
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): November 11, 2014

Zafgen, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-36510
(Commission
File Number)

20-3857670
(I.R.S. Employer
Identification No.)

175 Portland Street, 4th Floor
Boston, Massachusetts
(Address of principal executive offices)

02114
(Zip Code)

Registrant's telephone number, including area code (617) 622-4003

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition

On November 11, 2014, Zafgen, Inc. announced its financial results for the quarter ended September 30, 2014. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K. Also on November 11, 2014, certain members of Zafgen's management team held a conference call to discuss earnings and operating results for the quarter ended September 30, 2014. The Script from the conference call is furnished as Exhibit 99.2 hereto and is incorporated by reference herein.

The information in this Report on Form 8-K and Exhibits 99.1 and 99.2 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Zafgen, Inc. on November 11, 2014, furnished herewith.
99.2	Zafgen, Inc. Script from Conference Call on November 11, 2014.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 12, 2014

ZAFGEN, INC.

By: /s/ Thomas E. Hughes
Thomas E. Hughes, Ph.D.
Chief Executive Officer

EXHIBIT INDEX

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Zafgen Reports Third Quarter 2014 Financial Results

Quarter Highlighted by Significant Progress in Advancing Beloranib Clinical Development Program

Company Expects to Report Data from Three Clinical Trials in 2015

Increases Guidance at End of 2014 to Greater than \$100 million in Cash

BOSTON, Mass., November 11, 2014 – Zafgen, Inc. (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 third quarter 2014 financial results.

Recent Business Highlights

- Initiated and began dosing in the bestPWS (Beloranib Efficacy Safety and Tolerability in PWS) Phase 3 clinical trial in patients with Prader-Willi syndrome (PWS) in September.
- Completed enrollment in the ZAF-221 Phase 2a clinical trial in patients with hypothalamic injury-associated obesity (HIAO), including craniopharyngioma-associated obesity, in September.
- Multiple presentations at ObesityWeek 2014, including a poster presentation of the ZAF-211 Phase 2a clinical trial results in patients with PWS.
- Strengthened the Board of Directors through the return of pharmaceutical industry business development veteran, Frances K. Heller, as a director.

“This has been a productive quarter for Zafgen, particularly with the progress we have made recently in advancing beloranib in the clinic in multiple indications,” said Dr. Thomas Hughes, Chief Executive Officer of Zafgen.

“We continue to be well-capitalized as we move ahead with our mission of bringing life-changing treatment options to patients affected by obesity and obesity-related disorders. We look forward to reporting key data in 2015 from our three beloranib clinical trials; our Phase 2a proof of concept study (ZAF-221) in patients with hypothalamic injury-associated obesity (HIAO), our bestPWS (ZAF-311) Phase 3 study in Prader-Willi syndrome, and our Phase 2b study (ZAF-203) in patients with severe obesity and type 2 diabetes,” said Dr. Hughes.

Discussion of Third Quarter 2014 Financial Results

Cash and Cash Equivalents

As of September 30, 2014, the Company had cash and cash equivalents totaling \$127.0 million.

Net Loss

The Company reported a net loss for the three months ended September 30, 2014 of \$14.7 million, or \$0.65 per share, compared to a \$3.5 million net loss, or \$4.88 per share, for the three months ended September 30, 2013. The weighted average common shares (basic and diluted) outstanding used to compute net loss per share were 22,707,012 for the three months ended September 30, 2014, compared to 729,391 for the three months ended September 30, 2013.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2014 increased to \$12.1 million, compared to \$2.4 million in the three months ended September 30, 2013. The increase was primarily due to increased costs of \$2.1 million associated with the advancement of the Company's beloranib program, and \$6.7 million in expenses related to milestone payments, primarily to Chong Kun Dang Pharmaceutical Corporation (CKD Pharma), triggered by the initiation of the bestPWS Phase 3 clinical trial.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2014 increased to \$2.3 million, compared to \$1.1 million in the three months ended September 30, 2013, primarily due to increased personnel related costs of \$0.7 million and increased public company, professional fees, travel and other related costs of \$0.5 million period over period.

