
**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 14, 2015

Zafgen, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-36510
(Commission
File Number)

20-3857570
(I.R.S. Employer
Identification No.)

175 Portland Street
Boston, MA
(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))
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Item 8.01 Other Events

On October 14, 2015, Zafgen, Inc. (the “Company”) issued a statement noting that it had recently learned of a patient death in its ongoing double-blind, randomized, placebo-controlled Phase 3 bestPWS study of beloranib in patients with 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

| <u>Exhibit No.</u> | <u>Description</u> |
|------------------------|---|
| 99.1 | Statement issued by Zafgen, Inc. on October 14, 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 14, 2015

ZAFGEN, INC.

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

EXHIBIT INDEX

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ZAFGEN ISSUES STATEMENT

BOSTON, Oct. 14, 2015 (GLOBE NEWSWIRE) — 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 issued the following statement:

“Zafgen recently learned of a patient death which occurred in the Company’s ongoing double-blind, randomized, placebo-controlled Phase 3 bestPWS study of beloranib in Prader-Willi Syndrome, a rare genetic disorder with a high rate of mortality linked to obesity and its co-morbidities. The cause of death remains unknown at this time. According to normal practice, the event was reported to the U.S. Food and Drug Administration, at which point the Agency initiated a discussion with the Company. The Company is working with the Agency to expedite a review and understanding of this event, and to determine implications of the event on the conduct of the trial, and anticipates providing an update as its discussions with the Agency progress. The thoughts of the Company are with the family of the patient at this time. Zafgen remains committed to ensuring the safety of all patients enrolled in its studies.”

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, including the Phase 3 bestPWS study of beloranib in PWS, the expected requirements and timing of 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, the FDA not agreeing with Zafgen’s ultimate assessment of the recent patient death in Zafgen’s Phase 3 bestPWS study of beloranib in PWS, the FDA’s response to the recent patient death in Zafgen’s Phase 3 bestPWS study of beloranib in PWS, which could include additional safety measures in the conduct of the trial, or placing a partial or full clinical hold on the trial, Zafgen’s ability to successfully demonstrate the efficacy and safety of its product candidates, 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, manufacturing, marketing, sales and distribution of products, the outcome of litigation, and unexpected expenditures, as well as those risks, are 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
Michelle Strier
202-587-2582
mstrier@spectrumscience.com