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)
October 10, 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 7.01. Regulation FD Disclosure

On October 10, 2010, VIVUS, Inc. (the "Company") presented six poster presentations at the 28th Annual Scientific Meeting of The Obesity Society in San Diego, California. The posters are entitled as follows:

· Low-Dose, Controlled-Release Phentermine/Topiramate Reduces Hunger and Increases Satiety, Leading to Weight Loss in Overweight/Obese Adults;

· Clinically Meaningful Weight-Loss Outcomes With Low-Dose, Controlled-Release Phentermine/Topiramate in Overweight/Obese Patients;

· Low-Dose, Controlled-Release Phentermine/Topiramate Reduces Adiposity, Improves Cardiometabolic Risk in Overweight/Obese Patients;

· Low-Dose, Controlled-Release Phentermine/Topiramate for Weight Loss and Management of Type 2 Diabetes Mellitus;

· Weight Loss With Once-Daily, Low-Dose, Controlled-Release Phentermine/Topiramate Improves Plasma Alanine Transaminase Concentrations; and

· Improvements in Quality of Life With Low-Dose, Controlled-Release Phentermine/Topiramate in Overweight/Obese Subjects.

A graphical representation of each poster (including the reproduction of the contents) presented by the Company are attached hereto as Exhibits 99.1, 99.2, 99.3, 99.4, 99.5 and 99.6, respectively.

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	Poster entitled, "Low-Dose, Controlled-Release Phentermine/Topiramate Reduces Hunger and Increases Satiety, Leading to Weight Loss in Overweight/Obese Adults" and a reproduction of the contents thereof.
99.2	Poster entitled, "Clinically Meaningful Weight-Loss Outcomes With Low-Dose, Controlled-Release Phentermine/Topiramate in Overweight/Obese Subjects" and a reproduction of the contents thereof.
99.3	Poster entitled, "Low-Dose, Controlled-Release Phentermine/Topiramate Reduces Adiposity, Improves Cardiometabolic Risk in Overweight/Obese Patients" and a reproduction of the contents thereof.
99.4	Poster entitled, "Low-Dose, Controlled-Release Phentermine/Topiramate for Weight Loss and Management of Type 2 Diabetes Mellitus" and a reproduction of the contents thereof.
99.5	Poster entitled, "Weight Loss With Once-Daily, Low-Dose, Controlled-Release Phentermine/Topiramate Improves Plasma Alanine Transaminase Concentrations" and a reproduction of the contents thereof.
99.6	Poster entitled, "Improvements in Quality of Life With Low-Dose, Controlled-Release Phentermine/Topiramate in Overweight/Obese Subjects" and a reproduction of the contents thereof.

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/ John L. Slebir
John L. Slebir
General Counsel

Date: **October 11, 2010**

EXHIBIT INDEX

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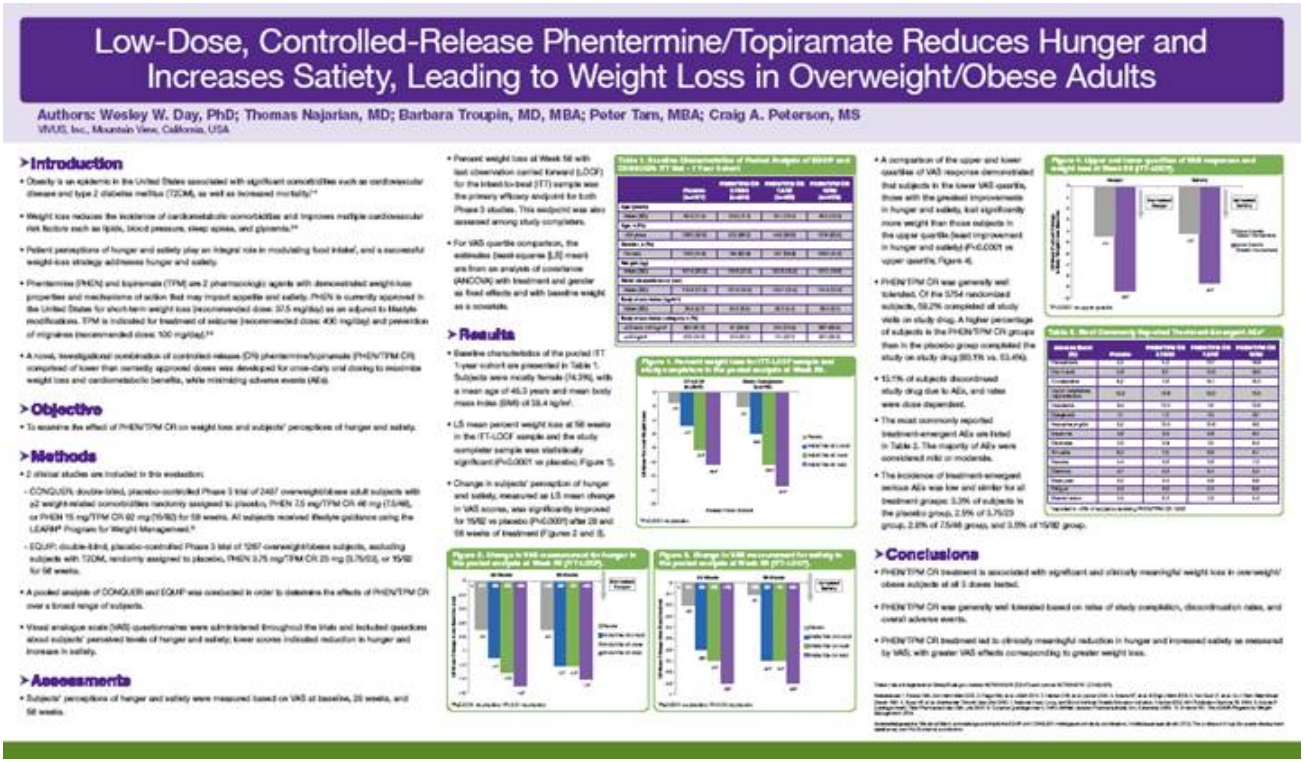
99.6	Poster entitled, "Improvements in Quality of Life With Low-Dose, Controlled-Release Phentermine/Topiramate in Overweight/Obese Subjects" and a reproduction of the contents thereof.

