
**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): March 9, 2016

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 March 9, 2016, Zafgen, Inc. announced its financial results for the fourth quarter of 2015 and the fiscal year ended December 31, 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, as amended (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 March 9, 2016, furnished herewith.

SIGNATURES

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

Date: March 9, 2016

ZAFGEN, INC.

By: /s/ Thomas E. Hughes
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 March 9, 2016, furnished herewith.

Zafgen Reports Fourth Quarter and Full Year 2015 Financial Results

- Conference call scheduled for 4:30 PM Eastern Time -

BOSTON, March 9, 2016 – Zafgen (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 fourth quarter and full year 2015 financial results, and provided an update on the Company's clinical program for beloranib.

“In recent months, we have reported compelling efficacy data from the ZAF-311 and ZAF-203 trials, providing additional context on the efficacy-safety profile of beloranib in severe obesity indications, and we are actively working to determine a path forward for beloranib in Prader-Willi syndrome,” said Thomas Hughes, Ph.D., Chief Executive Officer of Zafgen. “We plan to submit a comprehensive safety assessment and risk mitigation strategy for beloranib in PWS to the FDA as soon as practicable to address the full clinical hold and to support continued development in this setting.”

Recent Business Highlights

- In March 2016, Zafgen appointed Thomas O. Daniel, M.D. to the Company's Board of Directors. Dr. Daniel currently serves as Chairman of Celgene Research and was most recently President of Research and Early Development at Celgene Corporation.
- In February 2016, the Company reported that its Phase 2b trial of beloranib in severe obesity complicated by type 2 diabetes achieved its primary efficacy endpoint.
- In January 2016, Zafgen announced that its pivotal Phase 3 trial of beloranib in Prader-Willi syndrome (PWS) achieved both co-primary efficacy endpoints.
- In December 2015, the U.S. Food and Drug Administration (FDA) notified Zafgen that the beloranib investigational new drug (IND) application had been placed on full clinical hold due to an imbalance in severe venous thromboembolic events.
- Zafgen is currently developing a proposal for a risk mitigation strategy for beloranib in PWS, and intends to submit that proposal along with efficacy and safety data from the bestPWS ZAF-311 trial and ZAF-203 trial to the FDA to address the full clinical hold.

“The statistically significant efficacy data from both the ZAF-311 and ZAF-203 clinical trials underscore the potential of MetAP2 inhibitors in the treatment of complex metabolic disorders,” said Dr. Dennis Kim, Chief Medical Officer of Zafgen. “Beloranib, our lead product candidate, represents the first investigational drug to demonstrate, in a Phase 3 clinical trial in PWS, a positive impact on body weight and hyperphagia, two hallmark challenges facing this population, and we remain committed to developing a strategy for advancing beloranib in this indication.”

Fourth Quarter and Full Year 2015 Financial Results

“With our strong balance sheet, we believe we are well-positioned to execute on our business strategy and to fund operations,” said Patricia Allen, Chief Financial Officer of Zafgen. “Based on our current development timelines, we expect that our cash, cash equivalents and marketable securities balance will be greater than \$100 million at the end of calendar year 2016.”

Cash, Cash Equivalents and Marketable Securities

As of December 31, 2015, the Company had cash, cash equivalents and marketable securities totaling \$185.1 million.

Net Loss

The Company reported a net loss for the fourth quarter of 2015 of \$23.2 million, or \$0.85 per share, compared to a net loss of \$10.9 million, or \$0.48 per share, for the fourth quarter of 2014. The Company reported a net loss for the year ended December 31, 2015 of \$74.3 million, or \$2.78 per share, compared to a net loss of \$36.5 million, or \$3.00 per share, for the year ended December 31, 2014.

The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 27,238,079 for the fourth quarter of 2015, compared to 22,783,817 for the fourth quarter of 2014. The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 26,756,079 for the year ended December 31, 2015, compared to 12,189,155 for the year ended December 31, 2014.

Research and Development Expenses

Research and development expenses for the fourth quarter of 2015 were \$17.7 million, compared to \$7.3 million for the fourth quarter of 2014. Research and development expenses for the year ended December 31, 2015 were \$54.6 million, compared to \$27.4 million for the year ended December 31, 2014. The increase in research and development expenses for the quarter and year ended December 31, 2015 as compared to prior year periods was primarily due to increased costs associated with the advancement of the Company's beloranib program, ZGN-839 and second-generation MetAP2 inhibitors. Additionally, the Company had increases in personnel costs related to hiring new employees as well as non-cash stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses for the fourth quarter of 2015 were \$5.5 million, compared to \$3.3 million for the fourth quarter of 2014. General and administrative expenses for the year ended December 31, 2015 were \$19.2 million, compared to \$8.1 million for the year ended December 31, 2014. The increase in general and administrative expenses for the quarter and year ended December 31, 2015 as compared to prior year periods was primarily due to increased personnel related costs, increased professional fees, as well as increased non-cash stock-based compensation expense.

2016 Financial Guidance

The Company expects that its cash, cash equivalents and marketable securities balance will be greater than \$100 million at December 31, 2016.

Conference Call Information

Zafgen will host an investor conference call today, March 9, 2016 at 4:30 p.m., Eastern Time, to discuss the Company's fourth quarter 2015 and full year 2015 results as well as other forward-looking information about Zafgen's business. Investors and other interested parties may participate by dialing (973) 500-2177 in the United States or (844) 824-7428 outside the United States and referencing

conference ID number 59462061. The call will also be webcast live on the Company's website at <http://ir.zafgen.com/events.cfm>. A replay of this conference call will be available beginning at 7:30 p.m. ET on March 9, 2016 through March 23, 2016 by dialing (404) 537-3406 in the U.S. or (855) 859-2056 outside the U.S. To access the replay please provide Conference ID number 59462061.

