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)
May 3, 2010

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-33389**	**94-3136179**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1172 CASTRO STREET
MOUNTAIN VIEW, CA 94040
(Address of principal executive offices, including zip code)

(650) 934-5200
(Registrant's telephone number, including area code)

N/A
(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 (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition

On May 3, 2010, VIVUS, Inc. conducted a conference call during which members of its senior management team discussed financial results for the first quarter ended March 31, 2010 and certain other information. They also reported on product development highlights and responded to questions. A copy of the transcript of the conference call is attached hereto as Exhibit 99.1.

Item 7.01. Regulation FD Disclosure

On May 7, 2010, Kishore Gadde, MD, director of obesity clinical trials at Duke University and a lead investigator, will make a moderated poster presentation entitled, "12-Month Weight Loss and Triglyceride Changes With PHEN/TPM CR in Overweight and Obese Subjects With Hypertriglyceridemia," beginning at 8:30 a.m. at EuroPRevent 2010, the annual congress of the European Association for Cardiovascular Prevention and Rehabilitation, organized by the European Society of Cardiology, in Prague, Czech Republic. The moderated poster presentation is based on the results of the CONQUER (OB-303) study, which studied the effects of Qnexa®, an investigational drug candidate, on overweight or obese patients with two or more co-morbidities over 56 weeks. A copy of the poster to be presented by Dr. Gadde is attached hereto as Exhibit 99.2.

The information in this Form 8-K and the exhibits attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference into any of the Registrant's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Transcript of VIVUS, Inc. First Quarter 2010 Earnings Conference Call on May 3, 2010, 1:30 p.m. PT.
99.2	Poster dated May 7, 2010, entitled, "12-Month Weight Loss and Triglyceride Changes With PHEN/TPM CR in Overweight and Obese Subjects With Hypertriglyceridemia."

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.

VIVUS, INC.

By: /s/ Lee B. Perry
Lee B. Perry
Vice President and Chief Accounting Officer

Date: May 6, 2010

EXHIBIT INDEX

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MANAGEMENT DISCUSSION SECTION

Operator: Good day, ladies and gentlemen and thank you for your patience. You have joined the VIVUS First Quarter 2010 Results Call. At this time all participants are in a listen-only mode. [Operator Instructions] As a reminder, this conference may be recorded.

I would now like to turn the call over to your host, Mr. Tim Morris. Sir, you may begin.

Timothy E. Morris, Vice President, Finance and Chief Financial Officer

Thank you, operator. Before we get started, I would like to remind you that during the course of this conference call, VIVUS may make projections or other forward-looking statements regarding future events or future financial performance of the company. We wish to caution you that such statements are just predictions and actual events or results may differ materially.

Investors should read the risk factors set forth in the VIVUS Form 10-K for the year ended December 31, 2009, and the periodic reports filed with the Securities and Exchange Commission. These documents contain and identify important factors that could cause actual results to differ materially from those contained in our projections or forward-looking statements.

I will now turn the call over to Mr. Leland Wilson, CEO of VIVUS.

Leland F. Wilson, Chief Executive Officer

Thank you, Tim. Good afternoon and thank you for joining us today. Joining me on the call today along with Tim is VIVUS' President, Peter Tam.

Since we last spoke to you in March, a couple of significant dates have been established. First, we previously announced that the Endocrine and Metabolic Drug Advisory Committee is tentatively scheduled to review the company's new drug application for Qnexa on July 15th. VIVUS submitted its NDA on December 28, 2009 and is seeking approval to market Qnexa in the United States. On March 1, 2010 the FDA accepted the NDA filing for review. The target date for the FDA to complete its review is October 28, 2010. I think it goes without saying a positive review by the Advisory Committee represents a critical milestone for VIVUS. Peter will add additional thoughts on the panel in a moment.

Second, we announced this morning an important addition to our senior management team. Mike Miller joins VIVUS as Chief Commercial Officer and will be responsible for leading the Qnexa commercial efforts. Mr. Miller brings 30 years of commercial experience from executive positions in marketing, sales and business development in the pharmaceutical and biotechnology industries. Mike has played a central role in the launch, growth and success of multiple brands, expanding specialty and primary care markets and has managed business development activities and partnerships with several leading pharmaceutical companies. Most recently, Mike served as Vice President of BioOncology Business Unit at Genentech, where he presided over three marketing teams and three sales forces and drove topline growth for Herceptin, Tarceva, and Xeloda, to $2.5 billion in combined revenue in 2009.

He was also responsible for pre-launch activities for multiple pipeline products and the U.S. commercial collaboration with OSI Pharmaceuticals. Previously, Mike was Senior Vice President and Chief Commercial Officer of Connectics Corporation. He also served as Vice President at ALZA Corporation, a Johnson & Johnson Company, where he launched Ditropan XL and negotiated partnerships with companies including UCB Pharma, Abbott Laboratories and Bayer Corporation. Mike brings significant specialty and primary care experience to our management

team, and has the strategic vision, leadership skills and track record for success as we evaluate potential partners and to finalize commercial plans for Qnexa.

Finally, we filed notice last Friday that two of our directors, Graham Strachan and founder Virgil Place, would not stand for re-election at the Annual Shareholders Meeting and would consequently step down from the board. The reasons are purely personal and the timing was unexpected. We wish to thank Graham for his years of outstanding service as a Director. We especially wish to thank Virgil as our Founder of the company. Virgil started VIVUS 19 years ago and it is his vision and leadership that has brought us to this point. A nominating committee has been formed and will begin the process of selecting one new outside board member as soon as possible.

Additionally, I'd like to point out that in the next several months, we will have a significant presence through abstract presentations at seven major medical meetings in the U.S. and in Europe. Peter will share with you the details of those presentations.

Our primary focus in the second quarter will obviously be in preparation for the FDA Advisory Committee. Our internal team and consultants are working diligently to prepare the briefing documents and the multitudes of slides that are necessary to answer all the possible questions the panel may have. Further analyses have been completed as we go through the preparation of these slides and briefing documents, and this further analysis confirms the topline result of the risk benefit profile of Qnexa for overweight and obese patients remains very strong. We remain confident in our ability to gain approval of Qnexa.

With that, I'll now turn the call over to Peter for further comment.

Peter Y. Tam, President

Thanks, Lee. With the notification of the Advisory Committee meeting scheduled for July 15th, we have accelerated our preparation. We assembled a team of external experts to assist us in the preparation and presentation of the Qnexa clinical results. We are preparing the briefing package for the Advisory Committee and look forward to discussing our results with the panel. As Lee mentioned, the results of Qnexa as a potential treatment for obesity is beginning to be recognized by the medical community.