Below is a graphical representation of the poster entitled “Low-Dose, Controlled-Release Phentermine/Topiramate Reduces Hunger and Increases Satiety, Leading to Weight Loss in Overweight/Obese Adults”:



Below is a reproduction of the contents of the poster entitled “Low-Dose, Controlled-Release Phentermine/Topiramate Reduces Hunger and Increases Satiety, Leading to Weight Loss in Overweight/Obese Adults”:

Authors: Wesley W. Day, PhD; Thomas Najarian, MD; Barbara Troupin, MD, MBA; Peter Tam, MBA; Craig A. Peterson, MS
VIVUS, Inc., Mountain View, California, USA

· Introduction

· Obesity is an epidemic in the United States associated with significant comorbidities such as cardiovascular disease and type 2 diabetes mellitus (T2DM), as well as increased mortality.(1)-(4)

· Weight loss reduces the incidence of cardiometabolic comorbidities and improves multiple cardiovascular risk factors such as lipids, blood pressure, sleep apnea, and glycemia.(5),(6)

· Patient perceptions of hunger and satiety play an integral role in modulating food intake(7), and a successful weight-loss strategy addresses hunger and satiety.

· Phentermine (PHEN) and topiramate (TPM) are 2 pharmacologic agents with demonstrated weight-loss properties and mechanisms of action that may impact appetite and satiety. PHEN is currently approved in the United States for short-term weight loss (recommended dose: 37.5 mg/day) as an adjunct to lifestyle modifications. TPM is indicated for treatment of seizures (recommended dose: 400 mg/day) and prevention of migraines (recommended dose: 100 mg/day).(8),(9)

· A novel, investigational combination of controlled-release (CR) phentermine/topiramate (PHEN/TPM CR) comprised of lower than currently approved doses was developed for once-daily oral dosing to maximize weight loss and cardiometabolic benefits, while minimizing adverse events (AEs).

· Objective

· To examine the effect of PHEN/TPM CR on weight loss and subjects’ perceptions of hunger and satiety.

· Methods

· 2 clinical studies are included in this evaluation:

  · CONQUER: double-blind, placebo-controlled Phase 3 trial of 2487 overweight/obese adult subjects with ≥2 weight-related comorbidities randomly assigned 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 received lifestyle guidance using the LEARN® Program for Weight Management.(10)

  · EQUIP: double-blind, placebo-controlled Phase 3 trial of 1267 overweight/obese subjects, excluding subjects with T2DM, randomly assigned to placebo, PHEN 3.75 mg/TPM CR 23 mg (3.75/23), or 15/92 for 56 weeks.

· A pooled analysis of CONQUER and EQUIP was conducted in order to determine the effects of PHEN/TPM CR over a broad range of subjects.

· Visual analogue scale (VAS) questionnaires were administered throughout the trials and included questions about subjects' perceived levels of hunger and satiety; lower scores indicated reduction in hunger and increase in satiety.

· Assessments

· Subjects' perceptions of hunger and satiety were measured based on VAS at baseline, 28 weeks, and 56 weeks.

· Percent weight loss at Week 56 with last observation carried forward (LOCF) for the intent-to-treat (ITT) sample was the primary efficacy endpoint for both Phase 3 studies. This endpoint was also assessed among study completers.

· For VAS quartile comparison, the estimates (least-squares [LS] mean) are from an analysis of covariance (ANCOVA) with treatment and gender as fixed effects and with baseline weight as a covariate.

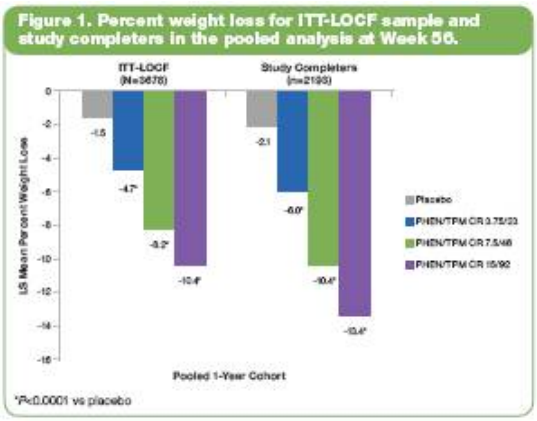
· Results

· Baseline characteristics of the pooled ITT 1-year cohort are presented in Table 1. Subjects were mostly female (74.3%), with a mean age of 48.3 years and mean body mass index (BMI) of 38.4 kg/m^2.

