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): October 22, 2015

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

DELAWARE	001-36510	20-3857570
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

175 Portland Street Boston, MA	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))

Item 8.01 Other Events

On October 22, 2015, Zafgen, Inc. issued a press release announcing that it has elected to close the randomized portion of its Phase 3 ZAF-311 clinical trial of beloranib in patients with Prader-Willi syndrome and its ZAF-203 Phase 2b clinical trial of beloranib in patients with severe obesity complicated by type 2 diabetes to proceed with analysis of the data from these trials. A copy of the statement 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 October 22, 2015.

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: October 22, 2015

ZAFGEN, INC.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by Zafgen, Inc. on October 22, 2015.

Exhibit 99.1

Zafgen Announces Beloranib Program Update

-Company Elects to Proceed with Data Analysis for the Pivotal Phase 3 Study in Prader-Willi Syndrome and the Phase 2b in Severe Obesity Complicated by Type 2 Diabetes-
-Open Label Extension Portion of Phase 3 Prader-Willi Syndrome Study to Continue-

BOSTON – Oct. 22, 2015 – Zafgen, Inc. (Nasdaq:ZFGN), a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by obesity and complex metabolic disorders, today announced a clinical update for beloranib, the Company's lead MetAP2 inhibitor product candidate.

After review of its ongoing clinical trials, the Company has elected to proceed with efficacy and safety data analysis and close the randomized portion of its Phase 3 ZAF-311 clinical trial of beloranib in patients with Prader-Willi syndrome (PWS) and its ZAF-203 Phase 2b clinical trial of beloranib in patients with severe obesity complicated by type 2 diabetes. Zafgen believes that a sufficient number of patients have completed randomized treatment in both clinical trials to assess the efficacy of beloranib and help inform next steps for the beloranib program. Following the partial clinical hold announced last week, the Company believes it can best preserve the integrity of the data in each clinical trial by closing the randomized portion of the clinical trials early. The Company, based on consultation with the U.S. Food and Drug Administration (FDA), expects ZAF-311 to remain a pivotal clinical trial. The Company expects to report top-line results from both the ZAF-311 and ZAF-203 clinical trials in the first quarter of 2016.

Zafgen will continue the six-month open label extension (OLE) of the ZAF-311 clinical trial in PWS to obtain important ongoing efficacy and safety data. As previously planned, the Company is continuing to offer an open-ended, unblinded extension study after patients have completed six months of OLE.

In consultation with the FDA, a full assessment of the safety and efficacy data from ZAF-311 will be performed to inform the design of ZAF-312, the Company's second PWS Phase 3 clinical trial. The FDA has informed the Company that it will review the ZAF-311 clinical trial results on the basis of an abbreviated data package.

"The strategic decision to analyze results from the ZAF-311 and ZAF-203 clinical trials early allows us to better preserve data integrity by limiting dose interruption in both clinical trials, and inform the future development of this important product candidate," said Dennis Kim, M.D., Chief Medical Officer of Zafgen. "PWS is a life-threatening and complex rare disorder that severely impacts the quality of life of both patients and their families, and we continue to believe that beloranib may have an important role in addressing hyperphagia and underlying obesity associated with this disorder. We will continue to treat, closely monitor and follow patients in the ZAF-311 extension portion of the clinical trial."

As previously reported, Zafgen learned of a patient death in the ongoing Phase 3 ZAF-311 clinical trial of beloranib in PWS, and it subsequently received notice from the FDA that beloranib has been placed on a partial clinical hold. Although the autopsy report remains to be received, the cause of death based on the death certificate has been determined to be respiratory failure due to pulmonary emboli. However, it is not known if this event was related to treatment with beloranib.

“Patient safety is paramount and we will continue to work with regulators on current and future clinical trials of beloranib. Beloranib has demonstrated important clinical outcomes in patients with complicated and severe obesity, including patients with PWS,” said Dr. Thomas Hughes, Chief Executive Officer of Zafgen. “We look forward to analyzing results from our ZAF-311 and ZAF-203 clinical trials, and to advancing our programs. We remain committed to the PWS community and to the development of beloranib.”

About Beloranib

Beloranib is a novel, first-in-class injectable small molecule therapy with a unique mechanism of action that reduces hunger while stimulating the use of stored fat as an energy source. Beloranib is a potent inhibitor of MetAP2, an enzyme that modulates the activity of key cellular processes that control metabolism. MetAP2 inhibitors work, at least in part, by directing MetAP2 binding to cellular stress mediators, and, thus, reducing the tone of signals that drive lipid synthesis by the liver and fat storage throughout the body. In this manner, MetAP2 inhibition increases metabolism of fat as an energy source. Zafgen holds exclusive worldwide rights (exclusive of South Korea) for the development and commercialization of beloranib. Zafgen exclusively licensed beloranib from Chong Kun Dang Pharmaceutical Corporation (CKD Pharma) of South Korea.

About Prader-Willi Syndrome (PWS)

Prader-Willi syndrome (PWS), the most common known genetic cause of life-threatening obesity, results in constant and unrelenting hunger that drives patients with PWS to engage in problematic hunger-related behaviors and to gain excessive weight. As a result, many of those affected with PWS become morbidly obese and suffer significant mortality. Currently, there is no cure for this disease. Although the cause of PWS is complex, it results from a deletion or loss of function of a cluster of genes on the 15th chromosome. PWS typically causes low muscle mass and function, short stature, incomplete sexual development, and a chronic feeling of hunger that, when coupled with a metabolism that utilizes drastically fewer calories than normal, can lead to excessive eating and life-threatening obesity. PWS occurs in males and females equally and in all races, with the same incidence around the world. Prevalence estimates have ranged from 1:8,000 to 1:50,000.

About Zafgen

Zafgen (Nasdaq:ZFGN) is a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by obesity and complex metabolic disorders. Zafgen is focused on developing novel therapeutics that treat the underlying biological mechanisms through the MetAP2 pathway. Beloranib, Zafgen’s lead product candidate, is a novel, first-in-class, twice-weekly subcutaneous injection being developed for the treatment of multiple indications, including severe obesity in two rare diseases, Prader-Willi syndrome and obesity caused by hypothalamic injury, including craniopharyngioma-associated obesity; and severe obesity in the general population. Zafgen is also developing ZGN-839, a liver-targeted MetAP2 inhibitor, for the treatment of nonalcoholic steatohepatitis, or NASH, and abdominal obesity, as well as second-generation MetAP2 inhibitors. Zafgen aspires to improve the lives of patients through targeted treatments and has assembled a team accomplished in bringing therapies to patients with both rare and prevalent 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 beloranib as a treatment for PWS, HIAO, including craniopharyngioma-associated obesity, and other forms of severe obesity, including severe obesity in patients with type 2 diabetes, its expectations with respect to the timing and success of its clinical trials of beloranib and other product candidates, the expected requirements and timing of additional requirements for ongoing and planned clinical trials, the need for additional clinical trials and pre-clinical studies, and its plans regarding commercialization of beloranib 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 obtain a release of the partial clinical hold that the FDA placed on beloranib, the risk that the FDA may decide to elevate the partial clinical hold on beloranib to a full clinical hold, Zafgen's ability to successfully demonstrate the efficacy and safety of beloranib and its other product candidates the risk that patients may be unwilling to re-consent to participate in the open-label expansion portion of ZAF-311 or that patients may be unwilling to consent to participate in future clinical trials, the pre-clinical and clinical results for its product candidates, which may not support further development, actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials, obtaining, maintaining and protecting 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, Zafgen's dependence on third parties for development, manufacture, marketing, sales and distribution of products, 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.

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