Zafgen Reports Fourth Quarter and Full Year 2017 Financial Results; Announces Positive Interim Data from Ongoing ZGN-1061 Phase 2 Proof-of-Concept Trial in Patients with Type 2 Diabetes

March 6, 2018

ZGN-1061 interim data suggest compound is safe and well-tolerated; no safety signals and placebo-like side effect profile

ZGN-1061 interim efficacy data indicate significant A1C lowering vs. placebo at 8 weeks

ZGN-1258 for Prader-Willi syndrome (PWS) added to the pipeline; IND enabling studies initiated

Ended 2017 with $102 million in cash, cash equivalents and marketable securities

BOSTON, March 06, 2018 (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 reported its fourth quarter and full year 2017 financial results.

“After a relatively quiet period of intense scientific work here at the company in 2017, Zafgen has emerged in 2018 with momentum, spanning an expanded pipeline of high potential development candidates, each targeting a specific and significantly underserved area within the broad metabolic disease category,” said Jeffrey Hatfield, Chief Executive Officer. “We are an energized team in 2018, executing on our operating plans, with the goal of delivering multiple value creating milestones throughout the year. Just today, we announced positive interim data from our ongoing Phase 2 proof-of-concept trial with ZGN-1061 involving patients with type 2 diabetes, which has further boosted our confidence and enthusiasm for the program going forward.”

Recent Corporate and Clinical Highlights

ZGN-1061

- Today, Zafgen announced encouraging results from an interim analysis of the ongoing 12 week Phase 2 proof-of-concept ZAF-1061-201 clinical trial of ZGN-1061 in type 2 diabetes, reflecting data from 57 patients at 8 weeks in the trial at the time of the interim analysis.
    - Interim data suggest that ZGN-1061 is safe and well-tolerated in the trial, with no safety signals observed or reported, and side effects generally comparable to placebo.
    - Interim analysis of efficacy data indicates that the 0.9 mg dose produced a statistically significant placebo adjusted change in A1C at 8 weeks of -0.57%, $p < 0.05$.
    - Based on the confidence instilled by the safety and tolerability results of this interim analysis, Zafgen has opted to explore the higher end of the therapeutic range of ZGN-1061 by adding a 1.8 mg dose arm to the trial. This arm will run nearly in parallel with completion of long-term toxicology studies for ZGN-1061, and is not expected to materially affect the timing of a potential Phase 2b trial. The company remains on track to announce full 12 week topline data from the core part of this proof-of-concept clinical trial mid-year. Results including the additional arm are expected in early 2019.

ZGN-1258

- Zafgen unveiled plans in early January to return to the rare metabolic disease space with ZGN-1258, targeting an initial indication in Prader-Willi syndrome (PWS).
    - This quarter, the company has initiated formal investigational new drug (IND) enabling studies with ZGN-1258.

Corporate

- In December 2017, the company completed a $20 million venture debt financing agreement with Silicon Valley Bank, increasing its cash, cash equivalents and marketable securities balance to $102.1 million as of December 31, 2017.
- In October 2017, Zafgen appointed Jeffrey Hatfield as its Chief Executive Officer. Mr. Hatfield is a veteran biotechnology and pharmaceutical industry leader, with over three decades of experience. Most recently, he served as the Chief Executive Officer of Vitae Pharmaceuticals, Inc., from the company’s formation until its acquisition by Allergan plc in October 2016.

Fourth Quarter and Full Year 2017 Financial Results

“Ending 2017 with $102 million in cash, cash equivalents and marketable securities, including the completion of the venture debt financing in December 2017, has provided the company with the necessary capital to achieve multiple potential value creating milestones as we continue to advance ZGN-1258 towards the clinic this year and continue to progress ZGN-1061 towards Phase 2 clinical trial data mid-year,” stated Patricia Allen, Chief Financial Officer. “We expect to end 2018 with greater than $40 million in cash, cash equivalents and marketable securities.”