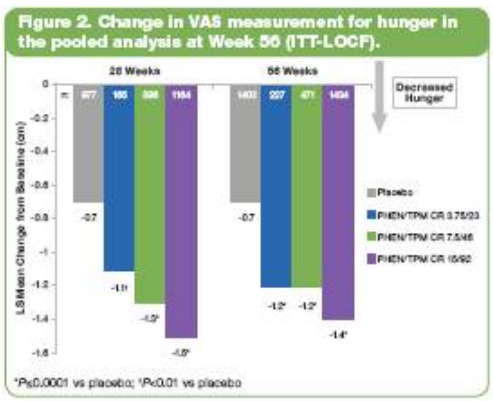
Table 1. Baseline Characteristics of Pooled Analysis of EQUIP and CONQUER: ITT Set - 1 Year Cohort

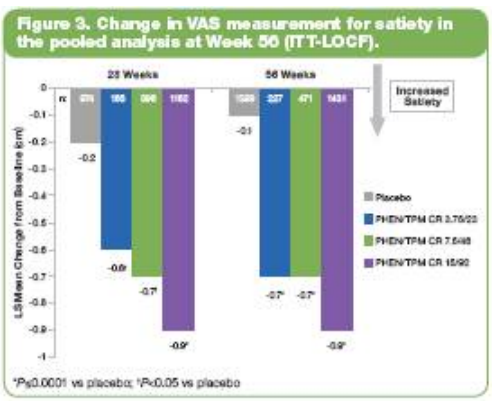
	Placebo (n=1477)	PHEN/TPM CR 3.75/23 (n=234)	PHEN/TPM CR 7.5/46 (n=488)	PHEN/TPM CR 15/92 (n=1479)
Age (years)				
Mean (SD)	48.5 (11.4)	43.0 (11.1)	51.1 (10.4)	48.0 (12.0)
Age, n (%)				
<65 years	1382 (93.6)	230 (98.3)	442 (90.6)	1376 (93.0)
Gender, n (%)				
Female	1102 (74.6)	194 (82.9)	341 (69.9)	1094 (74.0)
Weight (kg)				
Mean (SD)	107.5 (20.2)	118.6 (21.9)	102.8 (18.2)	107.1 (19.6)
Waist circumference (cm)				
Mean (SD)	115.8 (13.3)	121.5 (15.2)	112.7 (12.4)	115.5 (13.5)
Body mass index (kg/m^2)				
Mean (SD)	38.5 (5.7)	42.5 (6.5)	36.3 (4.4)	38.4 (5.7)
Body mass index category n (%)				
≥30 and <40 kg/m^2	904 (61.2)	91 (38.9)	344 (70.5)	887 (60.0)
≥40 kg/m^2	502 (34.0)	143 (61.1)	111 (22.7)	521 (35.2)

· LS mean percent weight loss at 56 weeks in the ITT-LOCF sample and the study completer sample was statistically significant (P<0.0001 vs placebo; Figure 1).

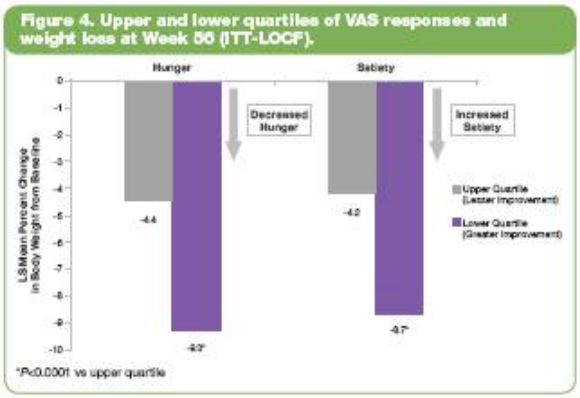


· Change in subjects' perception of hunger and satiety, measured as LS mean change in VAS scores, was significantly improved for 15/92 vs placebo (P<0.0001) after 28 and 56 weeks of treatment (Figures 2 and 3).





· A comparison of the upper and lower quartiles of VAS response demonstrated that subjects in the lower VAS quartile, those with the greatest improvements in hunger and satiety, lost significantly more weight than those subjects in the upper quartile (least improvement in hunger and satiety) (P<0.0001 vs upper quartile; Figure 4).



· PHEN/TPM CR was generally well tolerated. Of the 3754 randomized subjects, 59.2% completed all study visits on study drug. A higher percentage of subjects in the PHEN/TPM CR groups than in the placebo group completed the study on study drug (63.1% vs. 53.4%).

· 13.1% of subjects discontinued study drug due to AEs, and rates were dose dependent.

· The most commonly reported treatment-emergent AEs are listed in Table 2. The majority of AEs were considered mild or moderate.

Table 2. Most Commonly Reported Treatment-Emergent AEs*

Adverse Event (%)	Placebo	PHEN/TPM CR 3.75/23	PHEN/TPM CR 7.5/46	PHEN/TPM CR 15/92
Paresthesia	2.0	4.2	13.7	19.9
Dry mouth	2.9	6.7	13.5	19.5
Constipation	6.2	7.9	15.1	16.3
Upper respiratory tract infection	12.2	15.8	12.2	13.0
Headache	9.4	10.4	7.0	10.8
Dysgeusia	1.1	1.3	7.4	9.7
Nasopharyngitis	8.2	12.5	10.6	9.6
Insomnia	4.8	5.0	5.8	9.4
Dizziness	3.5	2.9	7.2	8.5
Sinusitis	6.3	7.5	6.8	8.1
Nausea	4.4	5.8	3.6	7.0
Diarrhea	4.7	5.0	6.4	5.4
Back pain	5.0	5.4	5.6	6.6
Fatigue	4.4	5.0	4.4	6.0
Blurred vision	3.5	6.3	4.0	5.5

*reported in >5% of subjects receiving PHEN/TPM CR 15/92

· The incidence of treatment-emergent serious AEs was low and similar for all treatment groups: 3.3% of subjects in the placebo group, 2.5% of 3.75/23 group, 2.8% of 7.5/46 group, and 3.5% of 15/92 group.

· Conclusions

· PHEN/TPM CR treatment is associated with significant and clinically meaningful weight loss in overweight/obese subjects at all 3 doses tested.

· PHEN/TPM CR was generally well tolerated based on rates of study completion, discontinuation rates, and overall adverse events.

· PHEN/TPM CR treatment led to clinically meaningful reduction in hunger and increased satiety as measured by VAS; with greater VAS effects corresponding to greater weight loss.

