
**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): May 9, 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 May 9, 2017, Zafgen, Inc. announced its financial results for the first 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, 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 May 9, 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: May 9, 2017

ZAFGEN, INC.

By: /s/ Thomas E. Hughes

Thomas E. Hughes, Ph.D.

President and Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Zafgen, Inc. on May 9, 2017, furnished herewith.

Zafgen Reports First Quarter 2017 Financial Results

-ZGN-1061 Phase 1 Data Support Continued Development; On Track to Initiate Phase 2 Clinical Trial in Patients with Type 2 Diabetes in Second Half of This Year-

BOSTON, May 9, 2017 – Zafgen, Inc. (Nasdaq:ZFGN), today announced its first quarter 2017 financial results.

“We recently achieved an important milestone in our clinical program for ZGN-1061, reporting positive topline data from the Phase 1 clinical trial of ZGN-1061, a MetAP2 inhibitor which has been optimized to improve glycemic control and body weight, with a favorable safety profile,” said Thomas Hughes, Ph.D., President and Chief Executive Officer of Zafgen. “The safety data and the early efficacy signals support the further development of this compound, and we plan to advance ZGN-1061 into a Phase 2 clinical trial in the second half of this year in patients with type 2 diabetes who are overweight or obese.”

Recent Clinical Highlights

- Earlier this month, Zafgen reported positive topline data from both the SAD and MAD portions of the Phase 1 clinical trial of ZGN-1061, the Company’s second generation MetAP2 inhibitor. ZGN-1061 was safe and well-tolerated, with no serious adverse events (SAEs), and no severe adverse events (AEs). There were no AEs leading to early withdrawal from the clinical trial.
- There was no prothrombotic effect observed with ZGN-1061. No treatment emergent venous thromboembolisms (VTEs), no clinically meaningful D-dimer elevations indicative of thrombosis and no elevations in mean D-dimer levels were observed in the dosing groups compared to baseline or placebo. There were no clinically significant changes in coagulation laboratory parameters or other key biomarkers of interest, including von Willebrand factor, soluble thrombomodulin, and plasminogen activator inhibitor-1.
- On average, patients treated with ZGN-1061 for four weeks lost weight relative to placebo-treated patients (-4.6 lbs, -2.2 lbs, and -3.8 lbs for 0.2 mg, 0.6 mg, and 1.8 mg, respectively vs. -0.51 lbs for placebo), with trends for improvements observed in waist circumference, food intake, low density lipoprotein-cholesterol, C-reactive protein, adiponectin and leptin.
- Based on the positive data from the Phase 1 clinical trial, together with non-clinical data supporting a differentiated profile and improved safety margin versus first generation MetAP2 inhibitors, the Company plans to initiate a Phase 2 clinical trial of ZGN-1061 in the second half of this year, in patients with type 2 diabetes who are overweight or obese.

First Quarter 2017 Financial Results

“Our focused and disciplined investment in ZGN-1061 will allow us to take this lead candidate through key value-creating milestones with our current resources,” stated Patricia Allen, Chief Financial Officer of Zafgen. “We continue to expect our cash runway to extend through the end of 2018, by which time we expect to have data from the Phase 2 clinical trial for ZGN-1061.”

Cash, Cash Equivalents and Marketable Securities

As of March 31, 2017, the Company had cash, cash equivalents and marketable securities totaling \$116.9 million.

Net Loss

The Company reported a net loss for the first quarter of 2017 of \$13.0 million, or \$0.48 per share, compared to a net loss of \$17.7 million, or \$0.65 per share, for the first quarter of 2016.

The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 27,350,673 for the first quarter of 2017, compared to 27,263,435 for the first quarter of 2016.

Research and Development Expenses

Research and development expenses for the first quarter of 2017 were \$9.7 million, compared to \$12.5 million for the first quarter of 2016. The decrease in research and development expenses for the first quarter of 2017 as compared to the prior year period was primarily due to a decrease in our beloranib program as well as a decrease in personnel related costs and consulting costs, partially offset by increased pre-clinical, manufacturing and clinical trial costs related to ZGN-1061 as we shifted focus to ZGN-1061 in July 2016.

