

**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 8, 2019

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.)

**3 Center Plaza, Suite 610
Boston, Massachusetts**
(Address of principal executive offices)

02108
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ZFGN	NASDAQ Global Market

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 2.02 Results of Operations and Financial Condition.

On August 8, 2019, Zafgen, Inc. (the “Company”) announced its financial results for the second quarter of 2019. 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, as amended (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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	<u>Press release issued by Zafgen, Inc. on August 8, 2019, furnished herewith.</u>

* * *

SIGNATURE

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 8, 2019

ZAFGEN, INC.

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



Zafgen Reports Second Quarter 2019 Operating and Financial Results

Agreement reached with U.S. FDA on in vivo animal study design and protocol to translate work from novel in vitro assays and establish relevant safety margins

Topline data from the in vivo study expected by the end of 2019

PATH for PWS study over-enrolled with continued strong support from Prader-Willi syndrome (PWS) community

Boston, August 8, 2019 – 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 reported its second quarter 2019 operating and financial results.

“Since the beginning of 2019, we have remained focused on gaining clarity on the path forward for ZGN-1061. With the recent alignment with the FDA on the design of an *in vivo* animal study, we are now preparing for the rapid initiation and strong execution of this study,” said Jeffrey Hatfield, Chief Executive Officer. “We expect to provide topline data by the end of 2019, which will be the driving factor that informs our future plans. In addition, we have strong financial resources, which we expect to last greater than two years, given our current operating plan.”

Corporate Updates

- In July 2019, Zafgen announced that it had reached agreement with the U.S. Food and Drug Administration (FDA) on an *in vivo* animal study design and protocol to establish relevant safety margins for ZGN-1061, its investigational MetAP2 inhibitor in development. The study is designed to translate the data from Zafgen’s newly developed *in vitro* assays of human endothelial cells and assessment of tissue factor expression with endothelial cells, along with other supportive assays, as it works toward resolving the previously announced clinical hold. Topline data from the *in vivo* animal study are expected by the end of 2019.
- In June 2019, Zafgen completed its enrollment for PATH for PWS, Zafgen’s natural history study conducted in collaboration with the Foundation for Prader-Willi Research (FPWR). The study over-enrolled in less than one year from its initiation, with approximately 700 participants across multiple age groups and other important segments of the PWS community, versus the initial goal of 500 participants. The data from this study are intended to inform the development and clinical trial design of potential new treatments for PWS.

- In June 2019, Zafgen presented the positive full results of its Phase 2 clinical trial for ZGN-1061 in an oral presentation at the American Diabetes Association's 79th Scientific Sessions. Zafgen also presented a poster on data demonstrating that treatment with ZGN-1061 improved measures of glycemic control, including insulin sensitivity and beta-cell function.

Second Quarter 2019 Financial Results

Cash, Cash Equivalents and Marketable Securities

As of June 30, 2019, the Company had cash, cash equivalents, and marketable securities totaling \$91.7 million. Based on recently implemented plans to reduce its operating expenses and prioritize key resources, Zafgen expects its projected cash runway to last greater than two years, given its current operating plan.

Net Loss

The Company reported a net loss for the second quarter of 2019 of \$12.1 million, or \$0.32 per share, compared to a net loss of \$15.8 million, or \$0.57 per share, for the second quarter of 2018.

The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 37.3 million for the second quarter of 2019 compared to 27.6 million for the same quarter of 2018.

Research and Development Expenses

Research and development expenses for the second quarter of 2019 were \$8.6 million compared to \$12.2 million for the second quarter of 2018. The decrease in research and development expenses compared to the prior year period was primarily due to completion of the second cohort of the Phase 2 clinical trial in type 2 diabetes for ZGN-1061, decreased spending and non-cash stock-based compensation expense related to our other clinical and nonclinical programs and activities, partially offset by an increase in costs related to ZGN-1345 as the program advances as a development stage candidate.

General and Administrative Expenses

General and administrative expenses for the second quarter of 2019 were \$3.6 million, compared to \$3.4 million for the second quarter of 2018. The increase in general and administrative expenses as compared to the prior year period was primarily due to an increase in personnel related costs and non-cash stock-based compensation expense.