These trials are registered at ClinicalTrials.gov, number NCT00554216 (EQUIP) and number NCT00553787 (CONQUER).

References: (1) Reaven GM. *Ann Intern Med* 2003. (2) Flegal KM, et al. *JAMA* 2010. (3) Haslam DW, et al. *Lancet* 2005. (4) Adams KF, et al. *N Engl J Med* 2006. (5) Van Gaal LF, et al. *Int J Obes Relat Metab Disord* 1997. (6) Kopp HP, et al. *Arterioscler Thromb Vasc Biol* 2003. (7) National Heart, Lung, and Blood Institute Obesity Education Initiative. October 2000. NIH Publication Number 00-4084. (8) Adipex-P [package insert]. Teva Pharmaceuticals USA; July 2005. (9) Topamax [package insert]. Ortho-McNeil-Janssen Pharmaceuticals, Inc.; December 2009. (10) Brownell KD. *The LEARN Program for Weight Management*. 2004.

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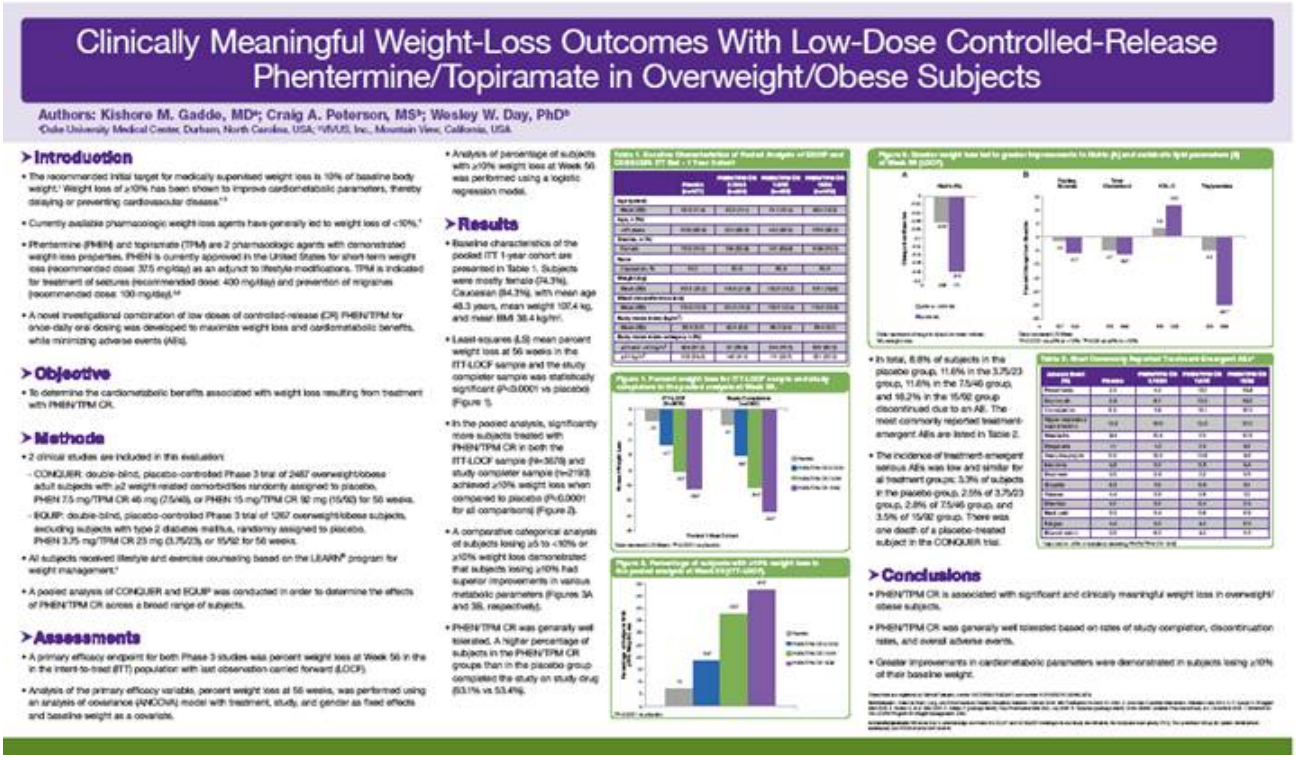
Below is a graphical representation of the poster entitled “Clinically Meaningful Weight-Loss Outcomes With Low-Dose Controlled-Release Phentermine/Topiramate in Overweight/Obese Subjects”:



Below is a reproduction of the contents of the poster entitled “Clinically Meaningful Weight-Loss Outcomes With Low-Dose Controlled-Release Phentermine/Topiramate in Overweight/Obese Subjects”:

Authors: Kishore M. Gadde, MD(a); Craig A. Peterson, MS(b); Wesley W. Day, PhD(b)

(a)Duke University Medical Center, Durham, North Carolina, USA; (b)VIVUS, Inc., Mountain View, California, USA

· **Introduction**

· The recommended initial target for medically supervised weight loss is 10% of baseline body weight.(1) Weight loss of ≥10% has been shown to improve cardiometabolic parameters, thereby delaying or preventing cardiovascular disease.(1)-(3)

· Currently available pharmacologic weight-loss agents have generally led to weight loss of <10%.(4)

· Phentermine (PHEN) and topiramate (TPM) are 2 pharmacologic agents with demonstrated weight-loss properties. PHEN is currently approved in the United States for short-term weight loss (recommended dose: 37.5 mg/day) as an adjunct to lifestyle modifications. TPM is indicated for treatment of seizures (recommended dose: 400 mg/day) and prevention of migraines (recommended dose: 100 mg/day).(5),(6)

· A novel investigational combination of low doses of controlled-release (CR) PHEN/TPM for once-daily oral dosing was developed to maximize weight loss and cardiometabolic benefits, while minimizing adverse events (AEs).