2014 Financial Guidance

As a result of increased clarity related to the timing of certain pre-clinical and clinical expenses, the Company now expects to end 2014 with greater than \$100 million in cash and cash equivalents, as compared to the previous estimate of greater than \$95 million.

"We are pleased to increase our cash guidance at the end of calendar year 2014 to greater than \$100 million from \$95 million in cash and cash equivalents," said Patricia Allen, Chief Financial Officer of Zafgen. "We believe this financial position enables us to continue to grow our business, including executing on and obtaining clinical data from three clinical trials we will be conducting in 2014 and 2015."

Conference Call

Zafgen will host an investor conference call today, November 11, 2014 at 4:30 p.m., Eastern Time, to discuss the Company's third quarter 2014 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. The call will also be webcast live on the Company's website at www.zafgen.com. You can access the replay for seven days by dialing 855-859-2056 in the United States and 404-537-3406 outside the United States and referencing conference ID number 23379815.

About Beloranib

Beloranib is a novel, first-in-class injectable small molecule therapy with a unique mechanism of action that reduces hunger while stimulating the use of stored fat as an energy source. Beloranib is a potent inhibitor of MetAP2, an enzyme that modulates the activity of key cellular processes that control metabolism. MetAP2 inhibitors work, at least in part, by directing MetAP2 binding to cellular stress mediators, and, thus, reducing the tone of signals that drive lipid synthesis by the liver and fat storage throughout the body. In this manner, MetAP2 inhibition increases metabolism of fat as an energy source. 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 Prader-Willi Syndrome

Prader-Willi syndrome (PWS), the most common known genetic cause of life-threatening obesity, results in constant and unrelenting hunger that drives patients with PWS to engage in problematic hunger-related behaviors and to gain excessive weight. As a result, many of those affected with PWS become morbidly obese and suffer significant mortality. Currently, there is no cure for this disease. Although the cause of PWS is complex, it results from a deletion or loss of function of a cluster of genes on the 15th chromosome. PWS typically causes low muscle mass and function, short stature, incomplete sexual development, and a chronic feeling of hunger that, when coupled with a metabolism that utilizes drastically fewer calories than normal, can lead to excessive eating and life-threatening obesity. PWS occurs in males and females equally and in all races, with the same incidence around the world. Prevalence estimates have ranged from 1:8,000 to 1:50,000.

About Hypothalamic Injury-Associated Obesity (HIAO)

When the hypothalamus, a small area of the brain responsible for many hormonal and metabolic functions including the desire to eat, is injured, a syndrome of intractable weight gain and hyperphagia (excessive hunger) can ensue, resulting in severe obesity and a poor quality of life. This rare and complicated medical condition occurs in affected individuals most commonly due to a benign central nervous system tumor called craniopharyngioma, which presents as a mass in or near the hypothalamus. When the tumor is treated with surgical resection and radiation therapy, the hypothalamus often becomes severely damaged and/or dysfunctional, which can result in loss of appetite control, hyperphagia, and reduction in metabolic rate. Craniopharyngioma-associated obesity incidence estimates have ranged from 0.13 to 0.17 per 100,000 per year. Other comparably located tumors such as pilocystic astrocytoma, medulloblastoma, and pineal germinoma, affect a smaller number of patients, but patients with these tumors can have a similar clinical presentation with respect to obesity. Rarely, this form of obesity also has been reported in cases of head trauma or stroke leading to injury to the hypothalamus.

