Zafgen Reports Second Quarter 2018 Operating and Financial Results

August 7, 2018

Phase 1 clinical trial for ZGN-1258 for Prader-Willi syndrome (PWS) expected to begin in the fourth quarter 2018

Multiple ZGN-1258 nonclinical studies accepted for presentation at upcoming Foundation for Prader-Willi Research (FPWR) Annual Conference

Initiated 1.8 mg dosing arm in ZGN-1061 Phase 2 clinical trial for type 2 diabetes; results from additional arm expected early 2019

Company to host conference call today at 4:30 PM ET

BOSTON, Aug. 07, 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 second quarter 2018 financial results.

“2018 is an important year of execution on our plan for our novel second-generation MetAP2 pipeline,” said Jeffrey Hatfield, Chief Executive Officer. “We’ve continued to make significant progress this year, highlighted by positive data from the initial part of our Phase 2 clinical trial of ZGN-1061 in patients with type 2 diabetes, launch of the natural history study of PWS, advancement towards clinical testing for ZGN-1258, strengthening of our balance sheet, and key personnel additions. We expect this progress to continue throughout the remainder of 2018 and beyond, with near-term milestones for all of our key pipeline programs.”

Recent Corporate and Program Highlights

ZGN-1258

- Zafgen progressed investigational new drug (IND) enabling studies for ZGN-1258, with Prader-Willi syndrome (PWS) as an initial indication. An IND allowance and initiation of a Phase 1 clinical trial for ZGN-1258 are anticipated in the fourth quarter of 2018.

- Zafgen and the Foundation for Prader-Willi Research (FPWR), a nonprofit organization founded to eliminate the challenges of PWS through the advancement of research and therapeutic development, launched a co-sponsored four-year natural history study, named PATH for PWS (**P**aving the way for **A**dvances in **T**reatments & **H**ealth for PWS), to advance understanding of the medical history of and medical events in people with PWS. PATH for PWS is a non-interventional, observational study to evaluate occurrences of serious medical events in PWS, intended to inform development and clinical trial design for potential new treatments for PWS, including ZGN-1258, Zafgen’s new, second-generation program for PWS designed to decrease hyperphagia, change the way the body metabolizes fat, and reduce fat mass.

- Zafgen reports today that multiple nonclinical studies will be presented at the FPWR Annual Conference which begins October 4, 2018, covering the following topics:
    - ZGN-1258 effects on food intake and body weight in mouse models of hyperphagia and obesity
    - ZGN-1258 effects on other behavioral manifestations commonly observed in PWS, such as low physical activity, anxiety, and obsessive-compulsive behaviors in mouse models
    - ZGN-1258 nonclinical differentiation on safety measures
    - PATH for PWS natural history study design

ZGN-1061

- Data from the Phase 2 clinical trial and two supportive nonclinical studies for ZGN-1061 were presented as late-breaker abstracts at the American Diabetes Association (ADA) 78th Scientific Sessions in Orlando, Florida in June 2018:
    - Zafgen announced positive full results from the initial part of its 12-week Phase 2 clinical trial of ZGN-1061 designed to demonstrate proof-of-concept efficacy and safety in patients with type 2 diabetes and establish a minimally effective dose. The clinical trial met all of its primary endpoints at a minimally effective dose of 0.9 mg dose, and 12-week data demonstrated a favorable safety and tolerability profile, with no treatment-related serious adverse events and no cardiovascular (CV) safety signals observed.
    - Nonclinical data on treatment with both ZGN-1061 and liraglutide suggest that combination therapy with these glucose-lowering agents may yield additive improvement in glycemic control and weight loss, demonstrating the effect of two complementary mechanisms – MetAP2 inhibition and GLP-1.
    - From nonclinical data in a nonalcoholic steatohepatitis (NASH) model, Zafgen observed that ZGN-1061 markedly reduced liver weight, NAS score and markers of liver damage. These NASH-related data, combined with previous gene expression data and clinical liver fat content data from Zafgen’s first-generation MetAP2 inhibitor, suggest potential clinical value in treating liver-specific metabolic conditions.

- As previously announced, based on the safety and tolerability results of the interim analysis for the ZGN-1061 Phase 2 proof-of-concept clinical trial detailed in March 2018, Zafgen opted to explore the higher end of the potential therapeutic range of ZGN-1061 by adding a 1.8 mg dose arm to the clinical trial. Patient dosing was initiated during the second quarter of 2018 and will run in parallel with completion of long-term toxicology studies for ZGN-1061. Results from this additional arm are expected in early 2019.

Corporate

- On July 2, 2018, Zafgen closed an underwritten public offering of 9.2 million shares of its common stock at a price to the public of $7.50 per share, including 1.2 million shares pursuant to the underwriters' exercise in full of their option to purchase additional common shares. The offering resulted in total gross proceeds of $69.0 million and net proceeds of approximately $64.6 million, after deducting the underwriting discounts and commissions and other estimated offering costs.

- In May 2018, Zafgen expanded its executive leadership team with the appointment of Brian McVeigh as Chief Business Officer (CBO). Mr. McVeigh brings over 25 years of pharmaceutical and biotech industry experience at GlaxoSmithKline (GSK) including 15 years of extensive experience in buy-side and sell-side business development deal making and investment management.

- In June 2018, industry veteran and healthcare policy expert Dr. Wendy Everett joined Zafgen's board of directors.