Cash, Cash Equivalents and Marketable Securities

As of December 31, 2017, the company had cash, cash equivalents and marketable securities totaling $102.1 million.

Net Loss

The company reported a net loss for the fourth quarter of 2017 of $13.1 million, or $0.48 per share, compared to a net loss of $10.4 million, or $0.38 per share, for the fourth quarter of 2016. For the full year 2017, the company reported a net loss of $52.0 million, or $1.90 per share, compared to $57.9 million, or $2.12 per share, for the full year 2016.

The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 27,489,397 for the fourth quarter of 2017 compared to 27,322,515 for the same quarter of 2016. For the full year 2017, weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 27,433,239 compared to 27,297,934 for the full year 2016.

Research and Development Expenses

Research and development expenses for the fourth quarter of 2017 were $10.9 million compared to $7.3 million for the fourth quarter of 2016. The increase in research and development expenses compared to the prior year period was primarily due to increased clinical trial costs related to ZGN-1061 and discovery and screening of new MetAP2 inhibitors, including ZGN-1258.The increase was partially offset by a decrease in spend related to the company’s first-generation MetAP2 inhibitor.

For the full year 2017, research and development expenses were $40.8 million, compared to $39.9 million for the full year 2016. The slight increase in research and development expenses for the full year period was primarily due to increased nonclinical, manufacturing and clinical trial costs related to ZGN-1061 and discovery and screening of new MetAP2 inhibitors, including ZGN-1258. The increase was partially offset by a decrease in spend related to the company’s first- generation MetAP2 inhibitor, including consultants, as well as reduced personnel-related costs as a result of the reduction in workforce during the third quarter of 2016.

General and Administrative Expenses

General and administrative expenses for the fourth quarter of 2017 were $2.4 million, compared to $3.2 million for the fourth quarter of 2016. The decrease in general and administrative expenses for the fourth quarter of 2017 as compared to the prior year period was primarily due to a decrease in non-cash stock-based compensation expense as well as a decrease in professional fees.

For the full year 2017, general and administrative expenses were $12.2 million, compared to $18.3 million for the full year 2016. The decrease in general and administrative expenses for the full year 2017 as compared to the prior year period was primarily due to a decrease in personnel-related costs primarily as a result of the reduction in workforce during the third quarter of 2016. There was also a decrease in professional fees and non-cash stock-based compensation expense period over period.

2018 Financial Guidance

The company expects that its cash, cash equivalents and marketable securities balance will be greater than $40 million as of December 31, 2018.

Conference Call Information

Zafgen will host an investor conference call today, March 6, 2018 at 4:30 p.m., Eastern Time, to discuss the company's fourth quarter 2017 and full year 2017 results as well as other forward-looking information about Zafgen's business. Investors and other interested parties may participate by dialing (844) 824-7428 in the United States or (973) 500-2177 outside the United States and referencing conference ID number 7184949. The call will also be webcast live on the company's website at https://zafgen.gcs-web.com/events-and-presentations. A replay of this conference call will be available beginning at 7:30 p.m. ET on March 6, 2018 through March 13, 2018 by dialing (855) 859-2056 in the United States or (404) 537-3406 outside the United States. To access the replay please provide Conference ID number 7184949.

