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, 2019

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. ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	ZFGN	NASDAQ Global Market

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2019, Zafgen, Inc. (the "Company") announced its financial results for the first quarter of 2019. 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, as amended, 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 May 9, 2019, furnished herewith.

* * *

SIGNATURE

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, 2019

ZAFGEN, INC.

By: /s/ Jeffrey S. Hatfield
Jeffrey S. Hatfield
Chief Executive Officer

Zafgen Reports First Quarter 2019 Operating and Financial Results

Recently announced positive results for second cohort of Phase 2 clinical trial of ZGN-1061

Company is currently in the formal regulatory process related to the clinical hold for ZGN-1061; Update still anticipated in Q2 2019

PATH for PWS study continues enrollment with strong support from PWS community

Boston, Mass., May 9, 2019 – Zafgen, Inc. (Nasdaq:ZFGN), a clinical-stage biopharmaceutical company leveraging its proprietary knowledge of MetAP2 systems biology to develop novel therapies for patients affected by a range of metabolic diseases, today reported its first quarter 2019 operating and financial results.

“Since our last update, we have continued to concentrate on addressing the FDA’s comments on the ZGN-1061 IND clinical hold. The team has generated a substantial amount of new data since ZGN-1061 was placed on clinical hold, which we believe support a constructive dialogue with the FDA,” said Jeffrey Hatfield, Chief Executive Officer. “We still expect to update investors on ZGN-1061 in the second quarter of 2019.”

Corporate Updates

ZGN-1061

- In January 2019, Zafgen announced positive data for the second cohort of its Phase 2 clinical trial of ZGN-1061 in patients with type 2 diabetes. The clinical trial met all of its primary objectives at the 1.8 mg dose, which included glycemic control, or change in A1C, and safety and tolerability. The data also showed a favorable safety and tolerability profile for ZGN-1061 through 12 weeks of treatment, with no treatment-related serious adverse events and no cardiovascular (CV) safety signals observed.
- Zafgen is currently in the formal regulatory process related to the previously disclosed clinical hold for ZGN-1061. An update on ZGN-1061 is still anticipated in Q2 2019.

ZGN-1258

- As previously announced in March 2019, Zafgen suspended plans to file an investigational new drug (IND) application for ZGN-1258 for Prader-Willi syndrome (PWS), based on an unexpected finding in muscle tissue in long-term rodent toxicology studies. Zafgen will provide an update on its plans for ZGN-1258 at a later time, if warranted, following further evaluation.

- PATH for PWS, Zafgen's natural history study conducted in collaboration with the Foundation for Prader-Willi Research (FPWR) continues enrollment. The data from this study are intended to inform the development and clinical trial design of potential new treatments.

Corporate

- In March 2019, Zafgen appointed a key executive to its leadership team, Priya Singhal, M.D., M.P.H., as Head of Research and Development, who brings nearly a decade of senior drug development experience in R&D strategy, drug safety and benefit-risk management. Dr. Singhal is responsible for leading and overseeing research, clinical and manufacturing strategy and implementation across the Company's portfolio of investigational MetAP2 inhibitors.

First Quarter 2019 Financial Results

Cash, Cash Equivalents and Marketable Securities

As of March 31, 2019, the Company had cash, cash equivalents, and marketable securities totaling $104.7 million.

Net Loss

The Company reported a net loss for the first quarter of 2019 of $13.1 million, or $0.35 per share, compared to a net loss of $16.0 million, or $0.58 per share, for the first quarter of 2018.

The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 37,313,947 for the first quarter of 2019 compared to 27,541,594 for the same quarter of 2018.

Research and Development Expenses

Research and development expenses for the first quarter of 2019 were $9.6 million compared to $12.4 million for the first quarter of 2018. The decrease in research and development expenses compared to the prior year period was primarily due to decreased clinical costs related to ZGN-1061 as the results of the second cohort of the Phase 2 clinical trial in type 2 diabetes were reported in January 2019. There was also a decrease in the ZGN-1258 program costs due to the suspension of the program during the first quarter of 2019. There were also decreases in discovery and screening costs and non-cash stock-based compensation expense in the first quarter of 2019 as compared to the first quarter of 2018. These decreases in research and development costs were partially offset by an increase in costs related to the ZGN-1345 program as the program advances as a development stage candidate.