Several of the Qnexa abstracts have been accepted for presentation at upcoming medical meetings. Tomorrow, May 4th, Dr. Suzanne Oparil, the cardiologist from the University of Alabama at Birmingham and past President of the American Society of Hypertension, will make an oral presentation

during the late-breaking clinical trial session entitled, “Once-Daily, Low-Dose, Controlled-Release Phentermine/Topiramate Improves Blood Pressure and Results in Weight Loss in Overweight/Obese Patients Through 28 Weeks.”

The presentation will be made at the American Society of Hypertension 25th Annual Scientific Meeting and Exposition in New York. This presentation will feature full data from all of the phase 3 Qnexa clinical studies showing the effects of Qnexa on systolic and diastolic blood pressure at 28 weeks. This presentation to the cardiovascular community is important as we believe this is the first time we have observed significant and meaningful effects on blood pressure with a weight loss agent alone.

On Thursday and Friday, May 6 and 7, Dr. Kishore Gadde, a principal investigator in the phase 3 trials, will present two posters during the EuroPRevent 2010 meeting in Prague. EuroPRevent is an annual meeting of the European Society of Cardiology, and it’s the main scientific meeting place for all who are engaged in the prevention of cardiovascular diseases in Europe. Dr. Gadde’s poster will include data on weight loss, the anti-hypertensive effects and changes in triglycerides after 12 months of Qnexa therapy. Dr. Tim Garvey will make an oral presentation highlighting the effects of Qnexa on weight-related co-morbidities in overweight and obese patients following Qnexa

treatment during the Third World Congress on Controversies to Consensus in Diabetes, Obesity and Hypertension, or CODHy, meeting in Prague May 15th. CODHy is a comprehensive congress fully devoted to clinical debates and controversial issues on a wide spectrum of topics such as diabetes, obesity and hypertension. Dr. Charles Bowden will present additional details from the phase 2 study of Qnexa in obstructive sleep apnea in a poster session during SLEEP 2010, the 24th annual meeting of the Associated Professional Sleep Society.

The SLEEP meeting will be held in San Antonio June 7 to 9. Dr. Timothy Garvey will make an oral presentation of the Qnexa trial results to the endocrine community on June 19th during the 92nd Annual Meeting of the Endocrine Society, or ENDO. During the American Diabetes Association, or ADA, annual scientific meeting this year in Orlando June 25 to 29, VIVUS and Qnexa will have a major presence.

All six of our Qnexa abstracts have been accepted. Doctors Garvey, Gadde and Donna Ryan, the President of the Obesity Society, will each present posters including posters during the moderated tour portion of the program.

The highlight of the ADA will be a podium presentation on Monday June 28th by Dr. Gadde featuring the significant weight loss of Qnexa in patients with Type 2 diabetes and the related effects of weigh loss on diabetes.

Lastly, the International Congress on Obesity, or ICO, in Stockholm July 11 to 15 will include two Qnexa presentations. Dr. David Allison will make a poster presentation on July 14th on the results of the EQUIP trial and Dr. Kishore Gadde will make an oral presentation on July 12th on the results of CONQUER study. We have additional abstracts submitted and we will continue to share the data from the studies with those in the medical and scientific communities.

For avanafil, Dr. Irwin Goldstein, a key opinion leader in the field of urology will present the TA-301 study results, the first phase 3 trial of avanafil in an oral presentation during the American Urology Association Annual Meeting in San Francisco on June 1st. We anticipate the second phase 3 avanafil trial in diabetics to report before the end of the second quarter.

I will now turn the call over to Tim to discuss our financial results and our IR activities. Tim?

Timothy E. Morris, Vice President, Finance and Chief Financial Officer

Thank you, Peter. At the end of March VIVUS had cash, cash equivalent and available-for-sale securities of approximately $195 million. This compares to the $207 million we had at the end of last year. As it relates to the rest of the financial results, I would refer you to the press release for more information on the first quarter.

On the Investor Relations front, conference season is beginning to heat up. We have six conference presentations over the next six weeks. Upcoming presentations include the Deutsche Bank Securities Conference in Boston on May the 5th; the JMP Securities Research Conference in San Francisco on May the 11th; the Bank of America/Merrill Lynch Healthcare Conference in New York City on May the 13th; the Rodman & Renshaw Global Healthcare Conference in London May the 18th, the Citi Group Annual Global Healthcare Conference in New York City May the 26th; the Needham Healthcare Conference in New York City June the 9th; the Jefferies Healthcare Conference in New York City June the 10, and lastly the Wells Fargo Securities Healthcare Conference in Boston on June the 23rd.

With that I’d like to turn the call back over to Leland for some closing comments and Q&A.

Leland F. Wilson, Chief Executive Officer

I personally just returned from the East Coast where I spent considerable amount of time with several of our major shareholders and institutional investors as well. The feedback from this group was very positive and they are very supportive of Qnexa and VIVUS. They are encouraged by our progress to date and anxiously await the panel meeting in July. Obviously, we are preparing for that advisory panel meeting with great effort and the confidence continues to build around VIVUS for a successful outcome of that meeting.

With that I’ll open the call back open for questions.

QUESTION AND ANSWER SECTION

Operator: Thank you, sir. [Operator Instructions] And our first question comes from Cory Kasimov of JPMorgan.

<Q — Cory Kasimov>: Hi, good afternoon, guys. Thanks for taking the questions. I've two for you relating to your panel preparation, so the first one — and then obviously it goes without saying, it's going to be a very interesting panel, and one that probably very different from most other advisory committees given that each of the drugs in Qnexa are so well characterized so one would think it makes it relatively easier to predict exactly what the FDA may focus on. So, to that end, how much of real world feedback are you seeking from physicians to use these drugs? Especially those — I guess probably the focus for many investors and the ones that I am talking to is topiramate and using that in a chronic type setting for migraine therapy? Are you bringing a lot of these types of physicians in and getting their advice and trying to anticipate what types of questions you may get from the panelists in July?

<A — Peter Tam>: Cory, it's Peter. Yes, we are talking to a lot of outside experts, retained their services to help us with speaking about the risk benefit of the product. So — as you said these are two drugs that are well characterized, we're using low doses, but this is really the first time that this combination is being tested in obese patients with weight-related comorbidity. We are getting a lot of positive feedback from these people during our discussions with them. So they are there to help us go through these risk benefits with the panel, and so far things are looking really positive.

<Q — Cory Kasimov>: Okay. And then the second question also related to the panel, and Peter, you had mentioned that you guys are already working with outside consultants in your preparation work. In addition to clinicians and investigators, are you also dealing with ex-FDA staffers, and if so can you kind of talk about where their focus has been on these preparations?

