
**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): August 4, 2016

Zafgen, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-36510
(Commission
File Number)

20-3857670
(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))
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Item 2.02 Results of Operations and Financial Condition.

On August 4, 2016, Zafgen, Inc. announced its financial results for the second quarter of 2016. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K and is incorporated by reference herein.

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 (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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

| <u>Exhibit No.</u> | <u>Description</u> |
|------------------------|---|
| 99.1 | Press release issued by Zafgen, Inc. on August 4, 2016, 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: August 4, 2016

ZAFGEN, INC.

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

EXHIBIT INDEX

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Zafgen Reports Second Quarter 2016 Financial Results

BOSTON, August 4, 2016 – 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 its second quarter 2016 financial results.

“The compelling efficacy data that we observed in our clinical trials of beloranib, our first-generation MetAP2 inhibitor, demonstrate the potential of MetAP2 inhibition to significantly reduce body weight, improve glycemic control and impact cardiovascular risk factors, and we are now leveraging our experience to focus on the development of our differentiated second generation candidate, ZGN-1061,” said Thomas Hughes, Ph.D., President and Chief Executive Officer of Zafgen. “ZGN-1061 has been optimized to offer the efficacy advantages of beloranib with an improved safety margin. We look forward to evaluating this promising candidate in the clinical setting as we advance our Phase 1 clinical trial.”

Recent Corporate and Clinical Highlights

- The Company is currently screening patients for its Phase 1 clinical trial of ZGN-1061, its second generation MetAP2 inhibitor. The clinical trial is designed to evaluate safety, tolerability and pharmacokinetics while also gaining an early indication of weight loss efficacy over four weeks of treatment. Zafgen continues to expect Phase 1 data by the end of the first quarter of 2017.
- In July 2016, Zafgen refocused its resources on the development of ZGN-1061 and suspended further development of beloranib. In connection with this announcement, the Company implemented a restructuring plan designed to align operations with its new development priorities focused on ZGN-1061.
- In June 2016, the Company presented the full data from its Phase 2b ZAF-203 clinical trial of beloranib in patients with severe obesity complicated by type 2 diabetes at the American Diabetes Association’s 76th Scientific Sessions. The efficacy data showed that treatment with a MetAP2 inhibitor was associated with an improvement in body composition, including a significant decrease in body weight, as well as glycemic control parameters including HbA1c, when compared to placebo.

Second Quarter 2016 Financial Results

“We have a strong balance sheet and are well-positioned to advance development of ZGN-1061 through key value-creating milestones,” stated Patricia Allen, Chief Financial Officer of Zafgen. “Our recent restructuring aligned our operations with a new focus on ZGN-1061, and extended our cash runway to the end of 2018, at which time we expect to have completed a Phase 2a clinical trial for ZGN-1061.”

Cash, Cash Equivalents and Marketable Securities

As of June 30, 2016, the Company had cash, cash equivalents and marketable securities totaling \$150.5 million.

Net Loss

The Company reported a net loss for the second quarter of 2016 of \$15.0 million, or \$0.55 per share, compared to a net loss of \$17.8 million, or \$0.66 per share, for the second quarter of 2015.

The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 27,272,225 for the second quarter of 2016, compared to 27,011,960 for the second quarter of 2015.

Research and Development Expenses

Research and development expenses for the second quarter of 2016 were \$10.2 million, compared to \$12.5 million for the second quarter of 2015. The decrease in research and development expenses for the quarter ended June 30, 2016 as compared to the prior year quarter was primarily due to the timing of preclinical, clinical and manufacturing costs related to beloranib. The decrease in expenses related to beloranib was partially offset by increased spending on ZGN-1061 during the three months ended June 30, 2016 as the program was progressing towards clinical development. There was also an increase in personnel related costs related to hiring new employees during the first three quarters of 2015, as well as an increase in consulting costs and non-cash stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses for the second quarter of 2016 were \$4.9 million, compared to \$5.1 million for the second quarter of 2015. The decrease in general and administrative expenses for the quarter ended June 30, 2016 as compared to the prior year quarter was primarily due to a decrease in professional fees, partially offset by an increase in non-cash stock-based compensation expense.

2016 Financial Guidance

The Company expects that its cash, cash equivalents and marketable securities balance will be greater than \$125 million at December 31, 2016.

About ZGN-1061

ZGN-1061 is a fumagillin-class, injectable small molecule second generation MetAP2 inhibitor that was discovered by Zafgen's researchers and, to date, has been shown to have an improved safety margin relative to previous inhibitors in the class. Like other MetAP2 inhibitors that have shown promise in the treatment of severe and complicated types of obesity, ZGN-1061 modulates the activity of key cellular processes that control the body's ability to make and store fat, and utilize fat and glucose as an energy source. ZGN-1061 is also anticipated to help reduce hunger and restore balance to fat metabolism, enabling calories to once again be used as a productive energy source, leading to weight loss and improved metabolic control. ZGN-1061 has a promising emerging profile and is currently in Phase 1 clinical development. Zafgen holds exclusive worldwide rights for the development and commercialization of ZGN-1061.