· **Objective**

· To determine the cardiometabolic benefits associated with weight loss resulting from treatment with PHEN/TPM CR.

· **Methods**

· 2 clinical studies are included in this evaluation:

  · CONQUER: double-blind, placebo-controlled Phase 3 trial of 2487 overweight/obese adult subjects with ≥2 weight-related comorbidities randomly assigned 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.

  · EQUIP: double-blind, placebo-controlled Phase 3 trial of 1267 overweight/obese subjects, excluding subjects with type 2 diabetes mellitus, randomly assigned to placebo, PHEN 3.75 mg/TPM CR 23 mg (3.75/23), or 15/92 for 56 weeks.

· All subjects received lifestyle and exercise counseling based on the LEARN® program for weight management.(7)

· A pooled analysis of CONQUER and EQUIP was conducted in order to determine the effects of PHEN/TPM CR across a broad range of subjects.

· **Assessments**

· A primary efficacy endpoint for both Phase 3 studies was percent weight loss at Week 56 in the in the intent-to-treat (ITT) population with last observation carried forward (LOCF).

· Analysis of the primary efficacy variable, percent weight loss at 56 weeks, was performed using an analysis of covariance (ANCOVA) model with treatment, study, and gender as fixed effects and baseline weight as a covariate.

· Analysis of percentage of subjects with ≥10% weight loss at Week 56 was performed using a logistic regression model.

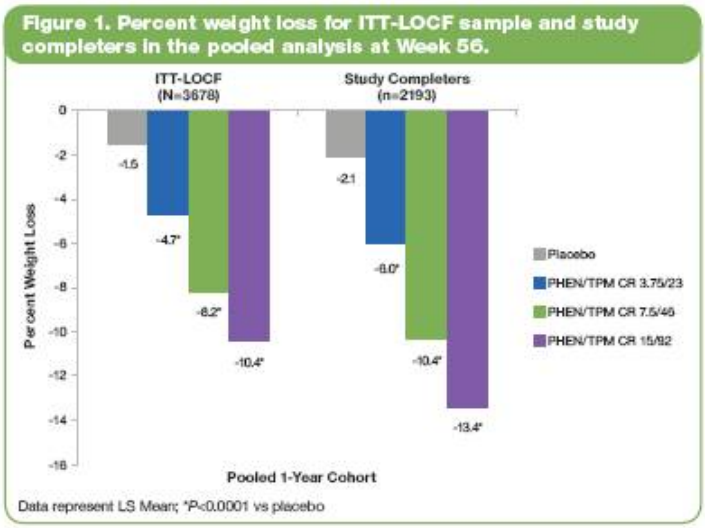
· Results

· Baseline characteristics of the pooled ITT 1-year cohort are presented in Table 1. Subjects were mostly female (74.3%), Caucasian (84.3%), with mean age 48.3 years, mean weight 107.4 kg, and mean BMI 38.4 kg/m^2.

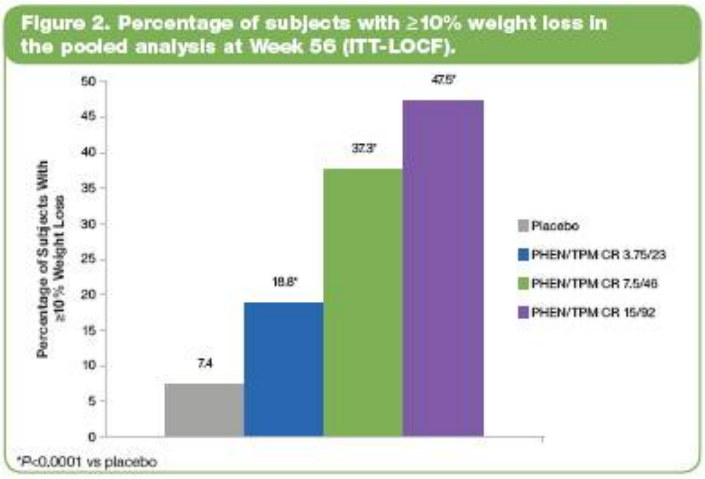
Table 1. Baseline Characteristics of Pooled Analysis of EQUIP and CONQUER: ITT Set - 1 Year Cohort

	Placebo (n=1477)	PHEN/TPM CR 3.75/23 (n=234)	PHEN/TPM CR 7.5/46 (n=488)	PHEN/TPM CR 15/92 (n=1479)
Age (years)				
Mean (SD)	48.5 (11.4)	43.0 (11.1)	51.1 (10.4)	48.0 (12.0)
Age, n (%)				
<65 years	1382 (93.6)	230 (98.3)	442 (90.6)	1376 (93.0)
Gender, n (%)				
Female	1102 (74.6)	194 (82.9)	341 (69.9)	1094 (74.0)
Race				
Caucasian, %	84.7	80.8	86.9	83.5
Weight (kg)				
Mean (SD)	107.5 (20.2)	118.6 (21.9)	102.8 (18.2)	107.1 (19.6)
Waist circumference (cm)				
Mean (SD)	115.8 (13.3)	121.5 (15.2)	112.7 (12.4)	115.5 (13.5)
Body mass index (kg/m^2)				
Mean (SD)	38.5 (5.7)	42.5 (6.5)	36.3 (4.4)	38.4 (5.7)
Body mass index category n (%)				
≥30 and <40 kg/m^2	904 (61.2)	91 (38.9)	344 (70.5)	887 (60.0)
≥40 kg/m^2	502 (34.0)	143 (61.1)	111 (22.7)	521 (35.2)