<A — Peter Tam>: Yes, our outside consultants range from thought leaders in various fields as well as former FDA reviewers. So they range from CMC to clin pharm to clinical. So, we are just getting the advice from all these experienced people that are available to us.

<Q — Cory Kasimov>: Okay. And then my last question would be on the board resignations announced late last week. I understand they are purely for personal reasons, but some may look at this just given the company's current inflection point, with some skepticism. Any reason to fear the timing of this whatsoever?

<A — Leland Wilson>: None whatsoever. These are for purely personal reasons that over time will become obvious to everyone, but there — if you stop and think about the individuals, you'll probably have some basic understanding of the situation. So they are purely personal and have nothing to do with anything going on within the company. So everybody should feel very confident in that.

<Q — Cory Kasimov>: All right, great. Thanks and good luck.

<A — Leland Wilson>: Thank you.

Operator: Thank you. Our next question comes from Alan Carr of Needham & Company.

<Q — Alan Carr>: Thanks for taking my question. Congratulations for bringing Mike Miller on board. I think — a good place to start here then would be in the commercialization area. What sort of efforts do you have ongoing there, and also wondering what your assessment of the market is telling you these days? How concentrated are the prescribers in weight-loss?

<A — Leland Wilson>: Okay. Well, yes, we are real excited to have Mike on board. I've followed Mike's career for a long time. We worked together at Syntex. It seems like a century ago, but Mike's been a shooting star in the pharmaceutical industry for a long, long time. We are very grateful to

have him on board. Mike, as I mentioned, has extensive experience both in business development and in launching major products, and so with that we are pursuing as we've said publicly before we're doing everything inside the company necessary for a successful launch of this product. And the reason for that is that if a partner comes on and we are well prepared for them to take it over and go from there. So it's necessary for us to do all that.

The second part of it is it really strengthens our negotiating position. And while we're talking about this effort, we can talk about partners, too, and what we've said is that the partners that we have that are interested, which are a substantial number, are obviously anticipating the outcome of the advisory panel. So this has been an area of great concern for products in the obesity market segment. So risks reduction around the advisory panel. Mike can help us both on the corporate partnering level as well as preparing for the launch.

And now talking about the concentration of prescribers for obesity and I take it your question is relative to how many could a small company reach with a relatively small sales organization? Well, the market for obesity is only partially developed. It's certainly my expectation that the market will develop to a much greater extent with a product that can get double-digit weight loss.

And so my belief is that you will see some concentration in high prescribers and they will be high prescribers, which are not the high prescribers of phentermine and Meridia et cetera today. There will be obesity clinic that establish and people who take this up as a specialty because it is, I think, a huge potential patient pool that physicians can tap into. So, we will see how that develops over time, but right now, it's a fairly diverse prescriber population and not really highly concentrated at the present time.

<Q — Alan Carr>: Great, thanks for that. And Tim any change to burn guidance for the year?

<A — Timothy Morris>: No, we haven't changed our guidance since the last call, Alan. Still approximately 95 for the year.

<Q — Alan Carr>: Great, thanks very much.

Operator: Thank you. Our next question comes from Mike King of Wedbush. Mr. King, your line is open.

<Q — Michael King>: I beg your pardon. Thank you for taking my question and congrats on your progress, guys. Just a couple of random questions. I just wanted to follow up on the previous question about commercialization, and I wonder if you guys could talk about — I think prior to the announcement of the panel date, it was expected that a panel would happen later in the year. So, I am just wondering how has the July panel, you know, play with your schedule? Has it thrown it off at all? Are you prepared to launch if, let's say, things go smoothly and there is a positive panel and a first cycle approval on the 28th of October? Will you be able to meet all the milestones you would have been able to meet had it happen later in 2010?

<A — Leland Wilson>: Well, I mean, actually it's an advantage in my view having the earlier panel, because it will give you additional time after the panel where your risks of hiring, for example, are reduced. And so we look at it as good — a very good risk reduction step. And to that point, I would comment that we have been actively engaged since January with the FDA and a review of this NDA. So, it has progressed, in my personal view, very satisfactorily, aggressively, and so I think the panel is just a review — the date of the panel is just kind of a statement of the FDA's readiness to have a panel for this product. And so I think everybody, both the FDA and VIVUS, are going to be at a high state of readiness on that date. So we're, as I said, very confident and really can't wait to get there.

<Q — Michael King>: Will you say anything about your ability to supply the market, Lee, sometime around or after the PDUFA date? And will we see evidence later in the year of you building clinical supply?

<A — Leland Wilson>: Yes. Your question regards the manufacturing activity. Yes, we have complete capability of having launch quantities available on October 28.

<Q — Michael King>: And have you been inspected, can you say if the plant's been inspected at your manufacturers?

<A — Leland Wilson>: Well, we use a contract manufacturer. The contract manufacturer has been inspected many times. We have not had an inspection on Qnexa at this time at that plant.

<Q — Michael King>: Okay. And can you say anything about whether your sites are being audited or is that an ongoing — your clinical sites, are they -?

<A — Leland Wilson>: Well, we don't comment on that. But you might know that in every NDA that I've been associated with at least, sites are audited. It's just standard activity.

<Q — Michael King>: Yes. No, I know that. I'm just saying are we there? Is the process active on the part of the agency now and — or does that need to happen? I'm just trying to figure out what gating items might -

<A — Leland Wilson>: The agency is extremely active on all aspects of the review.

<Q — Michael King>: Okay. And I don't mean to parse your words too finely, but you did say and maybe it's just my senility setting in again, but the wording in the press release said it was a tentative panel date. I don't know that you had used that term before but perhaps I'm mistaken.

<A — Leland Wilson>: My guess is it's kind of standard lingo from the FDA. They reserve the right to change it, but I haven't seen one change, but that doesn't mean they haven't changed.

<Q — Michael King>: But it's not official until it's in the Federal Register?

<A — Leland Wilson>: That's exactly right.

<Q — Michael King>: Okay. And then one final question and I'll jump back in the queue. Any thoughts — I mean, the data that I've been reading lately suggests that the obesity is starting to level off in adults but still climbing at an alarming rate in adolescents and the peds? And I'm just wondering what VIVUS can say at the moment about a commitment to studying Qnexa in a pediatric population?

<A — Leland Wilson>: Yes. Okay, a couple of things. I haven't noticed any decline in obese people around the neighborhood.

<Q — Michael King>: I'm just telling you what -

<A — Leland Wilson>: Not to be flipped with two-thirds of the population overweight and obese, the market hasn't gone away for sure. And what was the second part of question, again, Mike?

<Q — Michael King>: All I'm saying is that -

<A — Leland Wilson>: Pediatric plans. So, Peter, you might comment on our pediatric plan.