General and Administrative Expenses

General and administrative expenses for the first quarter of 2017 were \$3.6 million, compared to \$5.4 million for the first quarter of 2016. The decrease in general and administrative expenses for the first quarter of 2017 as compared to the prior year period was primarily due to a decrease in non-cash stock-based compensation and professional fees. For the first quarter of 2017 there was also a decrease in personnel related costs as compared to the prior year period primarily as a result of the reduction in workforce during the third quarter of 2016.

2017 Financial Guidance

The Company expects that its cash, cash equivalents and marketable securities balance will be greater than \$65 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 pre-clinical 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 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 recently completed its first Phase 1 clinical trial of ZGN-1061, and is planning to advance the compound to Phase 2 clinical testing in patients with type 2 diabetes who are overweight or obese. Zafgen holds exclusive worldwide rights for the development and commercialization of ZGN-1061.

About Zafgen

Zafgen (Nasdaq:ZFGN) is a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by metabolic diseases including type 2 diabetes and obesity. Zafgen is focused on developing novel therapeutics that treat the underlying biological mechanisms of metabolic diseases through the MetAP2 pathway. Zafgen 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, which is a novel, first-in-class, subcutaneous injection. Zafgen aspires to improve the lives of patients through targeted treatments and has assembled a team accomplished in bringing therapies to patients affected by 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 obesity, ZGN-1061's improved safety margin, including as it relates to pro-thrombotic characteristics, compared to first generation MetAP2 inhibitors, such as over beloranib, and Zafgen's expectations with respect to the timing and success of its pre-clinical 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 pre-clinical 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 pre-clinical studies and clinical trials of its product candidates, 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, 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 Annual Report on Form 10-K 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 March 31,	
	2017	2016
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	9,677	12,497
General and administrative	3,588	5,360
Total operating expenses	<u>13,265</u>	<u>17,857</u>
Loss from operations	<u>(13,265)</u>	<u>(17,857)</u>
Other income (expense):		
Interest income	227	209
Interest expense	(73)	(160)
Foreign currency transaction gains (losses), net	100	72
Total other income (expense), net	<u>254</u>	<u>121</u>
Net loss	<u>\$ (13,011)</u>	<u>\$ (17,736)</u>
Net loss per share, basic and diluted	<u>\$ (0.48)</u>	<u>\$ (0.65)</u>
Weighted average common shares outstanding, basic and diluted	<u>27,350,673</u>	<u>27,263,435</u>

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

	<u>March 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 28,632	\$ 32,352
Marketable securities	88,304	96,842
Tax incentive receivable	368	347
Prepaid expenses and other current assets	1,378	1,358
Total current assets	<u>118,682</u>	<u>130,899</u>
Property and equipment, net	630	661
Other assets	59	61
Total assets	<u>\$ 119,371</u>	<u>\$ 131,621</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,910	\$ 2,572
Accrued expenses	3,850	3,733
Notes payable, current	2,837	3,589
Total current liabilities	<u>8,597</u>	<u>9,894</u>
Total liabilities	<u>8,597</u>	<u>9,894</u>
Stockholders' equity:		
Preferred stock; \$0.001 par value per share; 5,000,000 shares authorized as of March 31, 2017 and December 31, 2016; no shares issued and outstanding as of March 31, 2017 and December 31, 2016	—	—
Common stock, \$0.001 par value per share; 115,000,000 shares authorized as of March 31, 2017 and December 31, 2016; 27,350,723 and 27,332,551 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively	27	27
Additional paid-in capital	361,370	359,329
Accumulated deficit	(250,560)	(237,549)
Accumulated other comprehensive loss	(63)	(80)
Total stockholders' equity	<u>110,774</u>	<u>121,727</u>
Total liabilities and stockholders' equity	<u>\$ 119,371</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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