
**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 4, 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 4, 2017, Zafgen, Inc. (the “Company”) announced that it ended the first quarter of 2017 with \$116.9 million in cash, cash equivalents and marketable securities and remains on track to end 2017 with greater than \$65 million in cash, cash equivalents and marketable securities. The Company expects to announce its full financial results for the first quarter of 2017 next week.

The information in this Item 2.02 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, as amended (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 7.01 Other Events

On May 4, 2017, the Company issued a press release announcing the results of its Phase 1 clinical trial of ZGN-1061, its second generation MetAP2 inhibitor. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information in this Item 7.01 and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of 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 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 4, 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 4, 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 4, 2017, furnished herewith.

Zafgen Announces Positive Topline Phase 1 Data for ZGN-1061, a Second Generation MetAP2 Inhibitor

- Clinical Trial Shows Weight Loss Trends of Up to One Pound Per Week and an Early Favorable Safety and Tolerability Profile -

- Improvements in Metabolic Parameters and Trends for Weight Loss Supportive of Drug Effect -

- Results Support Advancement to Phase 2 Clinical Trial in Patients with Type 2 Diabetes in the Second Half of This Year -

-Company to Host Conference Call at 4:30 PM Today -

BOSTON, May 4, 2017 – Zafgen, Inc. (Nasdaq:ZFGN) today announced positive topline data from its Phase 1 clinical trial of ZGN-1061, the Company's second generation MetAP2 inhibitor. ZGN-1061 demonstrated rapid drug absorption and clearance in line with pre-specified criteria established for the molecule, and was well-tolerated and safe, with no evidence of prothrombotic effects. Patients in the clinical trial experienced mean weight loss of up to approximately one pound per week.

"The results from this clinical trial mark an important first step in the clinical development of ZGN-1061, 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."

The Phase 1 clinical trial included a single ascending dose (SAD) phase, which enrolled healthy volunteers, and a multiple ascending dose (MAD) phase, which evaluated twice-weekly administration of ZGN-1061 in overweight or obese patients over four weeks. The SAD phase was comprised of six dosing cohorts ranging from 0.2 mg to 4.8 mg and the MAD phase was comprised of three dosing cohorts of 0.2 mg, 0.6 mg and 1.8 mg. The SAD phase included 39 volunteers (ZGN-1061 N=28, placebo N=11), 90% male and average body mass index (BMI) of 26 kg/m²; and the MAD phase included 29 patients (ZGN-1061 N=22, placebo N=7), 76% male and average BMI of 33 kg/m². Patients in the MAD phase were domiciled while receiving treatment and were subjected to inpatient safety monitoring for most of the clinical trial's 28-day duration.

Topline Data:

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. All AEs were of mild intensity in the MAD phase except one (toothache). The most common side effects were mild gastrointestinal issues, which were comparable between the ZGN-1061 and placebo groups, headache and procedural related irritation.

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.

ZGN-1061 demonstrated rapid drug exposure and clearance for all dose levels, in line with prospectively established criteria. Effective concentrations of drug were reached in circulation based on measurements of drug binding to the MetAP2 target enzyme.

“The data from this clinical trial provide a first view of the therapeutic potential of ZGN-1061 and its early favorable tolerability and safety profile,” stated Dr. Louis Aronne, the Sanford I. Weill Professor of Metabolic Research and a professor of clinical medicine at Weill Cornell Medicine.ⁱ “These early data provide a strong rationale for continued development of this promising molecule for the twin public health concerns of type 2 diabetes and obesity.”

“The compound showed a promising efficacy signal on weight loss and improvement in metabolic parameters, which is consistent with what we would expect to see with MetAP2 inhibition,” said Dennis Kim, M.D., Chief Medical Officer of Zafgen. “In addition, ZGN-1061 demonstrated more favorable pharmacokinetic and safety attributes compared to first generation MetAP2 inhibitors, with no clinically meaningful impact on sleep and no evidence of elevated thrombotic risk in this small clinical trial.”

Conference Call Information

Zafgen will host an investor conference call today, May 4, 2017 at 4:30 p.m., Eastern Time, to discuss the Phase 1 clinical trial data and provide a financial update. This call will replace the Company’s usual quarterly earnings call. Investors and other interested parties may participate by dialing (844) 824-7428 in the United States or (973) 500-2177 outside the United States and referencing conference ID number 13508906. 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 11:30 p.m. ET on May 4, 2017 through May 11, 2017 by dialing (855) 859-2056 in the United States or (404) 537-3406 outside the United States. To access the replay please provide Conference ID number 13508906.

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 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 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.

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i Dr. Aronne is a Zafgen stockholder and member of the Company's Clinical Advisory Board.