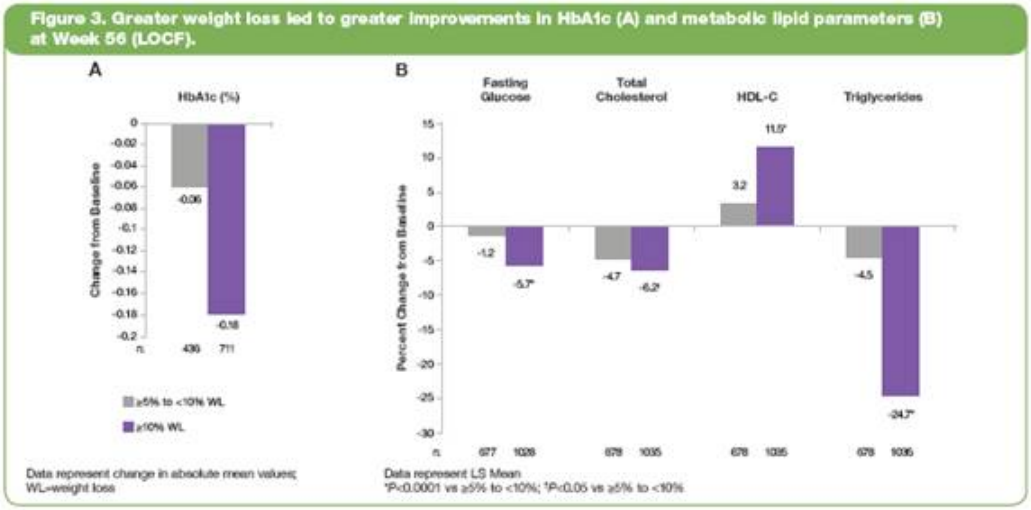
· Least-squares (LS) mean percent weight loss at 56 weeks in the ITT-LOCF sample and the study completer sample was statistically significant (*P*<0.0001 vs placebo) (Figure 1).



· In the pooled analysis, significantly more subjects treated with PHEN/TPM CR in both the ITT-LOCF sample (N=3678) and study completer sample (n=2193) achieved ≥10% weight loss when compared to placebo (*P*<0.0001 for all comparisons) (Figure 2).



· A comparative categorical analysis of subjects losing ≥5 to <10% or ≥10% weight loss demonstrated that subjects losing ≥10% had superior improvements in various metabolic parameters (Figures 3A and 3B, respectively).



· PHEN/TPM CR was generally well tolerated. A higher percentage of subjects in the PHEN/TPM CR groups than in the placebo group completed the study on study drug (63.1% vs 53.4%).

· In total, 8.8% of subjects in the placebo group, 11.6% in the 3.75/23 group, 11.6% in the 7.5/46 group, and 18.2% in the 15/92 group discontinued due to an AE. The most commonly reported treatment-emergent AEs are listed in Table 2.

Table 2. Most Commonly Reported Treatment-Emergent AEs*

Adverse Event (%)	Placebo	PHEN/TPM CR 3.75/23	PHEN/TPM CR 7.5/46	PHEN/TPM CR 15/92
Paresthesia	2.0	4.2	13.7	19.9
Dry mouth	2.9	6.7	13.5	19.5
Constipation	6.2	7.9	15.1	16.3
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Headache	9.4	10.4	7.0	10.8
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Nasopharyngitis	8.2	12.5	10.6	9.6
Insomnia	4.8	5.0	5.8	9.4
Dizziness	3.5	2.9	7.2	8.5
Sinusitis	6.3	7.5	6.8	8.1
Nausea	4.4	5.8	3.6	7.0
Diarrhea	4.7	5.0	6.4	5.4
Back pain	5.0	5.4	5.6	6.6
Fatigue	4.4	5.0	4.4	6.0
Blurred vision	3.5	6.3	4.0	5.5

*reported in >5% of subjects receiving PHEN/TPM CR 15/92

· The incidence of treatment-emergent serious AEs was low and similar for all treatment groups: 3.3% of subjects in the placebo group, 2.5% of 3.75/23 group, 2.8% of 7.5/46 group, and 3.5% of 15/92 group. There was one death of a placebo-treated subject in the CONQUER trial.

· Conclusions

· PHEN/TPM CR is associated with significant and clinically meaningful weight loss in overweight/obese subjects.

· PHEN/TPM CR was generally well tolerated based on rates of study completion, discontinuation rates, and overall adverse events.

· Greater improvements in cardiometabolic parameters were demonstrated in subjects losing ≥10% of their baseline weight.

These trials are registered at ClinicalTrials.gov, number NCT00554216 (EQUIP) and number NCT00553787 (CONQUER).

References: (1) National Heart, Lung, and Blood Institute Obesity Education Initiative. October 2000. NIH Publication Number 00-4084. (2) American Diabetes Association. *Diabetes Care* 2010. (3) Pi-Sunyer X. *Postgrad Med* 2009. (4) Rucker D, et al. *BMJ* 2007. (5) Adipex-P [package insert]. Teva Pharmaceuticals USA; July 2005. (6) Topamax [package insert]. Ortho-McNeil-Janssen Pharmaceuticals, Inc.; December 2009. (7) Brownell KD. *The LEARN Program for Weight Management*. 2004.

