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 30, 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))

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**

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 7.01 Regulation FD Disclosure.

On May 30, 2019, Zafgen, Inc. (the "Company") issued a press release announcing a regulatory update on ZGN-1061. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K and is incorporated herein by reference.

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 30, 2019, 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 30, 2019

ZAFGEN, INC.

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

Zafgen Announces Regulatory Update on ZGN-1061

Received FDA Type A meeting minutes related to previously announced clinical hold

FDA acknowledged newly developed in vitro *assays of human plasma coagulation and tissue factor expression qualitatively differentiate ZGN-1061*

Company is working with FDA to translate in vitro data and confirm relevant safety margins in an in vivo model

Additionally, Zafgen is exploring a second IND for ZGN-1061 in a population with higher unmet medical need

Boston, Mass., May 30, 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 announced the receipt of minutes from its Type A meeting with the U.S. Food and Drug Administration (FDA) regarding the clinical hold for ZGN-1061.

Zafgen provided key new data in advance of the meeting, including newly developed *in vitro* assays of human plasma coagulation using endothelial cells and assessment of tissue factor expression with endothelial cells, and other supportive new assays. The Company is working with FDA to gain alignment on an *in vivo* animal model to confirm relevant safety margins as a next step toward resolving the clinical hold. Zafgen will be prepared to rapidly implement the agreed upon work.

"The Type A meeting with the FDA for ZGN-1061 was marked by constructive dialogue and progress driven by the important new data that the team worked diligently to provide to inform the discussion. This effort for Zafgen was led by highly experienced members of our team, Dr. Priya Singhal, our new Head of R&D, and Lisa Percival, our Vice President of Regulatory," said Jeffrey Hatfield, Chief Executive Officer. "We believe the new *in vitro* data generated was encouraging, and the FDA was helpful with guidance regarding data needed to move forward in type 2 diabetes."

Additionally, the Company is evaluating serious, rare disease indications that have few or no approved therapies in which ZGN-1061 could potentially benefit patients. The FDA was supportive of Zafgen seeking guidance on a second investigational new drug application (IND) for ZGN-1061, as appropriate.

Zafgen will provide an update on development plans by the end of the third quarter of 2019.

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-1061 as a treatment for metabolic diseases, nonclinical or clinical options to resolve the clinical hold concerning ZGN-1061, and Zafgen's expectations with respect to the timing and success of its nonclinical studies and clinical trials of ZGN-1061 and its other product candidates, 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-1061, ZGN-1258, 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-1061, ZGN-1258, 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 and demonstrating the risk is reasonable to type 2 diabetes or other indications, Zafgen's ability to overcome the full clinical hold placed 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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