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): January 20, 2016

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 January 20, 2016, Zafgen, Inc. issued a press release announcing the top-line results from its pivotal Phase 3 trial of beloranib in Prader-Willi Syndrome. 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 January 20, 2016.

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: January 20, 2016

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 January 20, 2016.

Exhibit 99.1

Zafgen's Pivotal Phase 3 Trial of Beloranib in Prader-Willi Syndrome Achieves Co-Primary Efficacy Endpoints

- bestPWS Study is the first Phase 3 pivotal trial to show significant weight-loss and improve hyperphagia-related behaviors in PWS patients-

-Statistically significant at both 2.4 mg and 1.8 mg dose levels-

-Company plans to discuss results and path forward for beloranib with the FDA-

-Conference call scheduled for 8:30 AM Eastern Time-

BOSTON, January 20, 2016 — Zafgen (Nasdaq:ZFGN), a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by obesity and complex metabolic disorders, announced today positive efficacy results from the bestPWS ZAF-311 study, a pivotal, double-blind, placebo-controlled Phase 3 trial evaluating the safety and efficacy of beloranib, a MetAP2 inhibitor, in patients with Prader-Willi syndrome (PWS) during a six-month randomized treatment period. The clinical trial achieved its co-primary efficacy endpoints, as beloranib demonstrated a statistically significant reduction in both body weight and hyperphagia-related behaviors, making it the first investigational drug to demonstrate a positive impact on these two hallmark challenges in PWS.

Treatment with the 2.4 mg and the 1.8 mg doses of beloranib resulted in 9.45 percent ($p<0.0001$) and 8.20 percent ($p<0.0001$) reductions in body weight relative to placebo, respectively. Treatment with the 2.4 mg and the 1.8 mg doses of beloranib also resulted in reductions of hyperphagia-related behaviors of 7.0 units ($p=0.0001$) and 6.3 units ($p=0.0003$) relative to placebo, respectively, as measured by the Hyperphagia Questionnaire for Clinical Trials (HQ-CT).

"This clear efficacy outcome is a crucial first step in moving discussions forward with the Food and Drug Administration regarding continued development of beloranib," stated Thomas Hughes, Ph.D., Chief Executive Officer of Zafgen. "While we take the previously reported adverse events very seriously, we now have the robust data to provide greater perspective on the benefit/risk relationship of beloranib in this high-risk patient population. We thank our investigators, and the patients and their families for participating in the bestPWS ZAF-311 clinical trial."

PWS is the most common genetic cause of life-threatening obesity. Pathologic hunger-related behaviors, known as hyperphagia, dominate the lives of individuals with PWS, and drive patients to engage in problematic behaviors which can lead to excessive overeating, choking, and stomach rupture. Compounding the morbid obesity in PWS is slowed metabolism, psychiatric conditions including aggression, anxiety, and psychosis, higher risk for cardiopulmonary and metabolic co-morbidities; all of which contribute to a higher risk of obesity-related mortality.

"Prader-Willi syndrome significantly impacts the quality of life of affected individuals and their families, as it drives patients to engage in excessive overeating, or hyperphagia, and may also lead to morbid obesity, which can be life-threatening if not controlled," said Merlin G. Butler, M.D., Ph.D., FFACMG,

Professor of Psychiatry, Behavioral Sciences and Pediatrics, Director, Division of Research and Genetics, Department of Psychiatry, Behavioral Sciences and Pediatrics at the Kansas University Medical Center. “There are no treatment options for these life-limiting problems, so I believe the significant improvements seen in both hyperphagia and obesity in patients receiving beloranib during this six-month clinical trial are clinically meaningful and support a strong rationale for continued evaluation of beloranib as a potential treatment for PWS.”

On December 2, 2015, the Food and Drug Administration (FDA) notified Zafgen that the beloranib investigational new drug (IND) application had been placed on complete clinical hold due to an imbalance in severe venous thromboembolic events, including two patient deaths. In order to address the clinical hold, Zafgen plans to present to the FDA the efficacy and safety data from the bestPWS ZAF-311 study, data from the Phase 2b trial of beloranib in severe obesity complicated by type 2 diabetes, ZAF-203, expected later this quarter, and a proposal for a risk mitigation strategy for beloranib in PWS.

