
**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): November 10, 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 November 10, 2015, Zafgen, Inc. announced its financial results for the third 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 November 10, 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: November 10, 2015

ZAFGEN, INC.

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Zafgen, Inc. on November 10, 2015, furnished herewith.

Zafgen Announces Third Quarter 2015 Financial Results

Company to Host Conference Call at 4:30 PM Eastern Time to Review Progress with Beloranib Program

Ends Quarter with Cash, Cash Equivalents and Marketable Securities of \$204 Million; Increases Year-End Cash Guidance to Greater than \$180 Million

BOSTON – November 10, 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 third quarter 2015 financial results and provided an update on the Company's clinical development programs, including the pivotal Phase 3 ZAF-311 bestPWS clinical trial of beloranib in Prader-Willi syndrome (PWS) and the Phase 2b ZAF-203 clinical trial of beloranib in severe obesity complicated by type 2 diabetes.

Clinical Update

- In October, Zafgen announced that the U.S. Food and Drug Administration (FDA) had placed its beloranib program on partial clinical hold and that the Company had elected to close the randomized portion of its pivotal Phase 3 ZAF-311 bestPWS clinical trial and proceed with the efficacy and safety data analysis. The Company also elected to close its Phase 2b ZAF-203 clinical trial and proceed to data analysis. The Company continues to expect that it will report top-line data from both clinical trials in the first quarter of 2016.
- As previously reported, with newly implemented safety screening measures for thromboembolic disease, Zafgen is continuing its six-month open label extension (OLE) of the pivotal Phase 3 ZAF-311 bestPWS clinical trial in PWS to obtain important ongoing efficacy and safety data. The Company continues to offer an open-ended, unblinded extension study after patients have completed six months of OLE.

“We are focused on advancing our understanding of the potential efficacy and safety of beloranib in complex metabolic disorders, including PWS, and remain committed to the continued development of this promising program,” said Dr. Thomas Hughes, Chief Executive Officer of Zafgen. “The results from the pivotal Phase 3 ZAF-311 bestPWS and Phase 2b ZAF-203 clinical trials, together with the insights we are gaining from our thromboembolic disease screening and monitoring measures, will be critical in determining the potential benefit-risk profile for beloranib and next steps for the program, including the design of our second Phase 3 clinical trial for beloranib in PWS, ZAF-312.”

“Our newly implemented safety screening measures are progressing well as patients begin to resume open-label treatment in our ZAF-311 bestPWS clinical trial, with a continued focus on patient safety,” said Dr. Dennis Kim, Chief Medical Officer of Zafgen. “Resuming open-label treatment allows us to continue to provide beloranib as a potential treatment option to meet the urgent unmet medical need of patients with PWS, a life-threatening and complex rare disorder that severely impacts the quality of life of both patients and their families.”

Third Quarter 2015 Financial Results

“Our balance sheet remains strong,” said Patricia Allen, Chief Financial Officer of Zafgen. “With the revised beloranib development timeline and our anticipated cash burn rate, we now expect that our cash, cash equivalents and marketable securities balance at the end of calendar year 2015 will be greater than \$180 million.”

Cash, Cash Equivalents and Marketable Securities

As of September 30, 2015, the Company had cash, cash equivalents and marketable securities totaling \$204.0 million.

Net Loss

The Company reported a net loss for the third quarter of 2015 of \$19.9 million, or \$0.73 per share, compared to a net loss of \$14.7 million, or \$0.65 per share, for the third quarter of 2014. The weighted average common shares outstanding (basic and diluted) used to compute net loss per share were 27,138,667 for the third quarter of 2015, compared to 22,707,012 for the third quarter of 2014.

Research and Development Expenses

Research and development expenses for the third quarter of 2015 were \$14.2 million, compared to \$12.1 million for the third quarter of 2014. The increase in research and development expenses for the quarter ended September 30, 2015 as compared to the quarter ended September 30, 2014 was primarily due to increased costs associated with the advancement of the Company’s beloranib program, ZGN-839 and second-generation MetAP2 inhibitors, as well as personnel related costs. Partially offsetting these results was a \$6.7 million licensing fee, primarily to Chong Kun Dang Pharmaceutical Corporation (CKD Pharma) related to the initiation of the Company’s Phase 3 ZAF-311 bestPWS clinical trial, incurred in the quarter ended September 30, 2014.