<A — Peter Tam>: Yes. It's part of the NDA submission. We are — We submitted a pediatric plan in place. So there's a plan. I can't really comment in great detail on it other than the fact that we

thought this through very, very carefully that once Qnexa is approved, we're ready to get that plan kick started.

<A — Leland Wilson>: I think that's the important part here. It has to follow post approval and then we're also dealing with pediatric plans on the European theater as well.

<A — Peter Tam>: Yes.

<Q — Michael King>: All right. Terrific, guys. Thanks so much.

<A — Leland Wilson>: Okay.

Operator: Thank you. Our next question comes from Terence Flynn of Lazard Capital Markets.

<Q — Terence Flynn>: Hi. Thanks for taking the question. Just wondering on the — you didn't give us an update on the sleep apnea trial, and I think you guys said in the past you were planning to meet with FDA over the near-term to determine next steps. I was just wondering if you could give us a quick update there? Thanks.

<A — Peter Tam >: Yes, Terence, we did meet with the FDA and right now we're working out a late-stage phase 3 type of development plan with the FDA. So we'll provide more color, more detail in the next quarterly conference call.

<Q — Terence Flynn>: Okay. And — but you can't give us any more insights in terms of thinking about endpoints and size of trial?

<A — Leland Wilson>: I think — this is Lee, Terence. What I would say is that clearly, this is the first drug application that the FDA has dealt with for this indication. So there's a lot of negotiation, let's say, that goes on in establishing all the different parameters of how trials should be designed, the kind of patients we have, how long they have to treated, et cetera. So this was our first meeting with them; extremely receptive. They came well prepared, as you might expect. And so we're going through those discussions, as Peter said. And I expect to have them worked out relatively quickly. We'll wait and see until we have all the endpoints, the trial design, the patient populations and all those things and we'll let you know when we're ready to start phase 3.

<Q — Terence Flynn>: Okay. And will you guys seek an SPA?

<A — Leland Wilson>: Yes, we will.

<Q — Terence Flynn>: Okay. Thanks a lot.

Operator: Thank you. Our next question comes from Thomas Wei of Jefferies.

<Q — Thomas Wei>: I wanted to ask about Qnexa and whether you could share any of the insights that the FDA gave to you in their 74-day letter when you were notified about acceptance of the filing?

<A — Leland Wilson>: You want to take it, Peter, or do you want me to go?

<A — Peter Tam>: Well, yes, we — it's not a whole lot of insight. Certainly, the FDA is very quick with their review. All the questions so far have been expected and really nothing out of the ordinary. Various aspects of the NDA review from clinical, preclinical, I mean, just very comprehensive. It goes to show that the FDA is working very diligently on this NDA.

<Q — Thomas Wei>: And I wanted to just check on the presentation title for the hypertension meeting. When it refers to low-dose, that doesn't mean just the lowest dose of Qnexa, right? It wasn't effects seen across the entire dose range in the studies?

<A — Peter Tam>: Yes. We will be presenting the different doses at this meeting.

<A — Leland Wilson>: We typically characterize our product as the low-dose combination of phentermine and topiramate, so that's what that's referring to, yes.

<Q — Thomas Wei>: Okay. Perfect. And I did also want to just ask, given the fact that the same FDA panel meeting will have just spent the last day prior to yours debating cardiovascular risk with one of the diabetes drugs, I just wanted to get your sense of, or a reminder of, on a pooled basis, how many major cardiovascular adverse events did you have in those studies versus placebo? Do you know what the raw numbers are off the top of your head?

<A — Leland Wilson>: Yes. No, we have not — those are something that's being adjudicated, and we do not have the final data on those at this point. We're hopeful to have them by the advisory panel, but that's something that's outside of our hands right now because that's an independent adjudication committee. We feel very strongly, as you know, that the cardiovascular benefits of this drug are really outstanding. And so we're anxious to present our cardiovascular data. It is outstanding.

<Q — Thomas Wei>: But it's not part of the initial filing, and it probably won't be something that is going to be presented at the panel meeting?

<A — Leland Wilson>: Well, my personal preference is that I would like to present it, but we'll have wait for the adjudication to occur.

<Q — Thomas Wei>: Okay. And do you have a sense, just even generally, from the investigator coded number of cardiovascular events if you applied the same cardiovascular guidance criteria that exists for the diabetes drugs and did a meta-analysis of the phase 2 and 3 trials, are you — how many patients are you shy of being able to fulfill the criteria for the upper bound of the 95% confidence interval for, once again, separately as it has been applied to the diabetes drug?

<A — Leland Wilson>: We're as anxious as you are to get this data and get it out there to you guys, but let's wait until we have the final data before we comment on that. What I have said in the past is the number of events that we've had in this trial are not all that high. I think that's characteristic of obesity trials. They're not quite yet as sick as diabetic patient population, so the number of events are fairly low. But let's wait until we have that data to present it, and we're as anxious as you are to get it out there.

<Q — Thomas Wei>: And then one last question, just on psychiatric adverse events, I'm sure that you — the FDA has probably asked you for a similar meta-analysis like the one that was done for Acomplia. Can you share with us any findings from that analysis on how Qnexa looks versus placebo?

<A — Leland Wilson>: Well, I'm not quite sure exactly what you're asking about, but let me just speak a few words, maybe Peter can chime in as well. We have presented all the data that we have on our psychiatric AEs to this point. I mean, clearly, we have probably the most thorough and complete look at both depression and suicidality of any product that's ever been through the FDA through the Phase 3 program. And clearly, we really have zero indication of any suicidality. When you look at the PHQ-9 test scores, we actually have a slight improvement on treatment. If you look at quality of life, we have an improvement of every major — of every domain that is tested.

Now, the one area that we have focused on is the dropout rate for patients on depression, and as we have previously presented to you, the dropout rate is higher on the high dose, but that dropout

rate, the depression that was there, was primarily mild and manageable and resolved in the majority of cases while still on the drug and still on the study. So we think we have a very thorough and very convincing review of the psychiatric adverse events and we're really very confident that we're in very good shape here.

Remember now, as I always like to say, when you talk about the psychiatric adverse events, you're talking about topiramate in general. And so the doses that we use are very low compared to the approved doses of topiramate and the experience in the marketplace now. And then we have the counterbalancing activity, the complementary pharmacology of phentermine, which really I think helps to ameliorate some of those side effects. Importantly, I think in our study as well that we study patients —up to 30% of the patients came in with some kind of psychiatric history. High teens of patients we're on anti-depressions as my recollection, Peter. And so we have just done an A to Z look at this and really in my view there is really nothing here to report.

<Q — Thomas Wei>: Thanks very much. That's very helpful.

