
**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 7, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On November 7, 2017, Zafgen, Inc. announced its financial results for the third quarter of 2017. 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 7, 2017, furnished herewith.

EXHIBIT INDEX

Exhibit
No.

Description

99.1 [Press release issued by Zafgen, Inc. on November 7, 2017, 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 7, 2017

ZAFGEN, INC.

By: /s/ Patricia L. Allen
Patricia L. Allen
Chief Financial Officer

Zafgen Reports Third Quarter 2017 Financial Results

- *Initiated Phase 2 Clinical Trial for Second Generation MetAP2 Inhibitor ZGN-1061 -*
- *Expanded Executive Leadership Team -*
- *Ended Quarter with Cash, Cash Equivalents and Marketable Securities of \$93.2 Million -*

BOSTON, November 7, 2017 – Zafgen, Inc. (Nasdaq:ZFGN), a clinical-stage biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by type 2 diabetes, rare diseases and other metabolic diseases, today announced its third quarter 2017 financial results.

“Zafgen is dedicated to translating its global MetAP2 scientific leadership into transformative clinical therapies for metabolic disease patients most in need,” commented Jeffrey Hatfield, Chief Executive Officer of Zafgen. “In this quarter, the company has taken an important next step. After successfully completing a Phase 1 clinical trial earlier this year with our second generation MetAP2 inhibitor, ZGN-1061, this quarter we advanced ZGN-1061 into a Phase 2 clinical trial assessing 120 patients with type 2 diabetes who are obese and are failing to respond adequately to current therapies. We expect this trial to provide validating insight into the efficacy, tolerability and safety profile of our second generation approach. We look forward to providing an update on the status of the Phase 2 clinical trial, as well as an overall update on portfolio plans and strategy at the beginning of 2018.”

Recent Corporate and Clinical Highlights

- In September, Zafgen announced the initiation of ZAF-1061-201, the Company’s randomized, placebo-controlled Phase 2 clinical trial evaluating ZGN-1061 in approximately 120 patients with type 2 diabetes who are failing to respond adequately to current therapies. The primary objectives of this clinical trial are to assess three dosing cohorts of ZGN-1061 on glycemic control, safety and tolerability. The Company will also evaluate the effects of ZGN-1061 on multiple metabolic measures and cardiovascular risk factors including body weight. The protocol provides for an interim data analysis, expected in the first half of 2018.
- Also in September, Zafgen presented data for ZGN-1061 at the 53rd Annual Meeting of the European Association for the Study of Diabetes. The presentation included results from the Phase 1 clinical trial of ZGN-1061, as well as new preclinical data demonstrating the dose-dependent effect of ZGN-1061 on glucose tolerance, weight loss and several metabolic markers in diet-induced obese mice.
- In October, Zafgen appointed Jeffrey Hatfield as its Chief Executive Officer. Thomas Hughes, Ph.D., continues to serve as the Company’s President and has assumed the newly-created role of Chief Scientific Officer. Both Mr. Hatfield and Dr. Hughes serve on Zafgen’s Board of Directors. Mr. Hatfield is a veteran biotechnology and pharmaceutical industry leader, with over three decades of experience. Most recently, he served as Chief Executive Officer of Vitae Pharmaceuticals, Inc. from the company’s formation until its acquisition by Allergan plc in October 2016.

Third Quarter 2017 Financial Results

“As we advance ZGN-1061 through Phase 2 clinical trials and progress our preclinical efforts, we remain disciplined with the use of our current resources,” stated Patricia Allen, Chief Financial Officer of Zafgen. “We are making targeted and staged investments in our second generation portfolio in order to build value for our shareholders, and continue to expect that our cash, cash equivalents and marketable securities balance at the end of calendar year 2017 will be greater than \$70 million.”

Cash, Cash Equivalents and Marketable Securities

As of September 30, 2017, the Company had cash, cash equivalents and marketable securities totaling \$93.2 million.

Net Loss

The Company reported a net loss for the third quarter of 2017 of \$12.6 million, or \$0.46 per share, compared to a net loss of \$14.7 million, or \$0.54 per share, for the third quarter of 2016.

The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 27,483,550 for the third quarter of 2017, compared to 27,322,907 for the third quarter of 2016.

Research and Development Expenses

Research and development expenses for the third quarter of 2017 were \$9.7 million, compared to \$10.0 million for the third quarter of 2016. The slight decrease in research and development expenses for the third quarter of 2017 as compared to the prior year period was primarily due to the suspension of our first generation program as well as a decrease in personnel-related costs and consulting costs, as we shifted focus to ZGN-1061 in July 2016. This decrease was partially offset by increased preclinical, manufacturing and clinical trial costs related to ZGN-1061 and an investment in discovery and screening of new MetAP2 inhibitors.

General and Administrative Expenses

General and administrative expenses for the third quarter of 2017 were \$3.1 million, compared to \$4.8 million for the third quarter of 2016. The decrease in general and administrative expenses for the third quarter of 2017 as compared to the prior year period was primarily due to a decrease in personnel-related costs primarily as a result of the reduction in workforce during the third quarter of 2016. For the third quarter of 2017 there was also a decrease in professional fees and non-cash stock-based compensation expense.

2017 Financial Guidance

The Company continues to expect that its cash, cash equivalents and marketable securities balance will be greater than \$70 million as of December 31, 2017.