About Beloranib

Beloranib is a novel, first-in-class injectable small molecule therapy that works by inhibiting MetAP2, an enzyme that modulates the activity of key cellular processes that control metabolism. Once a person becomes obese, the body undergoes certain metabolic changes and becomes "programmed" to create and store more fat, making it much more difficult to reduce body weight. Beloranib is believed to help reduce hunger and restore balance to fat metabolism, enabling calories to once again be used as a productive energy source. Because beloranib works beyond just regulating hunger through the hypothalamus, it has the potential to be used in a variety of complex metabolic disorders such as Prader-Willi syndrome and hypothalamic injury associated obesity. 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 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 severe obesity in two rare diseases, Prader-Willi syndrome and obesity caused by hypothalamic injury, including craniopharyngioma-associated obesity. 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, which may be developed for the treatment of severe obesity in the general population. 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 expected cash balance as of December 31, 2016, Zafgen's expectations regarding beloranib as a treatment for PWS and obesity caused by hypothalamic injury, including craniopharyngioma-associated obesity, Zafgen's expectations regarding the use of other MetAP2 inhibitors as treatments for other forms of severe obesity, including severe obesity in the general population, Zafgen's expectations with respect to the timing and success of its non-clinical studies and clinical trials of beloranib and its other product candidates, the expected requirements and timing of additional requirements for planned clinical trials, and the need for additional clinical trials and pre-clinical studies, and Zafgen's plans regarding commercialization of beloranib 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 full clinical hold that the FDA placed on the investigational new drug application for beloranib, Zafgen’s ability to successfully demonstrate the efficacy and safety of beloranib and its other product candidates, the pre-clinical and clinical results for beloranib and its other product candidates, which may not support further development and marketing approval, actions of regulatory agencies, which may affect the initiation, timing and progress of pre-clinical studies and clinical trials, Zafgen’s ability to obtain, maintain and protect 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)

	Year Ended December 31,		
	2015	2014	2013
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	54,618	27,391	9,561
General and administrative	19,195	8,141	4,219
Total operating expenses	<u>73,813</u>	<u>35,532</u>	<u>13,780</u>
Loss from operations	<u>(73,813)</u>	<u>(35,532)</u>	<u>(13,780)</u>
Other income (expense):			
Interest income	438	28	—
Interest expense	(806)	(870)	—
Foreign currency transaction gains (losses), net	(105)	(104)	(247)
Total other income (expense), net	<u>(473)</u>	<u>(946)</u>	<u>(247)</u>
Net loss	<u>(74,286)</u>	<u>(36,478)</u>	<u>(14,027)</u>
Accretion of redeemable convertible preferred stock to redemption value	<u>—</u>	<u>(92)</u>	<u>(213)</u>
Net loss attributable to common stockholders	<u>\$ (74,286)</u>	<u>\$ (36,570)</u>	<u>\$ (14,240)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (2.78)</u>	<u>\$ (3.00)</u>	<u>\$ (19.53)</u>
Weighted average common shares outstanding, basic and diluted	<u>26,756,079</u>	<u>12,189,155</u>	<u>729,001</u>

ZAFGEN, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended December 31,	
	2015	2014
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	17,706	7,345
General and administrative	5,540	3,319
Total operating expenses	<u>23,246</u>	<u>10,664</u>
Loss from operations	<u>(23,246)</u>	<u>(10,664)</u>
Other income (expense):		
Interest income	193	26
Interest expense	(180)	(212)
Foreign currency transaction gains (losses), net	59	(81)
Total other income (expense), net	<u>72</u>	<u>(267)</u>
Net loss	<u>(23,174)</u>	<u>(10,931)</u>
Net loss per share, basic and diluted	<u>\$ (0.85)</u>	<u>\$ (0.48)</u>
Weighted average common shares outstanding, basic and diluted	<u>27,238,079</u>	<u>22,783,817</u>

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

	December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 35,595	\$ 58,103
Marketable securities	149,484	57,359
Tax incentive receivable	1,323	391
Prepaid expenses and other current assets	1,708	1,345
Total current assets	188,110	117,198
Property and equipment, net	902	79
Other assets	94	242
Total assets	<u>\$ 189,106</u>	<u>\$ 117,519</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 7,495	\$ 2,348
Accrued expenses	6,112	3,172
Notes payable, current	2,936	1,381
Total current liabilities	16,543	6,901
Notes payable, net of discount, long-term	3,453	6,177
Total liabilities	<u>19,996</u>	<u>13,078</u>
Stockholders' equity:		
Preferred stock; \$0.001 par value per share; 5,000,000 shares authorized at December 31, 2015 and 2014; no shares issued and outstanding at December 31, 2015 and 2014	—	—
Common stock, \$0.001 par value per share; 115,000,000 shares authorized at December 31, 2015 and 2014; 27,242,503 and 22,879,160 shares issued and outstanding at December 31, 2015 and 2014, respectively	27	23
Additional paid-in capital	348,961	209,838
Accumulated deficit	(179,671)	(105,385)
Accumulated other comprehensive loss	(207)	(35)
Total stockholders' equity	<u>169,110</u>	<u>104,441</u>
Total liabilities and stockholders' equity	<u>\$ 189,106</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.

Media/Investor Relations Contact:

Zafgen, Inc.
Patricia Allen
Chief Financial Officer
617-648-9792

Argot Partners

Investor Relations
Laura Perry or Glenn Garmon
212-600-1902
laura@argotpartners.com
glenn@argotpartners.com

Spectrum Science
Media Relations
Susan Francis
609-529-0676
sfrancis@spectrumsience.com