



## Zafgen to Explore Strategic Alternatives

September 5, 2019

### **Preliminary results from in vivo animal study not expected to warrant near-term resolution of clinical hold for ZGN-1061**

BOSTON, Sept. 05, 2019 (GLOBE NEWSWIRE) -- 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 announced plans to explore strategic options to maximize shareholder value. Potential strategic alternatives that may be evaluated include, but are not limited to, an acquisition, merger, business combination, in-licensing, or other strategic transaction involving the Company or its assets.

"Given the alignment and clarity of our recent work with the FDA, and the preliminary results from our ongoing nonclinical study to translate *in vitro* differentiation results into an *in vivo* model system, we believe there is low probability of resolving the clinical hold in the near-term. Because of this, Zafgen has determined that it is in the best interest of shareholders to expand our internal corporate development efforts and formally evaluate strategic alternatives," said Jeffrey Hatfield, Chief Executive Officer. "A transaction committee has been formed within the Board of Directors, and we will update investors as appropriate."

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. Based on preliminary results from this study reviewed this week, Zafgen does not presently expect the data to warrant resolution of the clinical hold for ZGN-1061.

Based on previously announced and recently implemented plans to reduce operating expenses and prioritize key resources, Zafgen expects its projected cash runway to last greater than two years, given its current operating plan.

The Company has retained MTS Health Partners L.P. as its exclusive advisor to assist the Company in exploring alternatives. There can be no assurance that the exploration of strategic alternatives will result in any transaction being entered into or consummated. The Company has not set a timetable for completion of this review process and the Company does not intend to comment further unless or until the Board of Directors has approved a definitive course of action, the review process is concluded, or it is determined that other disclosure is appropriate.

### **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](http://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 as a treatment for metabolic diseases, nonclinical or clinical options to resolve the clinical hold concerning ZGN-1061, Zafgen's expectations with respect to the timing and success of its nonclinical studies and clinical trials of ZGN-1061 and its other product candidates, Zafgen's plans to explore strategic alternatives, 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 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 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 placed on ZGN-1061 by the FDA and obtain regulatory approval, Zafgen's ability to explore strategic alternatives and enter into and consummate a transaction as a result of such process, 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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