May 10, 2016

Zafgen Reports First Quarter 2016 Financial Results

Conference call scheduled for 4:30 PM Eastern Time

BOSTON, May 10, 2016 (GLOBE NEWSWIRE) -- Zafgen (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 first quarter 2016 financial results, and provided an update on the Company's clinical program for beloranib.

"The compelling and consistent efficacy data emerging from our beloranib clinical trials in both PWS and severe obesity complicated by type 2 diabetes provide greater perspective on the efficacy-safety profile of beloranib in difficult-to-treat obesity indications," said Thomas Hughes, Ph.D., Chief Executive Officer of Zafgen. "We have made significant progress in our efforts to address the full clinical hold on the beloranib IND and are now moving toward discussions with the FDA. We expect to have more clarity on the potential path forward for beloranib in PWS over the next few months."

Recent Clinical Developments

- In January 2016, Zafgen announced that its pivotal Phase 3 bestPWS ZAF-311 clinical trial of beloranib in Prader-Willi syndrome, or PWS, achieved both co-primary efficacy endpoints of hyperphagia-related behaviors and weight loss.
- In February 2016, Zafgen reported that its ZAF-203 Phase 2b clinical trial of beloranib in severe obesity complicated by type 2 diabetes achieved its key efficacy endpoints, demonstrating statistically and clinically significant improvements in body weight and glycemic control.
- In April 2016, Zafgen presented new clinical data, which were selected for late-breaking presentations, from its pivotal Phase 3 bestPWS ZAF-311 clinical trial evaluating beloranib in PWS at the 98th Annual Meeting of The Endocrine Society, or ENDO 2016. In addition to achieving its co-primary efficacy endpoints of hyperphagia-related behaviors and weight loss, the clinical trial demonstrated that beloranib was associated with improvements in body composition including a reduction in fat mass, total cholesterol, LDL cholesterol, and other cardiometabolic risk factors when compared to placebo.
- In May 2016, Zafgen presented clinical data, which were selected for late-breaking poster presentations, from its pivotal Phase 3 bestPWS ZAF-311 clinical trial evaluating beloranib in PWS at the XIII International Congress on Obesity, or ICO.

"At the recent ENDO 2016 and ICO meetings, we presented the full data set from our Phase 3 bestPWS ZAF-311 clinical trial, the first Phase 3 pivotal clinical trial to show significant improvement in hyperphagia-related behaviors and weight loss in PWS patients," said Dennis Kim, M.D., Chief Medical Officer of Zafgen. "In addition to demonstrating a positive impact on body weight and excessive food-seeking behaviors, beloranib was associated with improvements in body composition and with a preferential loss of fat with minimal change in lean mass, underscoring the potential of our MetAP2 platform to impact metabolic disorders."

First Quarter 2016 Financial Results

"We have maintained conservative spending during the first quarter of 2016 as compared to the fourth quarter of 2015 as we clarify the potential path forward for beloranib. Our current cash balance provides us with the financial strength to execute on our business strategy and fund operations," said Patricia Allen, Chief Financial Officer of Zafgen. "We continue to expect that our cash, cash equivalents and marketable securities balance at the end of calendar year 2016 will be in excess of $100 million."

Cash, Cash Equivalents and Marketable Securities
As of March 31, 2016, the Company had cash, cash equivalents and marketable securities totaling $166.2 million.

Net Loss
The Company reported a net loss for the first quarter of 2016 of $17.7 million, or $0.65 per share, compared to a net loss of $13.5 million, or $0.53 per share, for the first quarter of 2015.

The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 27,263,435 for the first quarter of 2016, compared to 25,615,282 for the first quarter of 2015.

Research and Development Expenses
Research and development expenses for the first quarter of 2016 were $12.5 million, compared to $10.2 million for the first quarter of 2015. The increase in research and development expenses for the quarter ended March 31, 2016 as compared to the prior year quarter was primarily due to increased personnel costs related to hiring new employees during the first three quarters of 2015, as well as non-cash stock-based compensation expense.

General and Administrative Expenses
General and administrative expenses for the first quarter of 2016 were $5.4 million, compared to $3.0 million for the first quarter of 2015. The increase in general and administrative expenses for the quarter ended March 31, 2016 as compared to the prior year quarter was primarily due to increased non-cash stock-based compensation expense and increased professional fees.

2016 Financial Guidance
The Company expects that its cash, cash equivalents and marketable securities balance will be greater than $100 million at December 31, 2016.

Conference Call Information

Zafgen will host an investor conference call today, May 10, 2016 at 4:30 p.m., Eastern Time, to discuss the Company's first quarter 2016 results and other Company updates. 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 97205623. 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 May 10, 2016 through May 24, 2016 by dialing (855) 859-2056 in the U.S. or (404) 537-3406 outside the U.S. To access the replay please provide Conference ID number 97205623.