About ZGN-1061

ZGN-1061 is a fumagillin-class, injectable small molecule second generation MetAP2 inhibitor that was advanced into development due to its unique properties that maximize impact on metabolic parameters relevant to the treatment of type 2 diabetes and other related metabolic disorders. In preclinical studies, ZGN-1061 has demonstrated promising efficacy in animal models of type 2 diabetes and obesity, with an

improved pharmacokinetic profile and safety margin relative to previous molecules in the MetAP2 inhibitor class. As demonstrated clinically for MetAP2 inhibitors, ZGN-1061 is anticipated to improve glycemic control while also helping to restore balance to fat metabolism, enabling calories to once again be used as a productive energy source, leading to improved metabolic control and long-term weight loss. Zafgen completed its first Phase 1 clinical trial of ZGN-1061 earlier this year, and has advanced the compound to Phase 2 clinical testing in patients with type 2 diabetes who are obese and are failing to respond adequately to current therapies. Zafgen holds exclusive worldwide rights for the development and commercialization of ZGN-1061.

About Zafgen

Zafgen (Nasdaq:ZFGN) is a clinical-stage biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by type 2 diabetes, rare diseases and other metabolic diseases. Zafgen is focused on developing novel therapeutics that treat the underlying biological mechanisms of metabolic diseases through the MetAP2 pathway. The Company has pioneered the study of MetAP2 inhibitors in both common and rare forms of obesity, and in patients affected by type 2 diabetes. Zafgen's lead product candidate is ZGN-1061, a fumagillin-class, injectable small molecule second generation MetAP2 inhibitor that was advanced into development due to its unique properties that maximize impact on metabolic parameters relevant to the treatment of type 2 diabetes and other related metabolic disorders. The Company completed its first Phase 1 clinical trial of ZGN-1061, and has advanced ZGN-1061 to Phase 2 clinical testing in patients with type 2 diabetes who are obese and are failing to respond adequately to current therapies. Zafgen holds exclusive worldwide rights for the development and commercialization of ZGN-1061. The Company aspires to improve the lives of patients through targeted treatments and has assembled a team accomplished in bringing therapies to patients affected by type 2 diabetes, rare diseases and other 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 the use of ZGN-1061 and other MetAP2 inhibitors as treatments for metabolic diseases including type 2 diabetes and common and rare forms of obesity, ZGN-1061's improved safety margin, including as it relates to prothrombotic characteristics, compared to first generation MetAP2 inhibitors, such as beloranib, Zafgen's expectations with respect to the timing and success of its preclinical studies and clinical trials of ZGN-1061 and its other product candidates, and Zafgen's expected cash, cash equivalents and marketable securities balance as of December 31, 2017, 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 ZGN-1061 and its other product candidates and to differentiate ZGN-1061 and its other product candidates from first generation MetAP2 inhibitors, such as beloranib, the preclinical and clinical results for ZGN-1061 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 preclinical studies and clinical trials of its product candidates, Zafgen's forecasted cash, cash equivalents and marketable securities balance as of the end of its fiscal year, 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 when needed, Zafgen's dependence on third parties for development, manufacture, marketing, sales and distribution of product candidates, 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	9,723	10,001	29,928	32,661
General and administrative	3,117	4,830	9,713	15,089
Total operating expenses	<u>12,840</u>	<u>14,831</u>	<u>39,641</u>	<u>47,750</u>
Loss from operations	<u>(12,840)</u>	<u>(14,831)</u>	<u>(39,641)</u>	<u>(47,750)</u>
Other income (expense):				
Interest income	266	230	740	664
Interest expense	(31)	(132)	(157)	(432)
Foreign currency transaction gains (losses), net	20	58	115	79
Total other income (expense), net	<u>255</u>	<u>156</u>	<u>698</u>	<u>311</u>
Net loss	<u>\$ (12,585)</u>	<u>\$ (14,675)</u>	<u>\$ (38,943)</u>	<u>\$ (47,439)</u>
Net loss per share , basic and diluted	<u>\$ (0.46)</u>	<u>\$ (0.54)</u>	<u>\$ (1.42)</u>	<u>\$ (1.74)</u>
Weighted average common shares outstanding, basic and diluted	<u>27,483,550</u>	<u>27,322,907</u>	<u>27,414,314</u>	<u>27,286,323</u>

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

	<u>September 30,</u> 2017	<u>December 31,</u> 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 19,193	\$ 32,352
Marketable securities	73,987	96,842
Tax incentive receivable	469	347
Prepaid expenses and other current assets	2,007	1,358
Total current assets	<u>95,656</u>	<u>130,899</u>
Property and equipment, net	551	661
Other assets	57	61
Total assets	<u>\$ 96,264</u>	<u>\$ 131,621</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,676	\$ 2,572
Accrued expenses	3,090	3,733
Notes payable, current	1,268	3,589
Total current liabilities	<u>7,034</u>	<u>9,894</u>
Total liabilities	<u>7,034</u>	<u>9,894</u>
Stockholders' equity:		
Preferred stock; \$0.001 par value per share; 5,000,000 shares authorized as of September 30, 2017 and December 31, 2016; no shares issued and outstanding as of September 30, 2017 and December 31, 2016	—	—
Common stock, \$0.001 par value per share; 115,000,000 shares authorized as of September 30, 2017 and December 31, 2016; 27,483,925 and 27,332,551 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	27	27
Additional paid-in capital	365,723	359,329
Accumulated deficit	(276,492)	(237,549)
Accumulated other comprehensive loss	(28)	(80)
Total stockholders' equity	<u>89,230</u>	<u>121,727</u>
Total liabilities and stockholders' equity	<u>\$ 96,264</u>	<u>\$ 131,621</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 Company's audited consolidated financial statements for the year ended December 31, 2016.

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