

Zafgen Reports Fourth Quarter and Full Year 2016 Financial Results

On Track to Complete Dosing of Phase 1 Clinical Trial for ZGN-1061 by the End of the First Quarter of 2017

BOSTON, March 09, 2017 (GLOBE NEWSWIRE) -- Zafgen, Inc. (Nasdaq:ZFGN), a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by metabolic diseases including type 2 diabetes and obesity, today announced its fourth quarter and full year 2016 financial results.

"2017 is set to be a pivotal year for Zafgen, as we further elucidate the efficacy and safety profile for our second generation MetAP2 inhibitor, ZGN-1061, and establish a path forward for the candidate in underserved type 2 diabetes and obesity indications," said Thomas Hughes, Ph.D., President and Chief Executive Officer of Zafgen. "Over the past few months, we have progressed our ongoing Phase 1 clinical trial evaluating ZGN-1061 and, in parallel, have advanced our understanding of ZGN-1061's key differentiating characteristics from beloranib, with a particular emphasis on drug safety. Over the course of this coming year, we plan to leverage the data emerging from our clinical trials and non-clinical studies, along with discussions with experts and regulators, to define an efficient clinical development program for ZGN-1061 in commercially-relevant patient populations."

Recent and Upcoming Clinical Highlights

- The Company is currently conducting a Phase 1 clinical trial for ZGN-1061, a highly-differentiated, second generation MetAP2 inhibitor. The clinical trial includes a single ascending dose (SAD) portion, which is complete and enrolled approximately 48 healthy patients, as well as a multiple ascending dose (MAD) portion that is currently ongoing and evaluating twice-weekly administration of ZGN-1061 for safety, tolerability, and pharmacodynamic effects, including weight loss efficacy over four weeks in approximately 24 overweight and obese patients. The Company expects to complete dosing of the Phase 1 clinical trial of ZGN-1061 by the end of the first quarter of 2017, and report results early in the second guarter of 2017.
- Assuming that results of the Phase 1 clinical trial are positive and support advancement, the Company expects to initiate a Phase 2 clinical trial in Australia for ZGN-1061 in patients with obesity and type 2 diabetes in the second half of 2017.
- The Company has evaluated the properties of both ZGN-1061 and its predecessor compound beloranib with a particular focus on pro-thrombotic characteristics, and has developed a mechanistic basis for compound differentiation and the improved safety margin in non-clinical studies associated with ZGN-1061.

Fourth Quarter and Full Year 2016 Financial Results

"We are in a strong financial position, with a healthy balance sheet and an efficient clinical development plan that will take us through key value-creating milestones for ZGN-1061 with our current resources," stated Patricia Allen, Chief Financial Officer of Zafgen. "We continue to expect our cash runway to extend through the end of 2018, by which time we expect to have data from a Phase 2a clinical trial for ZGN-1061. Based on our current development timelines, we expect that our cash, cash equivalents and marketable securities balance will be greater than \$65 million at the end of calendar year 2017."

Cash, Cash Equivalents and Marketable Securities

As of December 31, 2016, the Company had cash, cash equivalents and marketable securities totaling \$129.2 million.

Net Loss

The Company reported a net loss for the fourth quarter of 2016 of \$10.4 million, or \$0.38 per share, compared to a net loss of \$23.2 million, or \$0.85 per share, for the fourth quarter of 2015. The Company reported a net loss for the year ended December 31, 2016 of \$57.9 million, or \$2.12 per share, compared to a net loss of \$74.3 million, or \$2.78 per share, for the year ended December 31, 2015.

The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 27,332,515 for the fourth quarter of 2016, compared to 27,238,079 for the fourth quarter of 2015. The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 27,297,934 for the year ended December 31, 2016, compared to 26,756,079 for the year ended December 31, 2015.

Research and Development Expenses

Research and development expenses for the fourth quarter of 2016 were \$7.3 million, compared to \$17.7 million for the fourth quarter of 2015. Research and development expenses for the year ended December 31, 2016 were \$39.9 million, compared to \$54.6 million for the year ended December 31, 2015. The decrease in research and development expenses for both periods as compared to the prior year periods was primarily due to a decrease in pre-clinical, clinical and manufacturing costs related to beloranib and ZGN-839, partially offset by increased costs related to ZGN-1061 as we shifted focus to ZGN-1061 in July 2016.

General and Administrative Expenses

General and administrative expenses for the fourth quarter of 2016 were \$3.2 million, compared to \$5.5 million for the fourth quarter of 2015. General and administrative expenses for the year ended December 31, 2016 were \$18.3 million, compared to \$19.2 million for the year ended December 31, 2015. The decrease in general and administrative expenses for both periods as compared to the prior year periods was primarily due to a decrease in professional fees. For the fourth quarter of 2016 there was also a decrease in personnel related costs as compared to the prior year period primarily as a result of the reduction in workforce during the third quarter of 2016.