Operator: Thank you. Our next question comes from Ian Sanderson of Cowen.

<Q — Ian Sanderson>: Good afternoon. Thanks for taking the question. Have you had any discussions with the FDA at this early stage regarding a REMS plan and would that be something that might be presented at the Advisory Committee?

<A — Peter Tam>: Yes, it's — we will be presenting that at the Advisory Committee. There is really nothing unusual or different than what is currently available for topiramate, so expect something similar to medication guide, communications plan to professionals as well as patients.

<Q — Ian Sanderson>: Okay. And I guess this would be the expectation, but do you know or do you know that the FDA will include cardiologists on the Advisory Committee panel?

<A — Peter Tam>: At this point we don't know the make-up of the panel, but we're certainly preparing for that. So yes, that is something we're preparing for.

<Q — Ian Sanderson>: Okay. And then quickly on avanafil, any update on filing plans there?

<A — Peter Tam>: The guidance that we've provided is that we plan to file an NDA about approximately the first half of next year.

<Q — Ian Sanderson>: Okay. Thank you.

<A — Peter Tam>: Okay.

Operator: Thank you. Our next question comes from James Omstrom of Wells Fargo Security.

<Q — James Omstrom>: Hi, guys. Actually, all my questions have been answered. Thank you.

<A — Leland Wilson>: Thank you.

Operator: Thank you. Our next question comes from Len Yaffe of StocDoc Partners.

<Q — Len Yaffe>: I had two questions. The first one was, as you talk to your physician clinician consultants, and of those who have participated in trials with other antiobesity drugs that have completed advanced stage clinical studies, what are the differences between Qnexa and other products that they highlight to you that they find to be either especially beneficial or potentially an adverse issue?

<A — Leland Wilson>: Well, Len, a great question. But as you know I really don't comment on other peoples' products, but we're very confident in both the efficacy from a weight loss standpoint and its effect on comorbidities, particularly cardiovascular comorbidities of our product. So I think we have the best in the class, but you'll have to check with the other guys to see what they think about their products as well.

< Q — Len Yaffe >: Okay. Then the second question is I've always been impressed with the FDA statisticians who have been able to call out, from their analysis findings, that the presenting companies often don't give voluntarily when they present their data before the FDA and your analysis of the drug either as it relates to efficacy or safety. Is there anything in either efficacy or safety that you find of concern to yourselves that you feel may be most focused on by the FDA and their statisticians that may be of concern?

<A — Leland Wilson>: Well, I'll state this upfront. We may be different than the other companies, but we spend 90% of our time trying to find any kind of little hook or issue that could become an issue with the FDA. And I can promise you that each of those issues that may or may not be an issue will be dealt with fully in the briefing document and in our presentation. We believe that it's just smart to address the tough issues right up front. And so we're doing that and you'll be able to read about everything that we have found that has any possible issues. And that includes former FDA reviewers. That includes the statisticians that are of note in our industry, and so we have tried to root out every possible question, and we'll deal with them openly and straight upfront in our briefing document and presentation.

<Q>: Great. Thank you so much.

Operator: Thank you. Our next question comes from Boris Peaker of Rodman & Renshaw.

<Q — Boris Peaker>: Hello, and thanks for taking my questions. Can you hear me?

<A — Leland Wilson>: Yes.

<Q — Boris Peaker>: So you've mentioned, in terms of partners, particularly being interested in the outcome of the panel. Obviously, it makes a lot of sense. I'm just wondering in your discussion with these potential partners, do you think a strong positive panel would be adequate for them to actually sign a deal, or do you anticipate for them to wait until the drug is actually approved and a label is available?

<A — Leland Wilson>: It's kind of in a question of — it has a couple of components to it. Yes, they're highly interested and I think it would trigger a decision. But as you know, once the decision is made as to putting the documents and negotiations, finalizing and doing all those kind of things, my expectation is that we'll be right upon the time of the FDA approval. And so I've done this for a lot of years and you can expect them to be looking for that approval before the ink dries on the document as well. That's my anticipation of how it's going to work.

<Q — Boris Peaker>: I see. And since you guys are ahead of your two other major competitors, do you think that they would be willing to sign a partnership before they know the outcome of the major competitors?

<A — Leland Wilson>: I really can't comment on them. As you know, we are — we have worked very hard to maintain all rights to Qnexa. We have raised money, thanks to many of you on the phone, necessary to take us to this point. So we believe we're in a very strong position to negotiate. And clearly a positive advisory panel and even an NDA approval will escalate the value of the product dramatically.

<Q — Boris Peaker>: And my last question is have you discussed perhaps an option strategy of some sort where somebody would pay a certain amount for preferential rights to partner later once a competitive data or competitive panel results come out?

<A — Leland Wilson>: No. We need to have — maintain the negotiating strength of the next-best alternative. So we have not restricted ourselves in anyway to achieve that end.

<Q — Boris Peaker>: Okay. Thank you for taking my questions.

<A — Leland Wilson>: You bet.

Operator: Thank you. Our next question comes from Mike King of Wedbush.

<Q — Michael King>: Thanks for taking the follow up. Can you guys comment about what — how mature will the data will be by the time you get to panel? Will you have full two-year efficacy and safety from both CONQUER and EQUIP by the time you get to panel?

<A — Peter Tam>: I think the timing is that we'll have the two-year data around the second half.

<A — Leland Wilson>: It's going to be really close in my judgment. We may have a draft report or a top line report, but don't hold us to that. It all comes in, in finalizing last patients and getting the reports done, et cetera. So it — your question is right on target. It is approximately about the time of the advisory panel.

<A — Peter Tam>: But keep in mind, as we've said before, this is not at all required as part of our NDA. We've provided the full 120-day safety update to the FDA that includes this study in a blinded fashion. So there is nothing here that would affect the review process in any way.

<Q — Michael King>: No, I understood. But Advisory Committee members ask a lot of questions and often times longer term follow-up data can provide answers to those questions.

<A — Peter Tam>: Yes.

<Q — Michael King>: That's all I'm saying. Okay. Thanks very much.