General and Administrative Expenses

General and administrative expenses for the first quarter of 2019 were $3.6 million, compared to $3.3 million for the first quarter of 2018. The increase in general and administrative expenses as compared to the prior year period was primarily due to an increase in personnel related costs and non-cash stock-based compensation expense.

About Zafgen

Zafgen (Nasdaq:ZFGN) is a clinical-stage biopharmaceutical company leveraging its proprietary MetAP2 biology platform to develop novel therapies for patients affected by complex metabolic diseases. Zafgen has pioneered the study of MetAP2 inhibitors in both common and rare metabolic disorders. Learn more at www.zafgen.com.

Safe Harbor Statement

Various statements in this release concerning Zafgen's future expectations, plans and prospects, including without limitation, Zafgen's expectations regarding the development and use of ZGN-1258, ZGN-1061, ZGN-1345 and other second-generation MetAP2 inhibitors as treatments for metabolic diseases including Prader-Willi syndrome, type 2 diabetes, liver diseases and obesity, the collection of medical history and medical events from PATH for PWS participants to inform development for potential treatments for Prader-Willi syndrome and Zafgen's expectations with respect to the timing and success of its ability to collect and analyze PATH for PWS data for development and clinical trial design and with respect to its nonclinical studies and clinical trials of ZGN-1258, ZGN-1061, ZGN-1345 and its other product candidates, Zafgen's expected cash, cash equivalents and marketable securities balance as of March 31, 2019, and Zafgen's expectations regarding the length of its cash runway, may constitute forward-looking statements for the purposes of the safe harbor provisions of 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-1258, ZGN-1061, ZGN-1345 and its other product candidates and to differentiate them from first generation MetAP2 inhibitors, such as beloranib, the nonclinical and clinical results for ZGN-1258, ZGN-1061, ZGN-1345 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 nonclinical studies and clinical trials of its product candidates, Zafgen's ability to successfully engage with the FDA concerning the clinical hold on a clinical trial of ZGN-1061 and to design and conduct a nonclinical study or clinical trial demonstrating sufficient data to exclude cardiovascular risk to an acceptable degree, Zafgen's ability to overcome the full clinical hold place on ZGN-1061 by the FDA and obtain regulatory approval, Zafgen's ability to continue to evaluate ZGN-1258 and to advance the program in nonclinical and clinical development, 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 ability to attract and retain personnel, 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 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, including without limitation Zafgen's Quarterly Reports on Form 10-Q. 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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ZAFGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Revenue	$ —	$ —
Operating expenses:		
Research and development	9,631	12,433
General and administrative	3,646	3,269
Total operating expenses	13,277	15,702
Loss from operations	(13,277)	(15,702)
Other income (expense):		
Interest income	642	267
Interest expense	(500)	(458)
Foreign currency transaction gains (losses), net	23	(63)
Total other income (expense), net	165	(254)
Net loss	$ (13,112)	$ (15,956)
Net loss per share, basic and diluted	$ (0.35)	$ (0.58)
Weighted average common shares outstanding, basic and diluted	37,313,947	27,541,594

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

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 36,423	$ 49,331
Marketable securities	68,243	68,735
Tax incentive receivable	1,550	1,536
Prepaid expenses and other current assets	1,259	1,728
Total current assets	107,475	121,330
Property and equipment, net	337	375
Operating lease right-of-use assets	883	—
Tax incentive receivable, net of current portion	94	—
Restricted cash	1,339	—
Other assets	57	57
Total assets	$ 110,185	$ 121,762
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,156	$ 3,590
Accrued expenses and other	3,299	4,261
Notes payable, current	7,273	5,455
Total current liabilities	13,728	13,306
Notes payable, long-term	13,526	15,185
Operating lease liabilities	567	—
Total liabilities	27,821	28,491
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of March 31, 2019 and December 31, 2018; no shares issued and outstanding as of March 31, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of March 31, 2019 and December 31, 2018; 37,323,079 and 37,287,221 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	37	37
Additional paid-in capital	446,383	444,212
Accumulated deficit	(364,057)	(350,945)
Accumulated other comprehensive loss	1	(33)
Total stockholders' equity	82,364	93,271
Total liabilities and stockholders' equity	$ 110,185	$ 121,762