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, hypothalamic injury-associated obesity, including craniopharyngioma-associated obesity; and 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 expectations regarding beloranib as a treatment for PWS and other forms of severe obesity, its expectations with respect to the timing and success of its clinical trials of beloranib, the expected timing of additional clinical trials, its plans regarding commercialization of beloranib and its expectations relating to available cash and cash equivalents at the end of 2014 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 its drug candidates, the pre-clinical and clinical results for its product candidates, which may not support further development of product candidates, actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials, obtaining, maintaining and protecting 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 the final prospectus related to Zafgen's initial public offering filed with the Securities and Exchange Commission pursuant to Rule 424(b) of the Securities Act, 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.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	12,076	2,444	20,046	7,038
General and administrative	2,285	1,080	4,822	2,981
Total operating expenses	<u>14,361</u>	<u>3,524</u>	<u>24,868</u>	<u>10,019</u>
Loss from operations	<u>(14,361)</u>	<u>(3,524)</u>	<u>(24,868)</u>	<u>(10,019)</u>
Other income (expense):				
Interest income	1	—	2	—
Interest expense	(213)	—	(658)	—
Foreign currency transaction gains (losses), net	(116)	20	(23)	(162)
Total other income (expense), net	<u>(328)</u>	<u>20</u>	<u>(679)</u>	<u>(162)</u>
Net loss and comprehensive loss	<u>(14,689)</u>	<u>(3,504)</u>	<u>(25,547)</u>	<u>(10,181)</u>
Accretion of redeemable convertible preferred stock to redemption value	—	(53)	(92)	(160)
Net loss attributable to common stockholders	<u>\$ (14,689)</u>	<u>\$ (3,557)</u>	<u>\$ (25,639)</u>	<u>\$ (10,341)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.65)</u>	<u>\$ (4.88)</u>	<u>\$ (2.97)</u>	<u>\$ (14.19)</u>
Weighted average common shares outstanding, basic and diluted	<u>22,707,012</u>	<u>729,391</u>	<u>8,618,793</u>	<u>728,862</u>

Zafgen, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	<u>September 30,</u> <u>2014</u>	<u>December 31,</u> <u>2013</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 127,030	\$ 35,517
Prepaid expenses and other current assets	1,221	224
Tax incentive receivable	<u>1,218</u>	<u>1,617</u>
Total current assets	129,469	37,358
Property and equipment, net	69	37
Other assets	<u>98</u>	<u>743</u>
Total assets	<u>\$ 129,636</u>	<u>\$ 38,138</u>
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 1,052	\$ 2,015
Accrued expenses	9,885	900
Notes payable, current	<u>684</u>	<u>—</u>
Total current liabilities	11,621	2,915
Notes payable, net of discount, long-term	<u>6,819</u>	<u>—</u>
Total liabilities	<u>18,440</u>	<u>2,915</u>
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock (Series A, B, C, D and E), \$0.001 par value; No shares and 99,292,610 shares authorized at September 30, 2014 and December 31, 2013, respectively; no shares and 94,483,404 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively; aggregate liquidation preference of \$104,588 at December 31, 2013	—	103,797
Stockholders' equity (deficit):		
Preferred stock; \$0.001 par value; 5,000,000 and no shares authorized at September 30, 2014 and December 31, 2013, respectively; no shares issued and outstanding at September 30, 2014 and December 31, 2013	—	—
Common stock, \$0.001 par value; 115,000,000 shares authorized at September 30, 2014 and December 31, 2013; 22,707,012 and 729,391 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	23	1
Additional paid-in capital	205,627	332
Accumulated deficit	<u>(94,454)</u>	<u>(68,907)</u>
Total stockholders' equity (deficit)	111,196	(68,574)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 129,636</u>	<u>\$ 38,138</u>

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in the final prospectus related to Zafgen's initial public offering filed with the Securities and Exchange Commission pursuant to Rule 424(b) of the Securities Act, which includes the audited consolidated financial statements for the year ended December 31, 2013.

Zafgen, Inc.
Q3 2014 Conference Call Script
November 11, 2014

Conference Call Leader Dial in: (844) 899-8011

Participant Toll Free Dial in:

Participants:

Brian Ritchie, FTI Consulting

Tom Hughes, CEO

Dennis Kim, CMO

Patty Allen, CFO

Operator

Good afternoon, ladies and gentleman, and welcome to Zafgen's third quarter 2014 financial results call. Please note that this call is being recorded. At this time, I would like to turn the call over to Brian Ritchie of FTI Consulting for introductions and opening remarks.

Brian Ritchie, Senior Director, FTI Consulting

Welcome and thank you for joining us for Zafgen's third quarter financial results conference call. Today, you'll hear from Dr. Tom Hughes, Chief Executive Officer, who will give an overview of the Company's recent achievements; Dr. Dennis Kim, Chief Medical Officer, who will provide a clinical update; and Patty Allen, Chief Financial Officer, who will discuss Zafgen's financial results. After their formal remarks, management, including Patrick Loustau, President, and Alicia Secor, Chief Commercial Officer, will be available to take your questions.