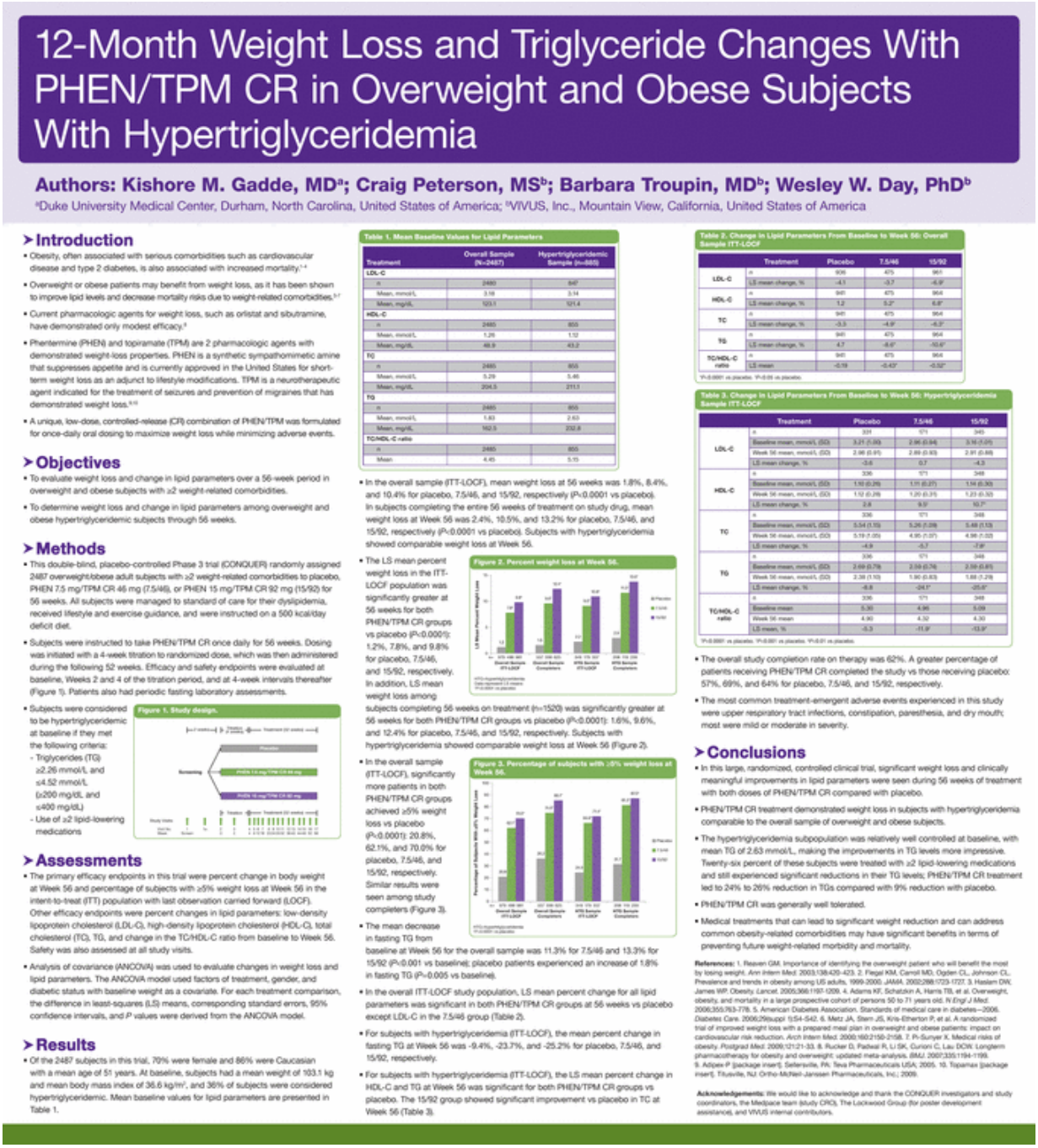
<A — Leland Wilson>: Okay. If there's no more questions, is that a fair statement, operator?

Operator: Yes, sir, it is.

Leland F. Wilson, Chief Executive Officer

Okay. Great. Thanks. And again, thanks everybody for really great questions today. So thanks a lot for that. We're — if I leave you with one message, it would be that we're very excited about going into this big game here, July 15, and we're well prepared and we're going to do a great job for you. So we can't wait for you to see it and to see the data and the issues that come up, as I hope I share with you my confidence and enthusiasm for a glorious day on July 15. So, thanks, everybody and we really appreciate your support. Thanks a lot.

Operator: Thank you, sir, and thank you, ladies and gentlemen, for your participation. This does conclude your program. You may disconnect your lines at this time. Have a nice Monday.



12-Month Weight Loss and Triglyceride Changes With PHEN/TPM CR in Overweight and Obese Subjects With Hypertriglyceridemia

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Introduction

- Obesity, often associated with serious comorbidities such as cardiovascular disease and type 2 diabetes, is also associated with increased mortality.(1)-(4)
- Overweight or obese patients may benefit from weight loss, as it has been shown to improve lipid levels and decrease mortality risks due to weight-related comorbidities.(5)-(7)
- Current pharmacologic agents for weight loss, such as orlistat and sibutramine, have demonstrated only modest efficacy.(8)
- Phentermine (PHEN) and topiramate (TPM) are 2 pharmacologic agents with demonstrated weight-loss properties. PHEN is a synthetic sympathomimetic amine that suppresses appetite and is currently approved in the United States for short-term weight loss as an adjunct to lifestyle modifications. TPM is a neurotherapeutic agent indicated for the treatment of seizures and prevention of migraines that has demonstrated weight loss.(9),(10)
- A unique, low-dose, controlled-release (CR) combination of PHEN/TPM was formulated for once-daily oral dosing to maximize weight loss while minimizing adverse events.

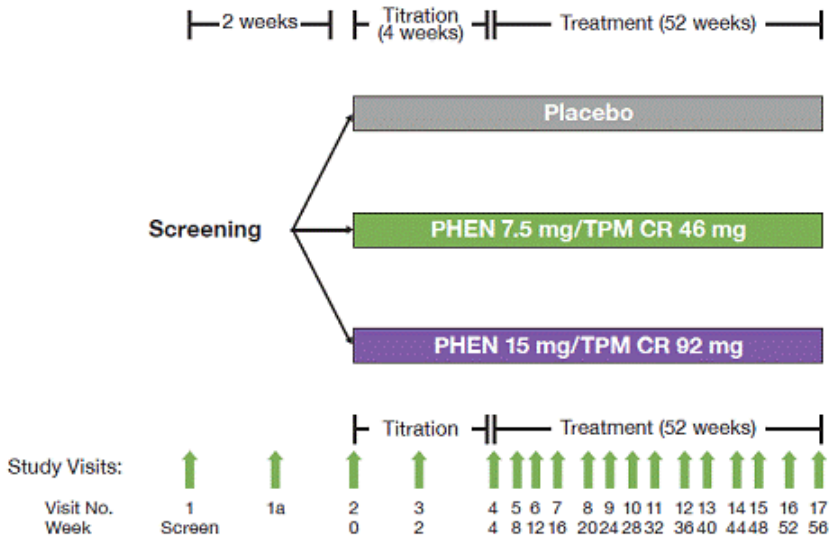
Objectives

- To evaluate weight loss and change in lipid parameters over a 56-week period in overweight and obese subjects with ≥2 weight-related comorbidities.
- To determine weight loss and change in lipid parameters among overweight and obese hypertriglyceridemic subjects through 56 weeks.