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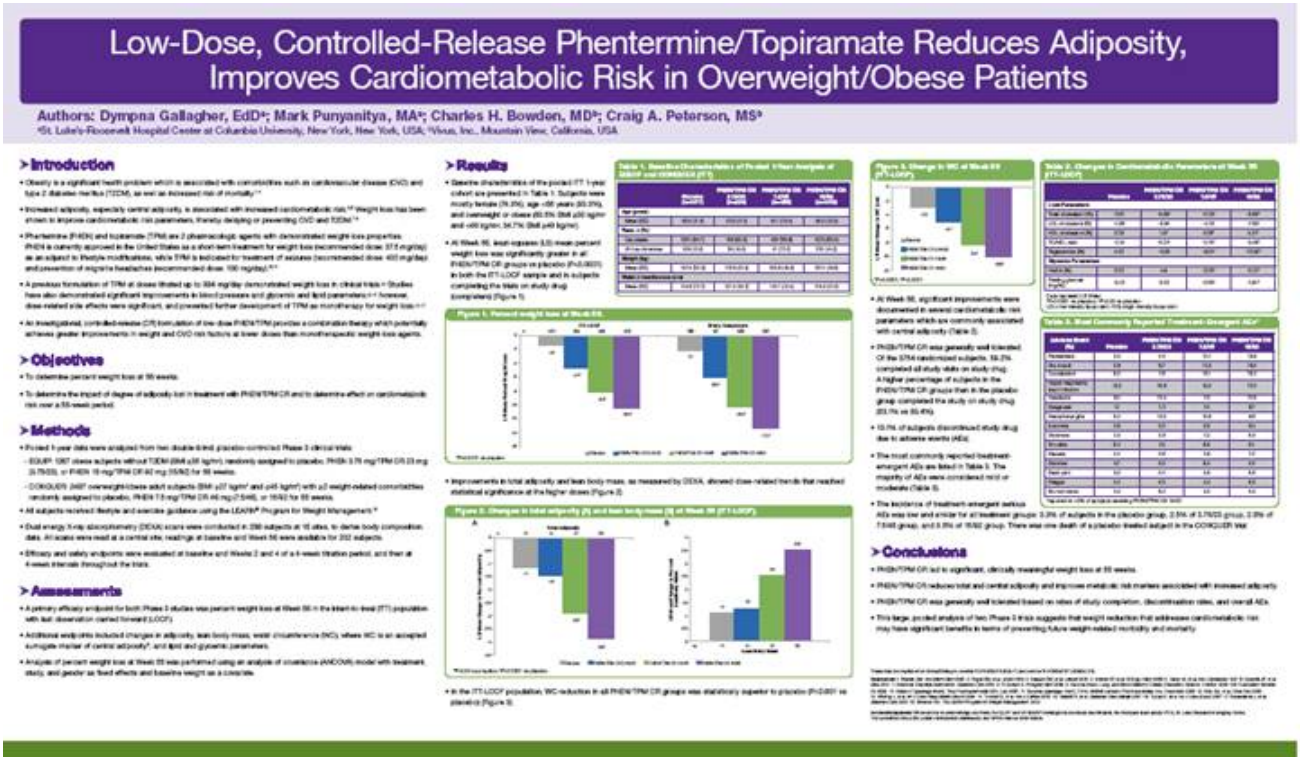


Below is a reproduction of the contents of the poster entitled “Low-Dose, Controlled-Release Phentermine/Topiramate Reduces Adiposity, Improves Cardiometabolic Risk in Overweight/Obese Patients”:

Authors: Dympna Gallagher, EdD(a); Mark Punyanitya, MA(a); Charles H. Bowden, MD(b); Craig A. Peterson, MS(b)

(a)St. Luke’s-Roosevelt Hospital Center at Columbia University, New York, New York, USA; (b)Vivus, Inc., Mountain View, California, USA

· Introduction

· Obesity is a significant health problem which is associated with comorbidities such as cardiovascular disease (CVD) and type 2 diabetes mellitus (T2DM), as well as increased risk of mortality.(1)-(4)

· Increased adiposity, especially central adiposity, is associated with increased cardiometabolic risk.(5),(6) Weight loss has been shown to improve cardiometabolic risk parameters, thereby delaying or preventing CVD and T2DM.(7)-(9)

· Phentermine (PHEN) and topiramate (TPM) are 2 pharmacologic agents with demonstrated weight-loss properties. PHEN is currently approved in the United States as a short-term treatment for weight loss (recommended dose: 37.5 mg/day) as an adjunct to lifestyle modifications, while TPM is indicated for treatment of seizures (recommended dose: 400 mg/day) and prevention of migraine headaches (recommended dose: 100 mg/day).(10),(11)

· A previous formulation of TPM at doses titrated up to 384 mg/day demonstrated weight loss in clinical trials.(12) Studies have also demonstrated significant improvements in blood pressure and glycemic and lipid parameters;(13)-(17) however, dose-related side effects were significant, and prevented further development of TPM as monotherapy for weight loss.(12)-(17)

· An investigational, controlled-release (CR) formulation of low-dose PHEN/TPM provides a combination therapy which potentially achieves greater improvements in weight and CVD risk factors at lower doses than monotherapeutic weight-loss agents.

· Objectives

· To determine percent weight loss at 56 weeks.

· To determine the impact of degree of adiposity lost in treatment with PHEN/TPM CR and to determine effect on cardiometabolic risk over a 56-week period.

· Methods

· Pooled 1-year data were analyzed from two double-blind, placebo-controlled Phase 3 clinical trials:

  · EQUIP: 1267 obese subjects without T2DM (BMI ³35 kg/m^2), randomly assigned to placebo, PHEN 3.75 mg/TPM CR 23 mg (3.75/23), or PHEN 15 mg/TPM CR 92 mg (15/92) for 56 weeks.

- CONQUER: 2487 overweight/obese adult subjects (BMI ³27 kg/m² and £45 kg/m²) with ³2 weight-related comorbidities randomly assigned to placebo, PHEN 7.5 mg/TPM CR 46 mg (7.5/46), or 15/92 for 56 weeks.