Before we begin, I'd like to remind you that the estimates and other forward-looking statements included in this call represent the Company's view as of today, November 11, 2014. Zafgen disclaims any obligation to update these statements to reflect future events or circumstances. Please refer to today's earnings release as well as Zafgen filings with the SEC for information concerning factors that could cause actual results to differ materially from those expressed or implied by such statements.

Please also note that this call is being simultaneously webcast online.

I will now turn the call over to Dr. Tom Hughes. Tom.

Dr. Tom Hughes, CEO

Thanks, Brian. Good afternoon, and welcome to our third quarter 2014 earnings conference call on this Veteran's Day.

We achieved two significant clinical milestones with our lead product candidate, beloranib, recently, including the initiation of our bestPWS Phase 3 trial in Prader Willi syndrome, or PWS. This is an important accomplishment for our company, and signifies our readiness to advance beloranib toward registration if the results of our Phase 3 trials support doing so.

PWS is a rare, complex metabolic syndrome characterized by hyperphagia, or insatiable hunger, and obesity that results from impaired functioning of the hypothalamus. We are especially excited about our progress here. By initiating this trial, we've taken a significant step toward meeting the desperate need for an effective treatment option for patients and families living with this devastating disease. The trial, which will test the efficacy and safety of our lead product candidate, is called, "bestPWS", or Beloranib Efficacy Safety and Tolerability in PWS.

We also recently completed enrollment of our Phase 2a trial for beloranib in hypothalamic injury-associated obesity, or HIAO. Similar to PWS, no highly effective marketed treatments are available for the management of obesity in HIAO patients. We are eager to continue moving forward with this trial to determine if beloranib has the potential to be a significant new treatment for this rare and life altering form of obesity.

These two important clinical achievements position us well for the data rich year we are anticipating in 2015. We expect data in 2015 from our Phase 3 bestPWS and our Phase 2a study ZAF-221 in HIAO, as well as from ZAF-203, our Phase 2b study of beloranib in patients in the general population with severe obesity and type 2 diabetes. Our CMO, Dr. Dennis Kim, will discuss all of this in greater detail shortly.

Before I discuss some of the quarter's other highlights, I'd like to talk a little bit more about beloranib, and why we're so excited about its potential. Beloranib is a highly potent inhibitor of methionine aminopeptidase 2, or MetAP2, an enzyme that modulates the activity of key cellular processes that control metabolism. MetAP2 inhibitors reduce the production of new fatty acid molecules by the liver and help convert stored fat into useful energy while reducing hunger. The mechanism of action for beloranib, being effective in peripheral tissues of the body, is expected to function similarly across the indications we are currently evaluating. These include PWS, HIAO and severe obesity in the general population.

This is an important point because as we continue to see the signals of activity that we've previously seen with beloranib in an indication such as PWS, it gives us confidence in the drug's potential in other obesity-related conditions, like HIAO

As a reminder, the therapeutic validity of beloranib has unfolded over the course of five clinical trials studying approximately 200 patients exposed to the drug. In these trials, beloranib has shown impressive weight loss, often up to a kilogram per week, with a wide range of improvements in cardiometabolic risk factors. The results from these trials have guided us toward attractive market opportunities for beloranib in obesity-related orphan indications and severe obesity in the general population.

Our work was recently highlighted at ObesityWeek 2014, which took place last week, here in Boston. On the first day of the conference, I gave an oral presentation at the pre-conference pharma update session on emerging obesity therapeutics, outlining our experience with beloranib and our pipeline of MetAP2 inhibitors.

On the following day, Dennis Kim participated in a panel on PWS that discussed clinical trial approaches to understanding and demonstrating treatment effects in hyperphagia and obesity. Hyperphagia is the increase in appetite associated with hypothalamic dysfunction, which occurs in PWS patients and certain HIAO patients. The underlying cause of hyperphagia, hypothalamic dysfunction, is one of the key areas in which we are studying beloranib.

