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 26, 2018

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** **(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 8.01 Other Events.

On November 26, 2018, Zafgen, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration had placed a clinical hold on the Investigational New Drug Application for a new proposed clinical trial of ZGN-1061. A copy of the press release is filed herewith as Exhibit 99.1 to this Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Zafgen, Inc. on November 26, 2018.

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 26, 2018

ZAFGEN, INC.

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

Exhibit 99.1

Zafgen Provides Update on Investigational New Drug Application for ZGN-1061

Boston, Mass., November 26, 2018 –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 that the Company received a letter last week from the U.S. Food and Drug Administration (FDA) placing a clinical hold on the Investigational New Drug Application (IND) for its first U.S. clinical trial of ZGN-1061, the Company's second-generation, investigational MetAP2 inhibitor currently in development for the treatment of type 2 diabetes.

The FDA cited the possibility of cardiovascular (CV) safety risk based on the Company's prior compound and outlined multiple potential paths for moving forward, including nonclinical or clinical options, to address these concerns in the ongoing development of ZGN-1061. The Company plans to assess these options and request a Type A meeting with the Agency to discuss next steps with the program.

Zafgen continues to advance its ongoing ex-U.S. Phase 2 clinical trial of ZGN-1061, which includes a 1.8 mg dose cohort. Dosing in this clinical trial was recently completed and, while still blinded, no CV safety signals have been observed to date. The Company remains on track to report topline data from this cohort in early 2019. Zafgen previously reported positive full 12-week results for its initial cohort of this Phase 2 proof-of-concept clinical trial, which included a range of doses up to 0.9 mg. In that initial cohort, ZGN-1061 met all primary endpoints, demonstrating proof-of-concept efficacy with robust A1C lowering effects, and a favorable safety and tolerability profile generally comparable to placebo, with no treatment-related serious adverse events and no CV safety signals observed.

With the delay of additional clinical development for ZGN-1061, Zafgen now expects the Company's cash runway will extend through calendar year 2020, with sufficient capital through multiple milestones.

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 and is currently advancing programs for type 2 diabetes, Prader-Willi syndrome and liver diseases. 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 multiple paths for moving forward, including nonclinical or clinical options to resolve the clinical hold concerning the IND for a new proposed clinical trial of ZGN-1061, the use of ZGN-1258, ZGN-1061, ZGN-1345 and other second-generation MetAP2 inhibitors as treatments for metabolic diseases including PWS, type 2 diabetes, liver diseases and obesity, Zafgen's expectations regarding its capital requirements and runway, 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, may constitute forward-looking statements for 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 engage with the FDA concerning the clinical hold on a clinical trial of ZGN-1061, to design and conduct a nonclinical study or clinical trial demonstrating sufficient data to exclude cardiovascular risk to an acceptable degree, collect and analyze medical history and medical events from PATH for PWS participants, the capacity for such data to inform clinical trial design and potential areas for future study, 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 ZGN-1258, ZGN-1061, ZGN-1345 and its other product candidates 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 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, 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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