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 of severe obesity and complex metabolic disorders through the MetAP2 pathway. Zafgen has pioneered the study of MetAP2 inhibitors in both common and rare forms of obesity. Zafgen's lead product candidate is ZGN-1061, which

is a novel, fumagillin-class MetAP2 inhibitor administered by subcutaneous injection and is currently in Phase 1 clinical development. Zafgen is also developing ZGN-839, a liver-targeted MetAP2 inhibitor, for the treatment of nonalcoholic steatohepatitis, or NASH, and abdominal obesity. Zafgen aspires to improve the lives of patients through targeted treatments and has assembled a team accomplished in bringing therapies to patients affected by 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 the use of ZGN-1061 and other MetAP2 inhibitors as treatments for severe obesity and complex metabolic disorders, Zafgen's expectations with respect to the timing and success of its pre-clinical studies and clinical trials of ZGN-1061 and its other product candidates, and Zafgen's expected cash, cash equivalents and marketable securities balance as of December 31, 2016, 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 successfully demonstrate the efficacy and safety of ZGN-1061 and its other product candidates, the pre-clinical and clinical results for ZGN-1061 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 pre-clinical 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, Zafgen's dependence on third parties for development, manufacture, marketing, sales and distribution of product candidates, 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.

ZAFGEN, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

| | <u>June 30,</u> <u>2016</u> | <u>December 31,</u> <u>2015</u> |
|---|--------------------------------|------------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 20,026 | \$ 35,595 |
| Marketable securities | 130,442 | 149,484 |
| Tax incentive receivable | 1,350 | 1,323 |
| Prepaid expenses and other current assets | 1,334 | 1,708 |
| Total current assets | 153,152 | 188,110 |
| Property and equipment, net | 1,256 | 902 |
| Tax incentive receivable | 331 | — |
| Other assets | 87 | 94 |
| Total assets | <u>\$ 154,826</u> | <u>\$ 189,106</u> |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,581 | \$ 7,495 |
| Accrued expenses | 4,976 | 6,112 |
| Notes payable, current | 3,057 | 2,936 |
| Total current liabilities | 10,614 | 16,543 |
| Notes payable, net of discount, long-term | 1,973 | 3,453 |
| Total liabilities | <u>12,587</u> | <u>19,996</u> |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock; \$0.001 par value per share; 5,000,000 shares authorized as of June 30, 2016 and December 31, 2015; no shares issued and outstanding as of June 30, 2016 and December 31, 2015 | — | — |
| Common stock, \$0.001 par value per share; 115,000,000 shares authorized as of June 30, 2016 and December 31, 2015; 27,272,261 and 27,242,503 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively | 27 | 27 |
| Additional paid-in capital | 354,661 | 348,961 |
| Accumulated deficit | (212,435) | (179,671) |
| Accumulated other comprehensive loss | (14) | (207) |
| Total stockholders' equity | <u>142,239</u> | <u>169,110</u> |
| Total liabilities and stockholders' equity | <u>\$ 154,826</u> | <u>\$ 189,106</u> |

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K, as amended, which includes the Company's audited consolidated financial statements for the year ended December 31, 2015.

ZAFGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
(Unaudited)

| | <u>Three Months Ended June 30,</u> | | <u>Six Months Ended June 30,</u> | |
|---|------------------------------------|--------------------|----------------------------------|--------------------|
| | <u>2016</u> | <u>2015</u> | <u>2016</u> | <u>2015</u> |
| Revenue | \$ — | \$ — | \$ — | \$ — |
| Operating expenses: | | | | |
| Research and development | 10,163 | 12,526 | 22,660 | 22,741 |
| General and administrative | 4,899 | 5,084 | 10,259 | 8,109 |
| Total operating expenses | <u>15,062</u> | <u>17,610</u> | <u>32,919</u> | <u>30,850</u> |
| Loss from operations | <u>(15,062)</u> | <u>(17,610)</u> | <u>(32,919)</u> | <u>(30,850)</u> |
| Other income (expense): | | | | |
| Interest income | 225 | 63 | 434 | 102 |
| Interest expense | (140) | (213) | (300) | (426) |
| Foreign currency transaction gains (losses), net | (51) | 4 | 21 | (54) |
| Total other income (expense), net | <u>34</u> | <u>(146)</u> | <u>155</u> | <u>(378)</u> |
| Net loss | <u>\$ (15,028)</u> | <u>\$ (17,756)</u> | <u>\$ (32,764)</u> | <u>\$ (31,228)</u> |
| Net loss per share , basic and diluted | <u>\$ (0.55)</u> | <u>\$ (0.66)</u> | <u>\$ (1.20)</u> | <u>\$ (1.19)</u> |
| Weighted average common shares outstanding, basic and diluted | <u>27,272,225</u> | <u>27,011,960</u> | <u>27,267,830</u> | <u>26,316,619</u> |

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