
**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 19, 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 March 19, 2015, Zafgen, Inc. announced its financial results for the fourth quarter of 2014 and the fiscal year ended December 31, 2014. 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 March 19, 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: March 19, 2015

ZAFGEN, INC.

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

EXHIBIT INDEX

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Zafgen Reports Fourth Quarter and Full Year 2014 Financial Results

Quarter and Full Year Highlighted by Further Progress in Advancing Beloranib Clinical Development Program

Company to Report Data from Ongoing Clinical Trials in Late 2015/Early 2016

Enters 2015 with Pro-Forma Cash and Marketable Securities of \$245 Million Following Recent Follow-on Offering

BOSTON, Mass., March 19, 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 fourth quarter and full year 2014 financial results.

Zafgen 2014 and Early 2015 Business Highlights

- Initiated a first Phase 3 trial through the bestPWS (Beloranib Efficacy Safety and Tolerability in PWS) clinical trial in patients with a rare genetic disorder, Prader-Willi syndrome (PWS), which began randomized treatment in September 2014
- Initiated a 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, which began randomized treatment in December 2014
- Announced positive results from a Phase 2a clinical trial of beloranib in patients with hypothalamic injury-associated obesity (HIAO), a rare condition that is also a difficult-to-treat severe form of obesity, in January 2015
- Two U.S. patents owned by Zafgen have issued during 2014 and 2015 that relate to methods of treating obesity using dosing regimens of beloranib, and one U.S. patent issued in 2014 that relates to compositions of beloranib
- Added to the NASDAQ Biotechnology Index (Nasdaq:NBI) in December 2014

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- Raised approximately \$230 million through a successful initial public offering (IPO) in June 2014 and a follow-on public offering in January 2015

“We are very pleased with our accomplishments for the fourth quarter of 2014 and moreover, the year as a whole, which has been one of the most productive in our Company’s history. We have made substantial progress in the clinical development of beloranib in multiple indications, all in continued support of our mission of bringing life-changing treatment options to patients affected by obesity and obesity-related disorders,” said Dr. Thomas Hughes, Chief Executive Officer of Zafgen.

“With promising data in hand from our recent Phase 2a proof of concept trial (ZAF-221) in patients with HIAO, we look forward to readouts from our bestPWS (ZAF-311) Phase 3 study in Prader-Willi syndrome, and our Phase 2b trial (ZAF-203) in patients with severe obesity complicated by type 2 diabetes,” said Dr. Hughes.

“We were pleased to have completed our IPO in June 2014 and our recent follow-on offering in January 2015 bringing in total net proceeds of approximately \$230 million,” said Patricia Allen, Chief Financial Officer of Zafgen. “We are investing this capital in the development of beloranib in multiple indications along with bringing forth our ZAF-839 program in nonalcoholic steatohepatitis, or NASH, and second-generation molecules to beloranib. We are also expanding our organization to deliver on our multiple development programs and create the foundation of our commercialization activities in anticipation of approval of beloranib in Prader-Willi syndrome.”

Fourth Quarter and Full Year 2014 Financial Results

Cash and Cash Equivalents and Marketable Securities

As of December 31, 2014, the Company had cash and cash equivalents and marketable securities totaling \$115.5 million.

In January 2015, the Company sold an aggregate of 3,942,200 shares of common stock through an underwritten public offering at \$35.00 per share, before underwriting discounts, which included the full-exercise of the underwriters’ option to purchase an additional 514,200 shares of common stock at \$35.00 per share. The net proceeds to the Company were approximately \$129.5 million.

Net Loss

The Company reported a net loss for the fourth quarter of 2014 of \$10.9 million, or \$0.48 per share, compared to a \$3.8 million net loss, or \$5.35 per share, for the fourth quarter of 2013. The Company reported a net loss for the year ended December 31, 2014 of \$36.5 million, or \$3.00 per share, compared to a \$14.0 million net loss, or \$19.53 per share, for the full year ended December 31, 2013. The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 22,783,817 for the fourth quarter of 2014, compared to 729,391 for the fourth quarter of 2013. The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 12,189,155 for the year ended December 31, 2014, compared to 729,001 for the year ended December 31, 2013.

Research and Development Expenses

Research and development expenses for the fourth quarter of 2014 were \$7.3 million, compared to \$2.5 million for the fourth quarter of 2013. Research and development expenses for the year ended December 31, 2014 were \$27.4 million, compared to \$9.6 million for the year ended December 31, 2013. The increase in research and development expenses for the quarter and year ended

December 31, 2014 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 other early stage development programs (consisting of our second-generation MetAP2 inhibitors). In addition, the increase for the year ended December 31, 2014 as compared to the prior year was a result of \$7.0 million in expenses related to milestone payments, primarily to Chong Kun Dang Pharmaceutical Corporation (CKD Pharma), triggered by the initiation of the bestPWS Phase 3 clinical trial which the Company initiated in September 2014.

General and Administrative Expenses

General and administrative expenses for the fourth quarter of 2014 were \$3.3 million, compared to \$1.2 million for the fourth quarter of 2013. General and administrative expenses for the year ended December 31, 2014 were \$8.1 million, compared to \$4.2 million for the year ended December 31, 2013. The increase in general and administrative expenses for the quarter and year ended December 31, 2014 as compared to prior year periods was primarily due to increased personnel related costs, increased travel and other related costs, and increased professional fees.

