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): August 8, 2017

Zafgen, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE	**001-36510**	**20-3857670**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

175 Portland Street, 4th Floor **Boston, Massachusetts**	**02114**
(Address of principal executive offices)	**(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 August 8, 2017, Zafgen, Inc. announced its financial results for the second 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

Exhibit No.	Description
99.1	Press release issued by Zafgen, Inc. on August 8, 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: August 8, 2017

ZAFGEN, INC.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by Zafgen, Inc. on August 8, 2017, furnished herewith.

Exhibit 99.1

Zafgen Reports Second Quarter 2017 Financial Results

-ZGN-1061 Phase 1 Data Support Continued Development for Obese Patients with Type 2 Diabetes-

-Company to Initiate Phase 2 Clinical Trial in Third Quarter of This Year-

-Ends Quarter with Cash, Cash Equivalents and Marketable Securities of $106 Million; Increases Year-End Cash Guidance to Greater than $70 Million-

BOSTON, August 8, 2017 – Zafgen, Inc. (Nasdaq:ZFGN), today announced its second quarter 2017 financial results.

“In the second quarter, we reached a critical milestone in the development program for ZGN-1061, demonstrating its favorable safety and pharmacokinetic profile with the results of the Phase 1 clinical trial of our optimized MetAP2 inhibitor, as well as early efficacy signals for ZGN-1061’s potential to improve glycemic control and body weight,” said Thomas Hughes, Ph.D., President and Chief Executive Officer of Zafgen. “We also presented two late-breaking abstracts at the American Diabetes Association’s (ADA) 77th Annual Scientific Sessions meeting in June, further highlighting that ZGN-1061 treatment results in improvements across multiple metabolic measures and demonstrates rapid drug absorption and clearance, with no evidence of prothrombotic effects. We believe ZGN-1061 offers a novel opportunity to address the unmet medical need of patients who face the dual challenges of type 2 diabetes and obesity. We are on track to initiate a Phase 2 clinical trial studying the effects of ZGN-1061 on glycemic control in patients with type 2 diabetes in the third quarter of this year. In addition to our work in the clinic, we are ramping-up manufacturing to provide bulk drug supply for our longer-term studies.”

Recent Clinical Highlights

- In May, Zafgen reported positive topline data from both the single ascending dose (SAD) and multiple ascending dose (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.
- In June, Zafgen presented additional data for ZGN-1061, in two late-breaking posters at the ADA’s 77th Annual Scientific Sessions. A poster titled “Single and Multiple Dose Evaluation of a Novel MetAP2 Inhibitor: Results of a Randomized, Double-Blind, Placebo-Controlled Clinical Trial” detailed the full results from the Phase 1 clinical trial of ZGN-1061, including new efficacy data related to secondary endpoints. Specifically, ZGN-1061 produced improvements in waist circumference relative to placebo and resulted in a trend for reduced food intake relative to placebo. The clinical trial also demonstrated

trends for reductions in LDL-cholesterol, and high-sensitivity C-reactive protein (hsCRP). Notably, there were greater reductions in mean LDL-cholesterol and hsCRP in ZGN-1061-treated subjects with abnormally elevated LDL or hsCRP at baseline. Additionally, the clinical trial showed a trend for reductions in leptin and increases in adiponectin with ZGN-1061 compared to placebo, reflective of favorable changes in adipose function and signaling.

In a second poster titled “The MetAP2 Inhibitor ZGN-1061 Improves Glycemia and has Weight Loss Efficacy with an Improved Safety Profile in Preclinical Models,” Zafgen presented preclinical data demonstrating that ZGN-1061 showed similar beneficial effects on glycemic control, body weight, and other metabolic endpoints, but with a greatly improved safety profile in comparison to the Company’s prior development compound beloranib. Data included results from a study comparing ZGN-1061, beloranib and vehicle in a mouse model of obesity and insulin resistance, as well as *in vitro* and *in vivo* data demonstrating the impact of ZGN-1061 versus beloranib on multiple thrombotic markers.