“We are actively working to better understand the mechanisms and incidence of underlying thromboembolic disease in PWS, as well as the potential impact of beloranib treatment on thrombosis in order to develop a strategy for risk mitigation in this underserved patient population,” Dr. Hughes said. “We plan to continue our dialog with the FDA given the robust efficacy results seen in the ZAF-311 trial.”

BestPWS ZAF-311 Efficacy and Safety Results

The bestPWS ZAF-311 study randomized 107 patients to receive twice-weekly subcutaneous injections of either 2.4 mg or 1.8 mg of beloranib or placebo. Seventy-four patients completed the full 26 weeks of treatment per the trial protocol, and 27 patients completed at least 75 percent of the randomized treatment period prior to the suspension of dosing in the trial in October 2015. There were six patients who discontinued early. The co-primary efficacy endpoints for this trial were improvement in hyperphagia-related behaviors and reduction in body weight. Patients in the trial were on average 20 years old, had an average BMI of 40 kg/m^2 and an average hyperphagia total score of 16.9, consistent with moderate to severe hyperphagia, at the beginning of randomized treatment. These baseline characteristics were well-balanced across the treatment arms. In agreement with the FDA, Zafgen has analyzed the data using a mixed model repeated measures (MMRM) approach to account for the missing endpoint data of the patients who did not complete the clinical trial.

	Average Weight at Baseline (kg)	*Percent Change in Body Weight	*Placebo-adjusted Change in Body Weight	p-value
2.4 mg beloranib (n=37)	105.7	-5.30%	-9.45%	<0.0001
1.8 mg beloranib (n=36)	97.5	-4.05%	-8.20%	<0.0001
Placebo (n=34)	100.9	+4.15%		

* Endpoint results shown are Least Squared mean values.

Patients in the ZAF-311 trial were markedly obese at baseline. Patients randomized to receive placebo displayed substantial (4.15%) gain in body weight over the course of the six months of randomized

treatment. Body weight gain in this patient population was anticipated, and typically occurs throughout life generally due to lack of effective treatments for managing obesity. Patients treated with beloranib, in contrast to placebo, lost weight, with the 2.4 mg dose arm displaying a 5.3 percent reduction from baseline, with a placebo-adjusted weight loss of 9.45 percent.

	Hyperphagia Questionnaire (HQ-CT) Score at Baseline	*Unit Change in HQ-CT Score	*Placebo-adjusted Change in HQ-CT Score	p-value
2.4 mg beloranib (n=37)	18.3	-7.4	-7.0	0.0001
1.8 mg beloranib (n=36)	17.4	-6.7	-6.3	0.0003
Placebo (n=34)	15.0	-0.4		

*Endpointresults shown are Least Squared mean values.

The HQ-CT is a PWS-specific study instrument that provides an assessment by caregivers of the food-seeking behaviors exhibited by patients. The scale provides a composite value from nine questions, each rated on a scale of zero to four units (total range of score of zero to 36). Patients in the ZAF-311 trial were enrolled only if their baseline HQ-CT total score was greater than 12 units, representing moderate-to-severe hyperphagia related behaviors at baseline. While hyperphagia-related behaviors were stable over six months of treatment in the placebo arm, both the 2.4 mg and 1.8 mg beloranib arms showed highly statistically significant reductions in HQ-CT total score, indicative of reduced hunger-associated behaviors.