About Zafgen

Zafgen (Nasdaq:ZFGN) is a clinical-stage biopharmaceutical company leveraging its proprietary knowledge of MetAP2 systems biology to develop novel therapies for patients affected by a range of complex metabolic diseases. Zafgen has pioneered the study of MetAP2 inhibitors in both common and rare metabolic disorders, and its current disease areas of focus are type 2 diabetes, Prader-Willi syndrome and liver diseases. The company’s lead product candidate is ZGN-1061, a MetAP2 inhibitor in Phase 2 clinical development with unique properties that maximize impact on metabolic parameters relevant to the treatment of type 2 diabetes and other related metabolic disorders. In 2018, Zafgen plans to file an investigational new drug (IND) application with the U.S. FDA and initiate Phase 1 clinical trials for ZGN-1258, its new molecule for the treatment of Prader-Willi syndrome and potential other rare and serious forms of obesity. 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 use of ZGN-1258, ZGN-1061 and other second-generation MetAP2 inhibitors as treatments for metabolic diseases including Prader-Willi syndrome, type 2 diabetes and potential other rare and serious forms of obesity and Zafgen's expectations with respect to the timing and success of its nonclinical studies and clinical trials of ZGN-1258, ZGN-1061 and its other product candidates, Zafgen’s expected cash, cash equivalents and marketable securities balance as of December 31, 2018, and Zafgen’s expectations regarding the length of its cash runway, 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-1258, ZGN-1061 and its other product candidates and to differentiate ZGN-1258, ZGN-1061 and its other product candidates from the company's first-generation MetAP2 inhibitor, the nonclinical and clinical results, including results from interim analyses of clinical trials, for ZGN-1258, 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 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 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 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 Contacts:
Zafgen, Inc.
Patricia Allen
Chief Financial Officer
617-648-9792

Media
Krystle Gibbs
Ten Bridge Communications
krystle@tenbridgecommunications.com
508-479-6358

Investors
John Woolford
Westwicke Partners
John.woolford@westwicke.com
443-213-0506

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

	Year Ended December 31,		
	2017	**2016**	**2015**
Revenue	$ -	$ -	$ -
Operating expenses:			
Research and development	40,839	39,936	54,618
General and administrative	12,160	18,289	19,195
Total operating expenses	52,999	58,225	73,813
Loss from operations	(52,999)	(58,225)	(73,813)
Other income (expense):			
Interest income	996	894	438
Interest expense	(165)	(529)	(806)
Foreign currency transaction gains (losses), net	140	(18)	(105)
Total other income (expense), net	971	347	(473)
Net loss	$ (52,028)	$ (57,878)	$ (74,286)
Net loss per share, basic and diluted	$ (1.90)	$ (2.12)	$ (2.78)
Weighted average common shares outstanding, basic and diluted	27,433,239	27,297,934	26,756,079

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

	Three Months Ended December 31,	
	2017	**2016**
Revenue	$ -	$ -

Operating expenses:		
Research and development	10,911	7,275
General and administrative	2,447	3,200
Total operating expenses	13,358	10,475
Loss from operations	(13,358)	(10,475)
Other income (expense):		
Interest income	256	230
Interest expense	(8)	(97)
Foreign currency transaction gains (losses), net	25	(97)
Total other income (expense), net	273	36
Net loss	$ (13,085)	$ (10,439)
Net loss per share , basic and diluted	$ (0.48)	$ (0.38)
Weighted average common shares outstanding, basic and diluted	27,489,397	27,322,515

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

	December 31, 2017	2016
Assets		
Current assets:		
Cash and cash equivalents	$ 40,777	$ 32,352
Marketable securities	61,275	96,842
Tax incentive receivable	946	347
Prepaid expenses and other current assets	1,927	1,358
Total current assets	104,925	130,899
Property and equipment, net	528	661
Other assets	57	61
Total assets	$ 105,510	$ 131,621
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,020	$ 2,572
Accrued expenses	4,273	3,733
Notes payable, current	-	3,589
Total current liabilities	7,293	9,894
Notes payable, long-term	20,000	-
Total liabilities	27,293	9,894
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of December 31, 2017 and 2016; no shares issued and outstanding as of December 31, 2017 and 2016	-	-
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of December 31, 2017 and 2016; 27,489,457 and 27,332,551 shares issued and outstanding as of December 31, 2017 and 2016, respectively	27	27
Additional paid-in capital	367,825	359,329
Accumulated deficit	(289,577)	(237,549)
Accumulated other comprehensive loss	(58)	(80)
Total stockholders' equity	78,217	121,727
Total liabilities and stockholders' equity	$ 105,510	$ 131,621

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 which includes the Company's audited consolidated financial statements for the year ended December 31, 2016.

Primary Logo

Source: Zafgen, Inc.