Methods

- This double-blind, placebo-controlled Phase 3 trial (CONQUER) randomly assigned 2487 overweight/obese adult subjects with ≥2 weight-related comorbidities to placebo, PHEN 7.5 mg/TPM CR 46 mg (7.5/46), or PHEN 15 mg/TPM CR 92 mg (15/92) for 56 weeks. All subjects were managed to standard of care for their dyslipidemia, received lifestyle and exercise guidance, and were instructed on a 500 kcal/day deficit diet.
- Subjects were instructed to take PHEN/TPM CR once daily for 56 weeks. Dosing was initiated with a 4-week titration to randomized dose, which was then administered during the following 52 weeks. Efficacy and safety endpoints were evaluated at baseline, Weeks 2 and 4 of the titration period, and at 4-week intervals thereafter (Figure 1). Patients also had periodic fasting laboratory assessments.
- Subjects were considered to be hypertriglyceridemic at baseline if they met the following criteria:
  - Triglycerides (TG) ≥2.26 mmol/L and ≤4.52 mmol/L (≥200 mg/dL and ≤400 mg/dL)
  - Use of ≥2 lipid-lowering medications

Figure 1. Study design.



Assessments

- The primary efficacy endpoints in this trial were percent change in body weight at Week 56 and percentage of subjects with ≥5% weight loss at Week 56 in the intent-to-treat (ITT) population with last observation carried forward (LOCF). Other efficacy endpoints were percent changes in lipid parameters: low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), total cholesterol (TC), TG, and change in the TC/HDL-C ratio from baseline to Week 56. Safety was also assessed at all study visits.
- Analysis of covariance (ANCOVA) was used to evaluate changes in weight loss and lipid parameters. The ANCOVA model used factors of treatment, gender, and diabetic status with baseline weight as a covariate. For each treatment comparison, the difference in least-squares (LS) means, corresponding standard errors, 95% confidence intervals, and *P* values were derived from the ANCOVA model.

Results

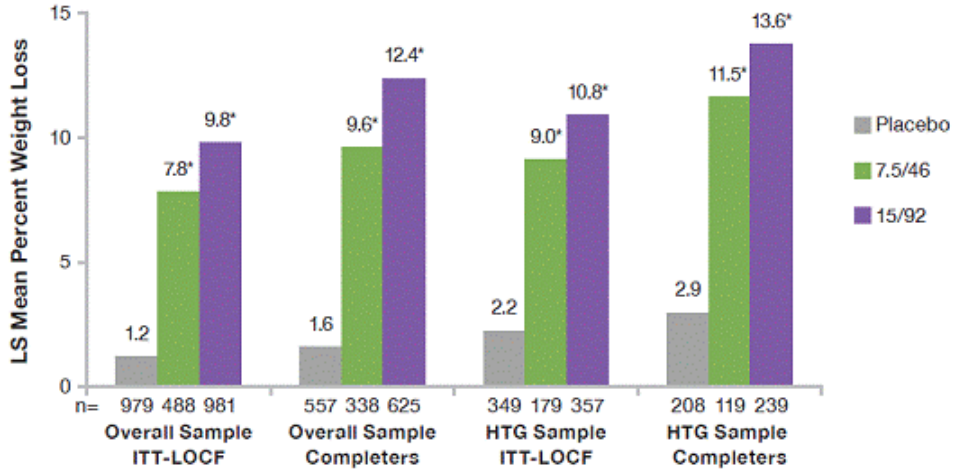
- Of the 2487 subjects in this trial, 70% were female and 86% were Caucasian with a mean age of 51 years. At baseline, subjects had a mean weight of 103.1 kg and mean body mass index of 36.6 kg/m2, and 36% of subjects were considered hypertriglyceridemic. Mean baseline values for lipid parameters are presented in Table 1.

Table 1. Mean Baseline Values for Lipid Parameters

Treatment	Overall Sample (N=2487)	Hypertriglyceridemic Sample (n=885)
LDL-C		
n	2480	847
Mean, mmol/L	3.18	3.14
Mean, mg/dL	123.1	121.4
HDL-C		
n	2485	855
Mean, mmol/L	1.26	1.12
Mean, mg/dL	48.9	43.2
TC		
n	2485	855
Mean, mmol/L	5.29	5.46
Mean, mg/dL	204.5	211.1
TG		
n	2485	855
Mean, mmol/L	1.83	2.63
Mean, mg/dL	162.5	232.8
TC/HDL-C ratio		
n	2485	855
Mean	4.45	5.15

- In the overall sample (ITT-LOCF), mean weight loss at 56 weeks was 1.8%, 8.4%, and 10.4% for placebo, 7.5/46, and 15/92, respectively (P<0.0001 vs placebo). In subjects completing the entire 56 weeks of treatment on study drug, mean weight loss at Week 56 was 2.4%, 10.5%, and 13.2% for placebo, 7.5/46, and 15/92, respectively (P<0.0001 vs placebo). Subjects with hypertriglyceridemia showed comparable weight loss at Week 56.
- The LS mean percent weight loss in the ITT-LOCF population was significantly greater at 56 weeks for both PHEN/TPM CR groups vs placebo (P<0.0001): 1.2%, 7.8%, and 9.8% for placebo, 7.5/46, and 15/92, respectively. In addition, LS mean weight loss among subjects completing 56 weeks on treatment (n=1520) was significantly greater at 56 weeks for both PHEN/TPM CR groups vs placebo (P<0.0001): 1.6%, 9.6%, and 12.4% for placebo, 7.5/46, and 15/92, respectively. Subjects with hypertriglyceridemia showed comparable weight loss at Week 56 (Figure 2).