We also had two posters at Obesity Week. One described the results of our Phase 2a proof of concept study, ZAF-211, of beloranib in PWS. This first poster was presented by the study's principal investigator, Dr. Jennifer Miller, who is a Pediatric Endocrinologist and Associate Professor of Medicine at University of Florida Health.

Our second poster was presented by Dr. Jolene Zhang from Louisiana State University, who presented results of studies in an animal model of HIAO showing that a close analog of beloranib effectively reduced food intake and body weight in obese animals with damage to their hypothalamus.

We have participated in Obesity Week for several years now, and as always, we value the opportunity to meet with patients, physicians, companies and industry organizations from around the world that also recognize the need for further advancements in both the understanding and clinical management of obesity as a disease. Last week was a great success for us and we look forward to being a part of this event again next year and in the years to come.

It is events like this, as well as the stories we hear about the patients and families participating in our clinical trials, that serve as terrific reminders of why we do what we do every day here at Zafgen. For instance, in our Phase 3 bestPWS trial that is currently enrolling patients, we have heard of one patient's family literally moving to a new house in a different state to be closer to a clinical trial site, and another patient's family is driving eight hours each way to and from one of our trial centers just to participate in the study. We are so grateful for the commitment of all of our patients' families, who serve as the inspiration for our mission, which is to bring life-changing treatment options to patients affected by obesity.

Before I turn the call over to Dennis for a detailed clinical update, I'd like to share a few additional highlights from the third quarter, and some of our most recent activities. We are continuing to grow our company, and in the third quarter, we strengthened our Board with the return of Fran Heller as an independent director. Fran brings a wealth of business development experience in the pharmaceutical industry, as well as a deep working knowledge of Zafgen's programs from her prior work on our Board. We are excited to work with her again, and to leverage her strategic and business development capabilities.

As we continue to build a best-in-class company, we are attracting high caliber candidates and have grown to ~20 employees, and recently made several key appointments. These include heads of Biology, Pharmacology & Toxicology, Drug Substance Manufacturing, IT, and Quality. We've also grown our Clinical functions to support our clinical trial program.

Now, I'd like to turn the call over to our CMO, Dr. Dennis Kim, for more details on our clinical development program. Dennis?

Dr. Dennis Kim, CMO

Thanks, Tom.

As Tom noted earlier, we've made significant clinical progress with beloranib recently.

Specifically, we completed enrollment and dosing for the randomized portion of ZAF-221, a double-blind, placebo controlled Phase 2a trial of twice weekly subcutaneous injections of 1.8mg beloranib in 14 adult patients with HIAO. The study aims to evaluate efficacy and safety over 4 weeks of treatment, followed by an optional 4-week open-label extension.

As a reminder, the primary outcome measure is change in body weight from baseline to the end of the randomized dosing period of 4 weeks. Secondary outcomes include changes in the patient's lipid profile, hs-CRP (a marker of systemic inflammation), sense of hunger, and quality of life. Patients participating in ZAF-221 are enrolled at 4 trial centers – 2 in the U.S. and 2 in Australia. We remain on track to complete this study before the end of 2014, and continue to expect to see top-line data from the randomized portion of the trial by very early 2015.

Moving on to our PWS Phase 3 trial, or bestPWS, we were excited to announce that we initiated this trial within the expected timeline in Q3. Recruitment has gone well so far and the interest to volunteer for the trial from the PWS community, thus far, has been greater than expected. In order to generate more robust data, and to better meet patient demand for study participation, we intend to increase the size of the trial to approximately 100 patients, from the originally planned 84 patients.

As a reminder, bestPWS is a double-blind, placebo controlled, US Phase 3 trial of twice weekly subcutaneous injections of beloranib at doses of 1.8 mg and 2.4 mg in obese adolescent patients above age 12 and adult patients with PWS to evaluate efficacy and safety over 6 and 12 months.

Primary outcome measures of bestPWS include change in hyperphagia-related behavior and change in total body fat mass. Secondary outcomes include changes in lipid profiles, total body mass, body weight, and the impact of the disease on the patient's and the family's quality of life. We are targeting enrollment at approximately 14 sites in the U.S., 7 of which are already up and running. We are optimistic that we will meet our enrollment timeline goal of enrolling all patients within a 6 month period. We therefore continue to expect 6 month primary efficacy and safety data from this study by the end of 2015.

