
**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 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 November 9, 2016, Zafgen, Inc. announced its financial results for the third quarter of 2016. 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 9, 2016, 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 9, 2016

ZAFGEN, INC.

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

EXHIBIT INDEX

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Zafgen Reports Third Quarter 2016 Financial Results

-Advancing Phase 1 Clinical Trial of ZGN-1061; Top-Line Results Expected First Quarter 2017-

BOSTON, November 9, 2016 – Zafgen, Inc. (Nasdaq:ZFGN), a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by metabolic diseases including type 2 diabetes and obesity, today announced its third quarter 2016 financial results.

“We have leveraged our experience with the MetAP2 pathway to develop ZGN-1061, a second-generation molecule that we believe is optimized to harness the powerful benefits of MetAP2 inhibition while minimizing the potential for adverse events,” said Thomas Hughes, Ph.D., President and Chief Executive Officer of Zafgen. “We are focused on advancing development of this highly differentiated compound, and expect to report top-line results from our ongoing Phase 1 clinical trial of ZGN-1061 in the first quarter of 2017. These results will further elucidate the candidate’s key differentiators relative to our first-generation MetAP2 inhibitor, and help inform the doses, design, and patient populations for our Phase 2 clinical program.”

Recent Corporate and Clinical Highlights

- Zafgen implemented a strategic restructuring in July to focus its resources on the development of ZGN-1061, a second generation MetAP2 inhibitor that originated from the Company’s discovery program as part of a multi-year campaign to identify novel compounds that avoided limiting preclinical safety concerns observed with its first-generation MetAP2 inhibitors. The Company is also leveraging its MetAP2 platform to discover additional, highly-differentiated, second-generation candidates that provide clear evidence of efficacy with promising safety margins. As a part of this restructuring, the Company has suspended development of its first-generation candidates, beloranib and ZGN-839, which were being developed for orphan obesity indications and nonalcoholic steatohepatitis, respectively.
- The Company commenced dosing in its ZGN-1061 Phase 1 clinical trial, which is progressing on schedule. The clinical trial includes a single ascending dose (SAD) portion, which will enroll up to 48 healthy patients, as well as a multiple ascending dose (MAD) portion that is evaluating twice-weekly administration of ZGN-1061 for safety, tolerability, and weight loss efficacy over four weeks in up to 24 obese patients. The Company continues to expect to report top-line results from its ongoing Phase 1 clinical trial of ZGN-1061 in the first quarter of 2017.

Third Quarter 2016 Financial Results

“Our strong balance sheet, coupled with the impact of our July restructuring, provides us with the resources to fund development of ZGN-1061 through key value-creating milestones,” stated Patricia Allen, Chief Financial Officer of Zafgen. “We expect our cash runway to extend through the end of 2018, by which time we expect to have data from a Phase 2a clinical trial for ZGN-1061.”

Cash, Cash Equivalents and Marketable Securities

As of September 30, 2016, the Company had cash, cash equivalents and marketable securities totaling \$138.7 million.

Net Loss

The Company reported a net loss for the third quarter of 2016 of \$14.7 million, or \$0.54 per share, compared to a net loss of \$19.9 million, or \$0.73 per share, for the third quarter of 2015.

The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 27,322,907 for the third quarter of 2016, compared to 27,138,667 for the third quarter of 2015.

Research and Development Expenses

Research and development expenses for the third quarter of 2016 were \$10.0 million, compared to \$14.2 million for the third quarter of 2015. The decrease in research and development expenses for the quarter ended September 30, 2016 as compared to the prior year quarter was primarily due to a decrease in preclinical, clinical and manufacturing costs related to beloranib and ZGN-839. These decreases were partially offset by increased spending on ZGN-1061 during the quarter ended September 30, 2016 as preclinical development and manufacturing activities continue and the Company initiated the Phase 1 clinical trial. There was also an increase in personnel related costs primarily related to severance expenses as a result of the reduction in workforce during the third quarter of 2016.