- Zafgen joined the Russell 2000 Index on June 25, 2018. The Annual Russell US Index reconstitution captures the largest US stocks as of May 11, 2018 ranking them by total market capitalization.

Second Quarter 2018 Financial Results

"The completion of our recent public offering of common stock has provided the Company with additional capital to advance the Company's pipeline through multiple value-creating milestones," said Patricia Allen, Chief Financial Officer. "We ended the quarter with $75.8 million of cash, cash equivalents and marketable securities and raised net proceeds of approximately $64.6 million from our recent public offering which closed in early July 2018."

Cash, Cash Equivalents and Marketable Securities

As of June 30, 2018, the Company had cash, cash equivalents and marketable securities totaling $75.8 million. In July 2018, the Company completed an underwritten public offering of its common stock, which included the full exercise of the underwriters' option to purchase additional shares, resulting in net proceeds of approximately $64.6 million. After giving effect to the estimated net proceeds from the Company's public offering of common stock, the unaudited pro forma cash, cash equivalents and marketable securities balance was $140.4 million as of June 30, 2018.

Net Loss

The Company reported a net loss for the second quarter of 2018 of $15.8 million, or $0.57 per share, compared to a net loss of $13.3 million, or $0.49 per share, for the second quarter of 2017.

The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 27,565,064 for the second quarter of 2018 compared to 27,407,408 for the same quarter of 2017.

Research and Development Expenses

Research and development expenses for the second quarter of 2018 were $12.2 million compared to $10.5 million for the second quarter of 2017. The increase in research and development expenses compared to the prior year period was primarily due to increased costs related to the ZGN-1258 program as IND enabling studies progressed during the quarter as the program advances towards the filing of an IND. The increase in research and development expenses was also the result of increased costs associated with the ongoing Phase 2 clinical trial for ZGN-1061. There were also increases in personnel related costs and non-cash stock-based compensation expense in the second quarter of 2018 as compared to the second quarter of 2017. These increases in research and development costs were partially offset by a decrease in nonclinical and manufacturing costs associated with our ZGN-1061 program.

General and Administrative Expenses

General and administrative expenses for the second quarter of 2018 were $3.4 million, compared to $3.0 million for the second quarter of 2017. The increase in general and administrative expenses as compared to the prior year period was primarily due to an increase in personnel related costs as well as an increase in professional fees primarily related to multi-country patent filing costs, partially offset by a decrease in non-cash stock-based compensation expense.

2018 Financial Guidance

The Company expects that its cash, cash equivalents and marketable securities balance will be greater than $100 million as of December 31, 2018.

Conference Call Information

Zafgen will host an investor conference call today, August 7, 2018 at 4:30 p.m., Eastern Time, to discuss the Company's second quarter 2018 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 9168629. 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 August 7, 2018 through August 14, 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 9168629.

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 and is currently advancing programs for type 2 diabetes, Prader-Willi syndrome and liver diseases. The Company's lead product candidate, ZGN-1061, a MetAP2 inhibitor for difficult-to-control type 2 diabetes, has successfully completed the initial part of a Phase 2 clinical trial. 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-1258, ZGN-1061 and other second-generation MetAP2 inhibitors as treatments for metabolic diseases including Prader-Willi syndrome, type 2 diabetes and 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 first-generation MetAP2 inhibitors, such as beloranib, the nonclinical and clinical results 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 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. 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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Condensed Consolidated Statements of Operations

(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	12,209	10,528	24,642	20,205
General and administrative	3,351	3,008	6,620	6,596
Total operating expenses	15,560	13,536	31,262	26,801

Loss from operations	(15,560)	(13,536)	(31,262)	(26,801)
Other income (expense):				
Interest income	324	247	591	474
Interest expense	(466)	(53)	(924)	(126)
Foreign currency transaction (losses) gains, net	(73)	(5)	(136)	95
Total other (expense) income, net	(215)	189	(469)	443
Net loss	$ (15,775)	$ (13,347)	$ (31,731)	$ (26,358)
Net loss per share, basic and diluted	$ (0.57)	$ (0.49)	$ (1.15)	$ (0.96)
Weighted average common shares outstanding, basic and diluted	27,565,064	27,407,408	27,553,394	27,379,122

Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)
(Unaudited)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 40,745	$ 40,777
Marketable securities	35,104	61,275
Tax incentive receivable	895	946
Prepaid expenses and other current assets	1,289	1,927
Total current assets	78,033	104,925
Tax incentive receivable	938	-
Property and equipment, net	472	528
Other assets	357	57
Total assets	$ 79,800	$ 105,510
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,010	$ 3,020
Accrued expenses	4,448	4,273
Notes payable, current	1,818	-
Total current liabilities	9,276	7,293
Notes payable, long-term	18,502	20,000
Total liabilities	27,778	27,293
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of June 30, 2018 and December 31, 2017; no shares issued and outstanding as of June 30, 2018 and December 31, 2017	-	-
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of June 30, 2018 and December 31, 2017; 27,578,989 and 27,489,457 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	28	27
Additional paid-in capital	373,308	367,825
Accumulated deficit	(321,308)	(289,577)
Accumulated other comprehensive loss	(6)	(58)
Total stockholders' equity	52,022	78,217
Total liabilities and stockholders' equity	$ 79,800	$ 105,510

Primary Logo

Source: Zafgen, Inc.