Based on the positive data from the Company’s Phase 1 clinical trial and preclinical data supporting a differentiated profile and improved safety margin versus first generation MetAP2 inhibitors, Zafgen plans to initiate a Phase 2 clinical trial, ZAF-1061-201, in the third quarter of this year in Australia and New Zealand. This clinical trial will be a three month assessment, enrolling approximately 120 patients with type 2 diabetes who are overweight or obese. Patients will be randomized 3:1 and will be assigned to either placebo or one of three ZGN-1061 dosing arms, 0.05 mg, 0.3 mg and 0.9 mg, which will be administered by subcutaneous injection every three days. The key objectives of this clinical trial are to assess glycemic control, body weight, as well as safety and tolerability, including coagulation related measures.

Second Quarter 2017 Financial Results

“Our priority continues to be utilizing our current resources to advance ZGN-1061 through key value-creating milestones,” stated Patricia Allen, Chief Financial Officer of Zafgen. “With our focus on advancing ZGN-1061 while managing our expenses and headcount, we now 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 June 30, 2017, the Company had cash, cash equivalents and marketable securities totaling $106.0 million.

Net Loss

The Company reported a net loss for the second quarter of 2017 of $13.3 million, or $0.49 per share, compared to a net loss of $15.0 million, or $0.55 per share, for the second quarter of 2016.

The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 27,407,408 for the second quarter of 2017, compared to 27,272,225 for the second quarter of 2016.

Research and Development Expenses

Research and development expenses for the second quarter of 2017 were $10.5 million, compared to $10.2 million for the second quarter of 2016. The slight increase in research and development expenses for the second quarter of 2017 as compared to the prior year period was primarily due to increased preclinical, manufacturing and clinical trial costs related to ZGN-1061, partially offset by a decrease in our beloranib program as well as a decrease in personnel-related costs and consulting costs, as we shifted focus to ZGN-1061 in July 2016.

General and Administrative Expenses

General and administrative expenses for the second quarter of 2017 were $3.0 million, compared to $4.9 million for the second quarter of 2016. The decrease in general and administrative expenses for the second quarter of 2017 as compared to the prior year period was primarily due to a decrease in professional fees and non-cash stock-based compensation. For the second 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 now expects that its cash, cash equivalents and marketable securities balance will be greater than $70 million as of December 31, 2017.

Conference Call Information

Zafgen will host an investor conference call today, August 8, 2017 at 4:30 p.m., Eastern Time, to discuss the Company's second quarter 2017 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 and referencing conference ID number 51918952. The call will also be webcast live on the Company's website at https://zafgen.gcs-web.com/events-and-presentations. A replay of this conference call will be available beginning at 7:30 p.m. ET on August 8, 2017 through August 15, 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 51918952.

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 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 prothrombotic characteristics, compared to first generation MetAP2 inhibitors, such as over beloranib, and 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, 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 STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	10,528	10,163	20,205	22,660
General and administrative	3,008	4,899	6,596	10,259
Total operating expenses	13,536	15,062	26,801	32,919
Loss from operations	(13,536)	(15,062)	(26,801)	(32,919)
Other income (expense):				
Interest income	247	225	474	434
Interest expense	(53)	(140)	(126)	(300)
Foreign currency transaction gains (losses), net	(5)	(51)	95	21
Total other income (expense), net	189	34	443	155
Net loss	$ (13,347)	$ (15,028)	$ (26,358)	$ (32,764)
Net loss per share , basic and diluted	$ (0.49)	$ (0.55)	$ (0.96)	$ (1.20)
Weighted average common shares outstanding, basic and diluted	27,407,408	27,272,225	27,379,122	27,267,830

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

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 31,726	$ 32,352
Marketable securities	74,266	96,842
Tax incentive receivable	368	347
Prepaid expenses and other current assets	1,605	1,358
Total current assets	107,965	130,899
Tax incentive receivable	234	—
Property and equipment, net	588	661
Other assets	58	61
Total assets	$ 108,845	$ 131,621
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,447	$ 2,572
Accrued expenses	2,709	3,733
Notes payable, current	2,063	3,589
Total current liabilities	9,219	9,894
Total liabilities	9,219	9,894
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of June 30, 2017 and December 31, 2016; no shares issued and outstanding as of June 30, 2017 and December 31, 2016	—	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of June 30, 2017 and December 31, 2016; 27,449,465 and 27,332,551 shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively	27	27
Additional paid-in capital	363,547	359,329
Accumulated deficit	(263,907)	(237,549)
Accumulated other comprehensive loss	(41)	(80)
Total stockholders' equity	99,626	121,727
Total liabilities and stockholders' equity	$ 108,845	$ 131,621

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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