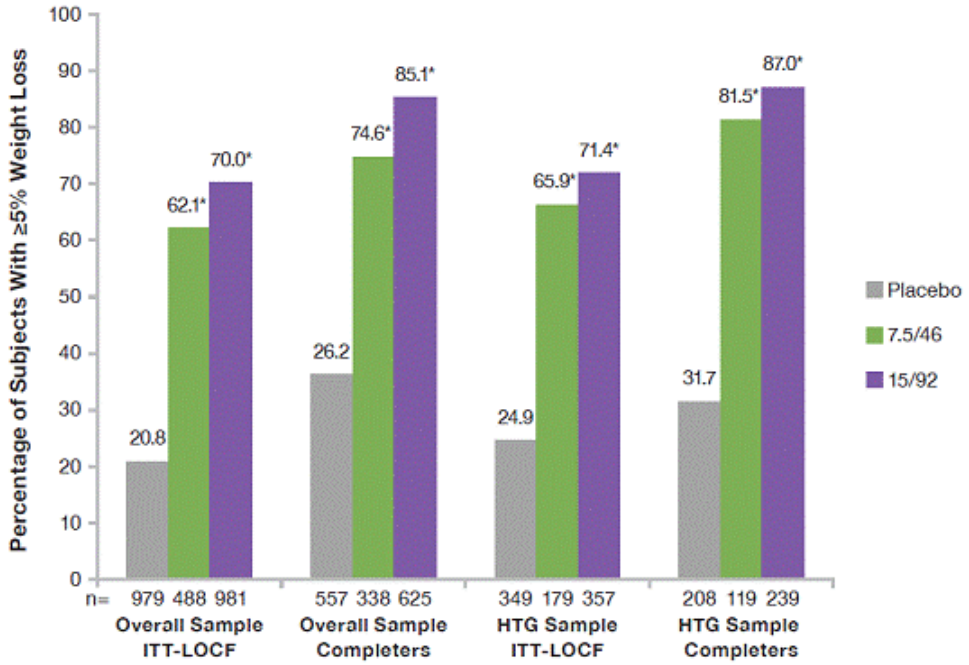
Figure 2. Percent weight loss at Week 56.



HTG=hypertriglyceridemia
Data represent LS means
*P<0.0001 vs placebo

- In the overall sample (ITT-LOCF), significantly more patients in both PHEN/TPM CR groups achieved ≥5% weight loss vs placebo (P<0.0001): 20.8%, 62.1%, and 70.0% for placebo, 7.5/46, and 15/92, respectively. Similar results were seen among study completers (Figure 3).

Figure 3. Percentage of subjects with ≥5% weight loss at Week 56.



HTG=hypertriglyceridemia
*P<0.0001 vs placebo

- The mean decrease in fasting TG from baseline at Week 56 for the overall sample was 11.3% for 7.5/46 and 13.3% for 15/92 (P<0.001 vs baseline); placebo patients experienced an increase of 1.8% in fasting TG (P=0.005 vs baseline).
- In the overall ITT-LOCF study population, LS mean percent change for all lipid parameters was significant in both PHEN/TPM CR groups at 56 weeks vs placebo except LDL-C in the 7.5/46 group (Table 2).

Table 2. Change in Lipid Parameters From Baseline to Week 56: Overall Sample ITT-LOCF

	Treatment	Placebo	7.5/46	15/92
LDL-C	n	936	475	961
	LS mean change, %	-4.1	-3.7	-6.9†
HDL-C	n	941	475	964
	LS mean change, %	1.2	5.2*	6.8*
TC	n	941	475	964
	LS mean change, %	-3.3	-4.9†	-6.3*
TG	n	941	475	964
	LS mean change, %	4.7	-8.6*	-10.6*
TC/HDL-C ratio	n	941	475	964
	LS mean	-0.19	-0.43*	-0.52*

*P<0.0001 vs placebo. †P<0.05 vs placebo.

- For subjects with hypertriglyceridemia (ITT-LOCF), the mean percent change in fasting TG at Week 56 was -9.4%, -23.7%, and -25.2% for placebo, 7.5/46, and 15/92, respectively.
- For subjects with hypertriglyceridemia (ITT-LOCF), the LS mean percent change in HDL-C and TG at Week 56 was significant for both PHEN/TPM CR groups vs placebo. The 15/92 group showed significant improvement vs placebo in TC at Week 56 (Table 3).

Table 3. Change in Lipid Parameters From Baseline to Week 56: Hypertriglyceridemia Sample ITT-LOCF

	Treatment	Placebo	7.5/46	15/92
LDL-C	n	331	171	345
	Baseline mean, mmol/L (SD)	3.21 (1.00)	2.96 (0.94)	3.16 (1.01)
	Week 56 mean, mmol/L (SD)	2.98 (0.91)	2.89 (0.93)	2.91 (0.88)
	LS mean change, %	-3.6	0.7	-4.3
HDL-C	n	336	171	348
	Baseline mean, mmol/L (SD)	1.10 (0.26)	1.11 (0.27)	1.14 (0.30)
	Week 56 mean, mmol/L (SD)	1.12 (0.28)	1.20 (0.31)	1.23 (0.32)
	LS mean change, %	2.8	9.5†	10.7*
TC	n	336	171	348
	Baseline mean, mmol/L (SD)	5.54 (1.15)	5.26 (1.09)	5.48 (1.13)
	Week 56 mean, mmol/L (SD)	5.19 (1.05)	4.95 (1.07)	4.98 (1.02)
	LS mean change, %	-4.9	-5.7	-7.8‡
TG	n	336	171	348
	Baseline mean, mmol/L (SD)	2.69 (0.79)	2.59 (0.74)	2.59 (0.81)
	Week 56 mean, mmol/L (SD)	2.38 (1.10)	1.90 (0.83)	1.88 (1.29)
	LS mean change, %	-8.8	-24.1*	-25.6*
TC/HDL-C ratio	n	336	171	348
	Baseline mean	5.30	4.96	5.09
	Week 56 mean	4.90	4.32	4.30
	LS mean, %	-5.3	-11.9†	-13.9*

*$P<0.0001$ vs placebo. †$P<0.001$ vs placebo. ‡$P<0.01$ vs placebo.

- The overall study completion rate on therapy was 62%. A greater percentage of patients receiving PHEN/TPM CR completed the study vs those receiving placebo: 57%, 69%, and 64% for placebo, 7.5/46, and 15/92, respectively.
- The most common treatment-emergent adverse events experienced in this study were upper respiratory tract infections, constipation, paresthesia, and dry mouth; most were mild or moderate in severity.

Conclusions

- In this large, randomized, controlled clinical trial, significant weight loss and clinically meaningful improvements in lipid parameters were seen during 56 weeks of treatment with both doses of PHEN/TPM CR compared with placebo.
- PHEN/TPM CR treatment demonstrated weight loss in subjects with hypertriglyceridemia comparable to the overall sample of overweight and obese subjects.
- The hypertriglyceridemia subpopulation was relatively well controlled at baseline, with mean TG of 2.63 mmol/L, making the improvements in TG levels more impressive. Twenty-six percent of these subjects were treated with ≥2 lipid-lowering medications and still experienced significant reductions in their TG levels; PHEN/TPM CR treatment led to 24% to 26% reduction in TGs compared with 9% reduction with placebo.
- PHEN/TPM CR was generally well tolerated.
- Medical treatments that can lead to significant weight reduction and can address common obesity-related comorbidities may have significant benefits in terms of preventing future weight-related morbidity and mortality.

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