology such as "anticipate," "believe," "could," "could increase the likelihood," "estimate," "expect," "intend," "is planned," "may," "should," "will," "will enable," "would be expected," "look forward," "may provide," "would" or similar terms, variations of such terms or the negative of those terms. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including, without limitation, Zafgen's ability to successfully demonstrate the efficacy and safety of its product candidates, the pre-clinical and clinical results for its product candidates, which may not support further development of such product candidates, actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials, obtaining, maintaining and protecting intellectual property, Zafgen's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties, competition from others developing products for similar uses, Zafgen's ability to manage operating expenses, Zafgen's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and new business initiatives, Zafgen's dependence on third parties for development, manufacture, marketing, sales and distribution of products, the outcome of litigation, and unexpected expenditures, as well as those risks more fully discussed in the section entitled "Risk Factors" in Zafgen's most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in Zafgen's subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Zafgen's views only as of today and should not be relied upon as representing its views as of any subsequent date. Zafgen explicitly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	12,526	4,695	22,741	7,970
General and administrative	5,084	1,291	8,109	2,537
Total operating expenses	<u>17,610</u>	<u>5,986</u>	<u>30,850</u>	<u>10,507</u>
Loss from operations	<u>(17,610)</u>	<u>(5,986)</u>	<u>(30,850)</u>	<u>(10,507)</u>
Other income (expense):				
Interest income	63	1	102	1
Interest expense	(213)	(443)	(426)	(445)
Foreign currency transaction gains (losses), net	4	28	(54)	93
Total other income (expense), net	<u>(146)</u>	<u>(414)</u>	<u>(378)</u>	<u>(351)</u>
Net loss	<u>(17,756)</u>	<u>(6,400)</u>	<u>(31,228)</u>	<u>(10,858)</u>
Accretion of redeemable convertible preferred stock to redemption value	—	(43)	—	(92)
Net loss attributable to common stockholders	<u>\$ (17,756)</u>	<u>\$ (6,443)</u>	<u>\$ (31,228)</u>	<u>\$ (10,950)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.66)</u>	<u>\$ (2.96)</u>	<u>\$ (1.19)</u>	<u>\$ (7.51)</u>
Weighted average common shares outstanding, basic and diluted	<u>27,011,960</u>	<u>2,178,465</u>	<u>26,316,619</u>	<u>1,457,931</u>

Zafgen, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 83,573	\$ 58,103
Marketable securities	136,547	57,359
Tax incentive receivable	367	391
Prepaid expenses and other current assets	1,143	1,345
Total current assets	221,630	117,198
Property and equipment, net	215	79
Tax incentive receivable	673	—
Other assets	84	242
Total assets	<u>\$ 222,602</u>	<u>\$ 117,519</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,297	\$ 2,348
Accrued expenses	4,441	3,172
Notes payable, current	2,820	1,381
Total current liabilities	11,558	6,901
Notes payable, net of discount, long-term	4,851	6,177
Total liabilities	<u>16,409</u>	<u>13,078</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; \$0.001 par value; 5,000,000 shares authorized at June 30, 2015 and December 31, 2014; no shares issued and outstanding at June 30, 2015 and December 31, 2014	—	—
Common stock, \$0.001 par value; 115,000,000 shares authorized at June 30, 2015 and December 31, 2014; 27,117,822 and 22,879,160 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	27	23
Additional paid-in capital	342,839	209,838
Accumulated deficit	(136,613)	(105,385)
Accumulated other comprehensive loss	(60)	(35)
Total stockholders' equity	206,193	104,441
Total liabilities and stockholders' equity	<u>\$ 222,602</u>	<u>\$ 117,519</u>

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K which includes the audited consolidated financial statements for the year ended December 31, 2014.