2015 Financial Guidance

The Company expects 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, March 19, 2015 at 4:30 p.m., Eastern Time, to discuss the Company's fourth quarter and full year 2014 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 www.zafgen.com. You can access the replay for seven days by dialing 855-859-2056 in the United States and 404-537-3406 outside the United States and referencing conference ID number 5923144.

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

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, hypothalamic injury-associated obesity, including craniopharyngioma-associated obesity; and 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 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, the expected timing of additional clinical trials, 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 drug 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 and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Year Ended December 31,		
	2014	2013	2012
	(in thousands, except per share data)		
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	27,391	9,561	11,544
General and administrative	8,141	4,219	2,247
Total operating expenses	<u>35,532</u>	<u>13,780</u>	<u>13,791</u>
Loss from operations	<u>(35,532)</u>	<u>(13,780)</u>	<u>(13,791)</u>
Other income (expense):			
Interest income	28	—	—
Foreign currency transaction gains (losses), net	(104)	(247)	8
Interest expense	(870)	—	(97)
Total other income (expense), net	<u>(946)</u>	<u>(247)</u>	<u>(89)</u>
Net loss	(36,478)	(14,027)	(13,880)
Accretion of redeemable convertible preferred stock to redemption value	(92)	(213)	(67)
Net loss attributable to common stockholders	<u>\$ (36,570)</u>	<u>\$ (14,240)</u>	<u>\$ (13,947)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (3.00)</u>	<u>\$ (19.53)</u>	<u>\$ (19.65)</u>
Weighted average common shares outstanding, basic and diluted	<u>12,189,155</u>	<u>729,001</u>	<u>709,678</u>
Comprehensive loss:			
Net loss	\$ (36,478)	\$ (14,027)	\$ (13,880)
Other comprehensive loss:			
Unrealized loss on marketable securities	(35)	—	—
Total other comprehensive loss	<u>(35)</u>	<u>—</u>	<u>—</u>
Total comprehensive loss	<u>\$ (36,513)</u>	<u>\$ (14,027)</u>	<u>\$ (13,880)</u>

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

	Three Months Ended	
	December 31, 2014	December 31, 2013
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	7,345	2,523
General and administrative	3,319	1,238
Total operating expenses	<u>10,664</u>	<u>3,761</u>
Loss from operations	<u>(10,664)</u>	<u>(3,761)</u>
Other income (expense):		
Interest income	26	—
Interest expense	(212)	—
Foreign currency transaction gains (losses), net	(81)	(85)
Total other income (expense), net	<u>(267)</u>	<u>(85)</u>
Net loss	<u>(10,931)</u>	<u>(3,846)</u>
Accretion of redeemable convertible preferred stock to redemption value	—	(53)
Net loss attributable to common stockholders	<u>\$ (10,931)</u>	<u>\$ (3,899)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.48)</u>	<u>\$ (5.35)</u>
Weighted average common shares outstanding, basic and diluted	<u>22,783,817</u>	<u>729,391</u>
Comprehensive loss:		
Net loss	\$ (10,931)	\$ (3,846)
Other comprehensive loss:		
Unrealized loss on investments	(35)	—
Total other comprehensive loss	<u>(35)</u>	<u>—</u>
Total comprehensive loss	<u>\$ (10,966)</u>	<u>\$ (3,846)</u>

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

	December 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 58,103	\$ 35,517
Marketable securities	57,359	—
Tax incentive receivable	391	1,617
Prepaid expenses and other current assets	1,345	224
Total current assets	117,198	37,358
Property and equipment, net	79	37
Other assets	242	743
Total assets	<u>\$ 117,519</u>	<u>\$ 38,138</u>
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 2,348	\$ 2,015
Accrued expenses	3,172	900
Notes payable, current	1,381	—
Total current liabilities	6,901	2,915
Notes payable, net of discount, long-term	6,177	—
Total liabilities	13,078	2,915
Commitments and contingencies		
Redeemable convertible preferred stock (Series A, B, C, D and E), \$0.001 par value;		
No shares and 99,292,610 shares authorized at December 31, 2014 and 2013, respectively; no shares and 94,483,404 shares issued and outstanding at December 31, 2014 and 2013, respectively; aggregate liquidation preference of \$104,588 at December 31, 2013	—	103,797
Stockholders' equity (deficit):		
Preferred stock; \$0.001 par value; 5,000,000 and no shares authorized at December 31, 2014 and 2013, respectively; no shares issued and outstanding at December 31, 2014 and 2013	—	—
Common stock, \$0.001 par value; 115,000,000 shares authorized at December 31, 2014 and 2013; 22,879,160 and 729,391 shares issued and outstanding at December 31, 2014 and 2013, respectively	23	1
Additional paid-in capital	209,838	332
Accumulated deficit	(105,385)	(68,907)
Accumulated other comprehensive loss	(35)	—
Total stockholders' equity (deficit)	104,441	(68,574)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 117,519</u>	<u>\$ 38,138</u>

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in the final prospectus related to Zafgen's public offering filed with the Securities and Exchange Commission pursuant to Rule 424(b) of the Securities Act, which includes the audited consolidated financial statements for the year ended December 31, 2013.