General and Administrative Expenses

General and administrative expenses for the third quarter of 2016 were \$4.8 million, compared to \$5.5 million for the third quarter of 2015. The decrease in general and administrative expenses for the quarter ended September 30, 2016 as compared to the prior year quarter was primarily due to a decrease in professional fees and non-cash stock-based compensation expense, partially offset by an increase in personnel related costs primarily related to severance expenses as a result of the reduction in workforce during the third quarter of 2016.

2016 Financial Guidance

The Company expects that its cash, cash equivalents and marketable securities balance will be greater than \$125 million at December 31, 2016.

About ZGN-1061

ZGN-1061 is a fumagillin-class, injectable small molecule second generation MetAP2 inhibitor that modulates the activity of key cellular processes that control the body's ability to make and store fat, and utilize fat and glucose as an energy source. In preclinical studies, ZGN-1061 has demonstrated promising efficacy and potency in animal models, with an improved pharmacokinetic profile and safety margin relative to previous molecules in the MetAP2 class. ZGN-1061 is anticipated to improve glycemic control while also helping to reduce hunger and 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. ZGN-1061 is currently in Phase 1 clinical development. 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. Zafgen's lead product candidate is ZGN-1061, which is a novel, first-in-class, twice-weekly 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, 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, 2016, 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, 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, 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 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 BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	<u>September 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 24,861	\$ 35,595
Marketable securities	113,796	149,484
Tax incentive receivable	1,403	1,323
Prepaid expenses and other current assets	1,515	1,708
Total current assets	141,575	188,110
Tax incentive receivable	331	—
Property and equipment, net	722	902
Other assets	84	94
Total assets	<u>\$ 142,712</u>	<u>\$ 189,106</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,640	\$ 7,495
Accrued expenses	4,580	6,112
Notes payable, current	3,119	2,936
Total current liabilities	11,339	16,543
Notes payable, net of discount, long-term	1,200	3,453
Total liabilities	<u>12,539</u>	<u>19,996</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; \$0.001 par value per share; 5,000,000 shares authorized as of September 30, 2016 and December 31, 2015; no shares issued and outstanding as of September 30, 2016 and December 31, 2015	—	—
Common stock, \$0.001 par value per share; 115,000,000 shares authorized as of September 30, 2016 and December 31, 2015; 27,329,233 and 27,242,503 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	27	27
Additional paid-in capital	357,322	348,961
Accumulated deficit	(227,110)	(179,671)
Accumulated other comprehensive loss	(66)	(207)
Total stockholders' equity	130,173	169,110
Total liabilities and stockholders' equity	<u>\$ 142,712</u>	<u>\$ 189,106</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, as amended, which includes the Company's audited consolidated financial statements for the year ended December 31, 2015.

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,	
	2016	2015	2016	2015
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	10,001	14,171	32,661	36,912
General and administrative	4,830	5,546	15,089	13,655
Total operating expenses	<u>14,831</u>	<u>19,717</u>	<u>47,750</u>	<u>50,567</u>
Loss from operations	<u>(14,831)</u>	<u>(19,717)</u>	<u>(47,750)</u>	<u>(50,567)</u>
Other income (expense):				
Interest income	230	143	664	245
Interest expense	(132)	(200)	(432)	(626)
Foreign currency transaction gains (losses), net	58	(110)	79	(164)
Total other income (expense), net	<u>156</u>	<u>(167)</u>	<u>311</u>	<u>(545)</u>
Net loss	<u>\$ (14,675)</u>	<u>\$ (19,884)</u>	<u>\$ (47,439)</u>	<u>\$ (51,112)</u>
Net loss per share, basic and diluted	<u>\$ (0.54)</u>	<u>\$ (0.73)</u>	<u>\$ (1.74)</u>	<u>\$ (1.92)</u>
Weighted average common shares outstanding, basic and diluted	<u>27,322,907</u>	<u>27,138,667</u>	<u>27,286,323</u>	<u>26,593,646</u>

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