About Beloranib

Beloranib is a novel, first-in-class injectable small molecule therapy that works by inhibiting MetAP2, an enzyme that modulates the activity of key cellular processes that control metabolism. Once a person becomes obese, the body undergoes certain metabolic changes and becomes "programmed" to create and store more fat, making it much more difficult to reduce body weight. Beloranib is believed to help reduce hunger and restore balance to fat metabolism, enabling calories to once again be used as a productive energy source. Because beloranib works beyond just regulating hunger through the hypothalamus, it has the potential to be used in a variety of complex metabolic disorders such as Prader-Willi syndrome and hypothalamic injury associated obesity. Zafgen holds exclusive worldwide rights (exclusive of South Korea) for the development and commercialization of beloranib. Zafgen exclusively licensed beloranib from Chong Kun Dang Pharmaceutical Corporation (CKD Pharma) of South Korea.

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 through the MetAP2 pathway. Beloranib, Zafgen's lead product candidate, is a novel, first-in-class, twice-weekly subcutaneous injection being developed for the treatment of multiple indications, including severe obesity in two rare diseases, Prader-Willi syndrome and obesity caused by hypothalamic injury, including craniopharyngioma-associated obesity; and severe obesity in the general population. Zafgen is also developing ZGN-839, a liver-targeted MetAP2 inhibitor, for the treatment of nonalcoholic steatohepatitis, or NASH, and abdominal obesity, as well as second-generation MetAP2 inhibitors, which may be developed for the treatment of severe obesity in the general population. Zafgen aspires to improve the lives of patients through targeted treatments and has assembled a team accomplished in bringing therapies to patients with both rare and prevalent metabolic diseases.

Safe Harbor Statement

Various statements in this release concerning Zafgen's future expectations, plans and prospects, including without limitation, Zafgen's expected cash balance as of December 31, 2016, Zafgen's expectations regarding beloranib as a treatment for PWS and obesity caused by hypothalamic injury, including craniopharyngioma-associated obesity, Zafgen's expectations regarding the use of other MetAP2 inhibitors as treatments for other forms of severe obesity, including severe obesity in the general population, Zafgen's expectations with respect to the timing and success of its pre-clinical studies and clinical trials of beloranib and its other product candidates, the expected requirements and timing of additional requirements for planned clinical trials, and the need for additional clinical trials and pre-clinical studies, and Zafgen's plans regarding commercialization of beloranib 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 obtain a release of the full clinical hold that the FDA placed on the investigational new drug application for beloranib, Zafgen's ability to successfully demonstrate the efficacy and safety of beloranib and its other product candidates, the pre-clinical and clinical results for beloranib 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, 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 products, 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 Annual Report on Form 10-K, as amended, 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 STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenue	$ —	$ —
Operating expenses:		
Research and development	12,497	10,215
General and administrative	5,360	3,025
Total operating expenses	17,857	13,240
Loss from operations	(17,857)	(13,240)
Other income (expense):		
Interest income	209	39
Interest expense	(160)	(213)
Foreign currency transaction gains (losses), net	72	(58)
Total other income (expense), net	121	(232)
Net loss	$ (17,736)	$ (13,472)
Net loss per share, basic and diluted	$ (0.65)	$ (0.53)
Weighted average common shares outstanding, basic and diluted	27,263,435	25,615,282

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

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 31,450	$ 35,595
Marketable securities	134,734	149,484

Tax incentive receivable	1,389	1,323
Prepaid expenses and other current assets	1,271	1,708
Total current assets	168,844	188,110
Tax incentive receivable	144	-
Property and equipment, net	954	902
Other assets	90	94
Total assets	$ 170,032	$ 189,106
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,146	$ 7,495
Accrued expenses	6,739	6,112
Notes payable, current	2,996	2,936
Total current liabilities	12,881	16,543
Notes payable, net of discount, long-term	2,723	3,453
Total liabilities	15,604	19,996
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 authorized at March 31, 2016 and December 31, 2015; no shares issued and outstanding at March 31, 2016 and December 31, 2015	-	-
Common stock, $0.001 par value per share; 115,000,000 shares authorized at March 31, 2016 and December 31, 2015; 27,268,943 and 27,242,503 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	27	27
Additional paid-in capital	351,807	348,961
Accumulated deficit	(197,407)	(179,671)
Accumulated other comprehensive gain (loss)	1	(207)
Total stockholders' equity	154,428	169,110
Total liabilities and stockholders' equity	$ 170,032	$ 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, as amended, which includes the audited consolidated financial statements for the year ended December 31, 2015.

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