Turning to our program for beloranib in patients in the general population with severe obesity and type 2 diabetes, we remain on track to initiate ZAF-203, a Phase 2b efficacy and safety trial in these patients, later this year. As a reminder, the study will aim to demonstrate weight loss over a 6-12 month period and improvements in glycemic control of men and women with BMIs between 30 to 60 kg/m². We are currently looking to enroll approximately 100 to 150 patients into this study across about 15 sites, and we anticipate initial 6-month interim results in the fourth quarter of 2015. We will provide more information on this trial after the trial is initiated.

Finally, we are continuing to develop ZGN-839, an orally active novel MetAP2 inhibitor, which has shown early promise in animal models of NASH and type 2 diabetes. We continue to expect to file an IND for ZGN-839 in the first half of 2015 to establish clinical proof of concept, safety and tolerability of the drug, and remain excited by the prospect of moving this program forward.

With that, I'll turn the call over to Patty, who will take you through our financial results for the third quarter.

Patty Allen, CFO

Thanks, Dennis and good afternoon everyone.

As Tom mentioned at the top of the call, this has been an important quarter for us, both in terms of progress with our beloranib clinical program, and our overall growth as a recently public company.

To date we have not yet generated any revenue. For the third quarter of 2014, we reported a net loss of \$14.7 million, or \$0.65 per share, compared to a \$3.5 million net loss, or \$4.88 per share, for the quarter ended September 30, 2013. The weighted shares outstanding used to compute net loss per share were 22.7 million shares for the third quarter of 2014, compared to 729 thousand shares in the third quarter of 2013 which was prior to our IPO. Our operating losses were primarily driven by research and development costs associated with our beloranib development program, as well as beloranib-related milestone payments, which I will discuss in a bit more detail shortly. We had 22.7M shares outstanding as of September 30, 2014.

Moving to Research and Development expenses - for the three months ended September 30, 2014, R&D expenses increased to \$12.1 million, compared to \$2.4 million in the three months ended September 30, 2013. The increase was primarily due to increased costs of \$2.1 million associated with the advancement of our beloranib program and \$6.7 million in one-time expenses related to milestone payments owed primarily to CKD Pharma, from whom we license beloranib. These milestone payments were triggered by the initiation of the bestPWS Phase 3 clinical trial. Please note, however, from a cash perspective, these expenses were unpaid as of quarter end, and will be paid in Q4.

Moving on to General and Administrative expenses – as we expected and previously communicated, G&A expenses for the third quarter of 2014 increased to \$2.3 million, compared to \$1.1 million in the third quarter in 2013, primarily due to increased personnel-related costs of \$700 thousand for positions added to support our growth as a publically traded company. We also saw increased public company costs, professional fees, travel and other related costs of \$500 thousand period over period.

With respect to our cash position – as of September 30, 2014, we had cash and cash equivalents totaling \$127 million. We expect that this cash balance will allow us to continue to grow our business and fund our operations for approximately the next 24 months. As a reminder, this cash on hand will also enable us to obtain data in 2015 from our three clinical trials – the ZAF-221 trial in HIAO, 6 month results from the bestPWS Phase 3 trial and the interim data from the ZAF-203 Phase 2b trial in severe obesity in the general population.

As a result of increased clarity related to the timing of certain pre-clinical and clinical expenses, I am pleased to report that we now expect to end 2014 with greater than \$100 million in cash and cash equivalents, as compared to the Company's previous estimate of greater than \$95 million.

With that, I will turn the call back to the operator for questions. Operator?

[Q+A session]

We will now open the call for questions.

[Post-Q+A session]

Operator

I'd now like to turn the call back to Dr. Hughes for closing remarks.

Dr. Tom Hughes, CEO

I'd like to thank everyone again for joining our third quarter conference call. As we said during our first call in August, this has been a truly exceptional year for us already and we are very excited about our future. As we look beyond the end of this year and on to 2015, we look forward to sharing new data from our three beloranib clinical trials. We remain committed to significantly improving the health and well-being of patients affected by obesity, and look forward to updating you on our further progress on our next call.

Enjoy the rest of your day.