The most common adverse events (AEs) were injection site bruising, aggression, and hyperphagia, generally of mild and transient nature. Of these, only injection site bruising was notable as being reported more frequently in patients taking beloranib compared to placebo. There were a total of five serious adverse events (SAEs); aggression (placebo, 2.4 mg beloranib), ankle fracture (placebo), mental status change (1.8 mg beloranib), and pulmonary embolism (1.8 mg beloranib). Four patients withdrew due to adverse events in the 1.8 mg beloranib treatment group (abnormal behavior, anxiety, mental status changes, and pulmonary embolism) and two patients in the 2.4 mg beloranib group (injection site pain and psychotic disorder). Many of these adverse events, specifically psychiatric disorders, are commonly observed as background comorbidities in PWS patients. At the end of the randomized treatment period, there were no clinically significant abnormal patterns regarding laboratory values, vital signs, or electrocardiography (ECG) findings. As previously disclosed, across the completed trials comprising the beloranib clinical program, there has been an association of venous thromboembolic events reported in patients treated with beloranib versus placebo, including one fatal case of pulmonary embolism (1.8 mg beloranib) during the randomized portion of the bestPWS study that was reported in October 2015. No other venous thromboembolic events were reported during the blinded randomized portion of the bestPWS study. As previously reported, a second patient death associated with pulmonary embolism (2.4 mg beloranib) and two cases of deep vein thrombosis (1.8 mg and 2.4 mg beloranib) occurred during the open-label extension portion of the bestPWS study. No other deaths have occurred in the course of the beloranib program.

Zafgen plans to present the full safety and efficacy data set from the bestPWS Phase 3 trial, including impact on body composition, cardiovascular disease risk markers, metabolic endpoints, and quality of life measures at upcoming medical meetings.

Conference Call Information

Zafgen will host an investor conference call today, January 20, 2016 at 8:30 a.m., Eastern Time, to discuss the trial results in more detail. Investors and other interested parties may participate by dialing (844) 824-7428 in the United States or (973) 500-2177 outside the United States. The call will also be webcast live on the Company's website at http://ir.zafgen.com/events.cfm. You can access the replay for seven days by dialing (855) 859-2056 in the United States or (404) 537-3406 outside the United States and referencing conference ID number 32720188.

About Beloranib

Beloranib is a novel, first-in-class injectable small molecule therapy that works by inhibiting MetAP2, an enzyme that modulates the activity of key cellular processes that control metabolism. Once a person becomes obese, the body undergoes certain metabolic changes and becomes "programmed" to create and store more fat, making it much more difficult to reduce body weight. Beloranib is believed to help reduce hunger and restore balance to fat metabolism, enabling calories to once again be used as a productive energy source. Because beloranib works beyond just regulating hunger through the hypothalamus, it has the potential to be used in a variety of complex metabolic disorders such as Prader-Willi syndrome and hypothalamic injury associated obesity. 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), is the most common known genetic cause of life-threatening obesity. A dysfunctional signaling to the hypothalamus results in constant and unrelenting perception of starvation, driving patients with PWS to engage in problematic hunger-related behaviors, known as hyperphagia, 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. Patients with PWS have a shortened life expectancy of approximately 32 years, as a result of an estimated three percent annual death rate for the PWS population. Common causes of mortality in PWS include respiratory disease, cardiac disease, infection, choking, gastric rupture, and pulmonary embolism.

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, obesity caused by hypothalamic injury, including craniopharyngioma-associated obesity, and other forms of severe obesity, including severe obesity in patients with type 2 diabetes, Zafgen's expectations with respect to the timing and success of its clinical trials of beloranib and its other product candidates, the expected requirements and timing of additional requirements for planned clinical trials, and the need for additional clinical trials and pre-clinical studies, and Zafgen's 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 full clinical hold that the FDA placed on the investigational new drug application for beloranib, Zafgen's ability to successfully demonstrate the efficacy and safety of beloranib and its other product candidates, the pre-clinical and clinical results for beloranib 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, 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, 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.

Media/Investor Relations Contact:

Zafgen, Inc.
Patricia Allen
Chief Financial Officer
617-648-9792

Argot Partners
Investor Relations
David Pitts or Laura Perry
212-600-1902
david@argotpartners.com
laura@argotpartners.com

Spectrum Science
Media Relations
Susan Francis
609-529-0676
sfrancis@spectrumscience.com