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. 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 the development and use of ZGN-1061, ZGN-1258, ZGN-1345 and other second-generation MetAP2 inhibitors as treatments for metabolic diseases including Prader-Willi syndrome, type 2 diabetes, liver diseases and obesity, the collection of medical history and medical events from PATH for PWS participants to inform development for potential treatments for Prader-Willi syndrome and Zafgen's expectations with respect to the timing and success of its ability to collect and analyze PATH for PWS data for development and clinical trial design and with respect to its nonclinical studies and clinical trials of ZGN-1061, ZGN-1258, ZGN-1345 and its other product candidates, Zafgen's expected cash, cash equivalents and marketable securities balance as of June 30, 2019, and Zafgen's expectations regarding the length of its cash runway, may constitute forward-looking statements for the 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 demonstrate the efficacy and safety of ZGN-1061, ZGN-1258, ZGN-1345 and its other product candidates and to differentiate them from first generation MetAP2 inhibitors, such as beloranib, the nonclinical and clinical results for ZGN-1061, ZGN-1258, 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 execute the *in vivo* animal study designed in alignment with the FDA, establish acceptable safety margins on ZGN-1061 based on the results of such study and resolve the clinical hold on ZGN-1061 based on the results of such study, Zafgen's ability to overcome the full clinical hold place on ZGN-1061 by the FDA and obtain regulatory approval, Zafgen's ability to continue to evaluate ZGN-1258 and to advance the program in nonclinical and clinical development, 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 ability to attract and retain personnel, 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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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>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	8,572	12,209	18,203	24,642
General and administrative	3,618	3,351	7,264	6,620
Total operating expenses	<u>12,190</u>	<u>15,560</u>	<u>25,467</u>	<u>31,262</u>
Loss from operations	<u>(12,190)</u>	<u>(15,560)</u>	<u>(25,467)</u>	<u>(31,262)</u>
Other income (expense):				
Interest income	561	324	1,203	591
Interest expense	(478)	(466)	(978)	(924)
Foreign currency transaction (losses) gains, net	(22)	(73)	1	(136)
Total other income (expense), net	<u>61</u>	<u>(215)</u>	<u>226</u>	<u>(469)</u>
Net loss	<u>\$ (12,129)</u>	<u>\$ (15,775)</u>	<u>\$ (25,241)</u>	<u>\$ (31,731)</u>
Net loss per share, basic and diluted	<u>\$ (0.32)</u>	<u>\$ (0.57)</u>	<u>\$ (0.68)</u>	<u>\$ (1.15)</u>
Weighted average common shares outstanding, basic and diluted	<u>37,326,853</u>	<u>27,565,064</u>	<u>37,320,436</u>	<u>27,553,394</u>

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

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 37,240	\$ 49,331
Marketable securities	54,418	68,735
Tax incentive receivable	1,532	1,536
Prepaid expenses and other current assets	811	1,728
Total current assets	94,001	121,330
Property and equipment, net	968	375
Operating lease right-of-use assets	7,342	—
Tax incentive receivable, net of current portion	214	—
Restricted cash	1,339	—
Other assets	20	57
Total assets	<u>\$ 103,884</u>	<u>\$ 121,762</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,056	\$ 3,590
Accrued expenses	3,516	4,261
Operating lease liabilities, current	618	—
Notes payable, current	7,273	5,455
Total current liabilities	13,463	13,306
Notes payable, long-term	11,853	15,185
Operating lease liabilities	6,429	—
Total liabilities	<u>31,745</u>	<u>28,491</u>
Stockholders' equity:		
Preferred stock; \$0.001 par value per share; 5,000,000 shares authorized as of June 30, 2019 and December 31, 2018; no shares issued and outstanding as of June 30, 2019 and December 31, 2018	—	—
Common stock, \$0.001 par value per share; 115,000,000 shares authorized as of June 30, 2019 and December 31, 2018; 37,326,895 and 37,287,221 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	37	37
Additional paid-in capital	448,258	444,212
Accumulated deficit	(376,186)	(350,945)
Accumulated other comprehensive income (loss)	30	(33)
Total stockholders' equity	72,139	93,271
Total liabilities and stockholders' equity	<u>\$ 103,884</u>	<u>\$ 121,762</u>