2017 Financial Guidance

The Company expects that its cash, cash equivalents and marketable securities balance will be greater than \$65 million as of December 31, 2017.

Conference Call Information

Zafgen will host an investor conference call today, March 9, 2017 at 4:30 p.m., Eastern Time, to discuss the Company's fourth quarter 2016 and full year 2016 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 77476849. The call will also be webcast live on the Company's website at http://ir.zafgen.com/events.cfm. A replay of this conference call will be available beginning at 7:30 p.m. ET on March 9, 2017 through March 16, 2017 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 77476849.

About ZGN-1061

ZGN-1061 is a fumagillin-class, injectable small molecule second generation MetAP2 inhibitor that 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. In pre-clinical studies, ZGN-1061 has demonstrated promising efficacy and potency in animal models of type 2 diabetes and obesity, with an improved pharmacokinetic profile and safety margin relative to previous molecules in the MetAP2 class. ZGN-1061 is anticipated to improve glycemic control while also helping to reduce hunger and restore balance to fat metabolism, enabling calories to once again be used as a productive energy source, leading to improved metabolic control and long-term weight loss. ZGN-1061 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 metabolic diseases including type 2 diabetes and obesity. Zafgen is focused on developing novel therapeutics that treat the underlying biological mechanisms of metabolic diseases 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, first-in-class, twice-weekly subcutaneous injection. 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 metabolic diseases including type 2 diabetes and obesity, including the improved safety margin, including as it relates to pro-thrombotic characteristics, associated with ZGN-1061 over beloranib, 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, 2017, 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 when needed, 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 forwardlooking statements, whether as a result of new information, future events or otherwise.

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

	Year Ended December 31,					
		2016		2015		2014
Revenue	\$	-	\$	-	\$	<u>-</u>
Operating expenses:						
Research and development		39,936		54,618		27,391
General and administrative		18,289		19,195		8,141
Total operating expenses		58,225		73,813		35,532
Loss from operations		(58,225)		(73,813)		(35,532)
Other income (expense):						
Interest income		894		438		28
Interest expense		(529)		(806)		(870)
Foreign currency transaction gains (losses), net		(18)		(105)		(104)
Total other income (expense), net		347	_	(473)		(946)
Net loss		(57,878)		(74,286)		(36,478)
Accretion of redeemable convertible preferred stock to redemption value		-		-		(92)
Net loss attributable to common stockholders	\$	(57,878)	\$	(74,286)	\$	(36,570)
Net loss per share attributable to common stockholders, basic and diluted	\$	(2.12)	\$	(2.78)	\$	(3.00)
Weighted average common shares outstanding, basic and diluted		27,297,934		26,756,079		12,189,155

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

	Three Months Ended December 31,						
Revenue	20	2016					
	\$	-	\$	-			
Operating expenses:							
Research and development		7,275		17,706			
General and administrative		3,200		5,540			

Total operating expenses	10,475	23,246
Loss from operations	(10,475)	(23,246)
Other income (expense):		
Interest income	230	193
Interest expense	(97)	(180)
Foreign currency transaction gains (losses), net	(97)	59_
Total other income (expense), net	36	72
Net loss	\$ (10,439)	\$ (23,174)
Net loss per share, basic and diluted	\$ (0.38)	\$ (0.85)
Weighted average common shares outstanding, basic and diluted	27,332,515	27,238,079

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

	December 3			r 31,
		2016		2015
Assets				
Current assets:				
Cash and cash equivalents	\$	32,352	\$	35,595
Marketable securities		96,842		149,484
Tax incentive receivable		347		1,323
Prepaid expenses and other current assets		1,358		1,708
Total current assets		130,899		188,110
Property and equipment, net		661		902
Other assets		61		94
Total assets	\$	131,621	\$	189,106
Liabilities and Stockholders' Equity	_		_	
Current liabilities:				
Accounts payable	\$	2,572	\$	7,495
Accrued expenses		3,733		6,112
Notes payable, current		3,589		2,936
Total current liabilities		9,894		16,543
Notes payable, net of discount, long-term		-		3,453
Total liabilities		9,894		19,996
Stockholders' equity:	_	'		
Preferred stock; \$0.001 par value per share; 5,000,000 shares authorized as of December 31, 2016 and 2015; no shares issued and outstanding as of December 31, 2016 and 2015		_		_
Common stock, \$0.001 par value per share; 115,000,000 shares authorized as of December 31, 2016 and 2015; 27,332,551 and 27,242,503 shares issued and outstanding as of December 31, 2016 and 2015,				
respectively		27		27
Additional paid-in capital		359,329		348,961
Accumulated deficit		(237,549)		(179,671)
Accumulated other comprehensive loss	_	(80)		(207)
Total stockholders' equity		121,727		169,110
Total liabilities and stockholders' equity	\$	131,621	\$	189,106

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, 2015.

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