General and Administrative Expenses

General and administrative expenses for the third quarter of 2015 were \$5.5 million, compared to \$2.3 million for the third quarter of 2014. The increase in general and administrative expenses for the quarter ended September 30, 2015 as compared to the quarter ended September 30, 2014 was primarily due to increased personnel related costs, and increased professional and consulting fees, primarily commercial-readiness activities related to PWS.

2015 Financial Guidance

The Company now expects that its cash, cash equivalents and marketable securities balance will be greater than \$180.0 million at December 31, 2015.

Conference Call Information

Zafgen will host an investor conference call today, November 10, 2015 at 4:30 p.m., Eastern Time, to discuss the Company's third 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 72381816.

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 methionine aminopeptidase 2, or 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 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 methionine aminopeptidase 2, or 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 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, 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, including craniopharyngioma-associated obesity, and other forms of severe obesity, including severe obesity in patients with type 2 diabetes, its expectations with respect to the timing and success of its clinical trials of beloranib and other product candidates, the expected requirements and timing of additional requirements for ongoing and planned clinical trials of beloranib and other product candidates, the need for additional clinical trials and pre-clinical studies for beloranib and its other product candidates, its plans regarding commercialization of beloranib for PWS, and its anticipated cash, cash equivalents and marketable securities balance 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 obtain a release of the partial clinical hold that the FDA placed on beloranib, the risk that the FDA may decide to elevate the partial clinical hold on beloranib to a full clinical hold, Zafgen's ability to successfully demonstrate the efficacy and safety of beloranib and its other product candidates the risk that patients may be unwilling to re-consent to participate in the open-label expansion portion of its ZAF-311 clinical trial or that patients may be unwilling to consent to participate in future clinical trials, the pre-clinical and clinical results for its product candidates, which may not support further development, actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials, obtaining, maintaining and protecting its 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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	14,171	12,076	36,912	20,046
General and administrative	5,546	2,285	13,655	4,822
Total operating expenses	<u>19,717</u>	<u>14,361</u>	<u>50,567</u>	<u>24,868</u>
Loss from operations	<u>(19,717)</u>	<u>(14,361)</u>	<u>(50,567)</u>	<u>(24,868)</u>
Other income (expense):				
Interest income	143	1	245	2
Interest expense	(200)	(213)	(626)	(658)
Foreign currency transaction gains (losses), net	(110)	(116)	(164)	(23)
Total other income (expense), net	<u>(167)</u>	<u>(328)</u>	<u>(545)</u>	<u>(679)</u>
Net loss	<u>(19,884)</u>	<u>(14,689)</u>	<u>(51,112)</u>	<u>(25,547)</u>
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	(92)
Net loss attributable to common stockholders	<u>\$ (19,884)</u>	<u>\$ (14,689)</u>	<u>\$ (51,112)</u>	<u>\$ (25,639)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.73)</u>	<u>\$ (0.65)</u>	<u>\$ (1.92)</u>	<u>\$ (2.97)</u>
Weighted average common shares outstanding, basic and diluted	<u>27,138,667</u>	<u>22,707,012</u>	<u>26,593,646</u>	<u>8,618,793</u>

ZAFGEN, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 38,763	\$ 58,103
Marketable securities	165,191	57,359
Tax incentive receivable	334	391
Prepaid expenses and other current assets	1,802	1,345
Total current assets	206,090	117,198
Property and equipment, net	303	79
Tax incentive receivable	975	—
Other assets	79	242
Total assets	<u>\$ 207,447</u>	<u>\$ 117,519</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,151	\$ 2,348
Accrued expenses	6,556	3,172
Notes payable, current	2,877	1,381
Total current liabilities	13,584	6,901
Notes payable, net of discount, long-term	4,162	6,177
Total liabilities	<u>17,746</u>	<u>13,078</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; \$0.001 par value; 5,000,000 shares authorized at September 30, 2015 and December 31, 2014; no shares issued and outstanding at September 30, 2015 and December 31, 2014	—	—
Common stock, \$0.001 par value; 115,000,000 shares authorized at September 30, 2015 and December 31, 2014; 27,233,574 and 22,879,160 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	27	23
Additional paid-in capital	346,203	209,838
Accumulated deficit	(156,497)	(105,385)
Accumulated other comprehensive loss	(32)	(35)
Total stockholders' equity	<u>189,701</u>	<u>104,441</u>
Total liabilities and stockholders' equity	<u>\$ 207,447</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.

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