- All subjects received lifestyle and exercise guidance using the LEARN® Program for Weight Management.(18)

- Dual energy X-ray absorptiometry (DEXA) scans were conducted in 288 subjects at 16 sites, to derive body composition data. All scans were read at a central site; readings at baseline and Week 56 were available for 202 subjects.

- Efficacy and safety endpoints were evaluated at baseline and Weeks 2 and 4 of a 4-week titration period, and then at 4-week intervals throughout the trials.

· Assessments

- A primary efficacy endpoint for both Phase 3 studies was percent weight loss at Week 56 in the intent-to-treat (ITT) population with last observation carried forward (LOCF).

- Additional endpoints included changes in adiposity, lean body mass, waist circumference (WC), where WC is an accepted surrogate marker of central adiposity(6), and lipid and glycemic parameters.

- Analysis of percent weight loss at Week 56 was performed using an analysis of covariance (ANCOVA) model with treatment, study, and gender as fixed effects and baseline weight as a covariate.

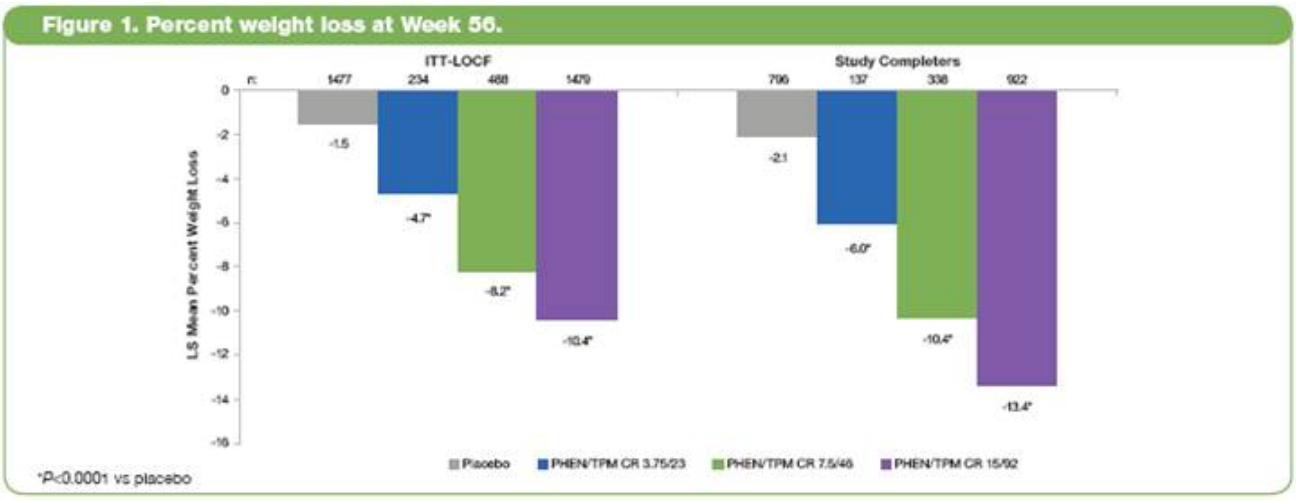
· Results

- Baseline characteristics of the pooled ITT 1-year cohort are presented in Table 1. Subjects were mostly female (74.3%), age <65 years (93.3%), and overweight or obese (60.5% BMI ³30 kg/m² and <40 kg/m²; 34.7% BMI ³40 kg/m²).

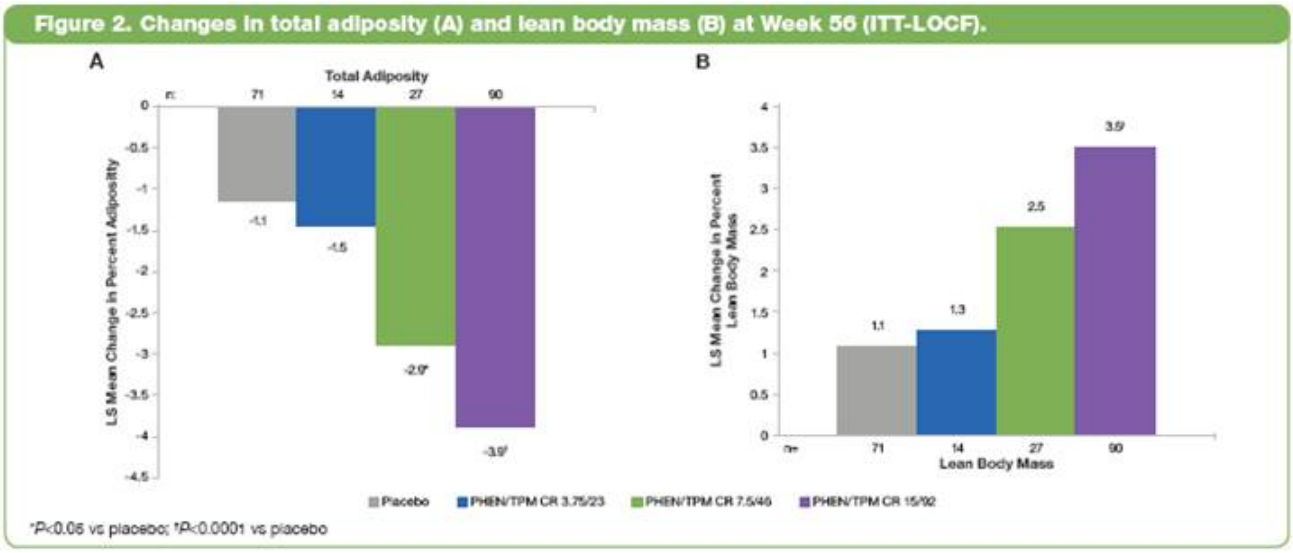
Table 1. Baseline Characteristics of Pooled 1-Year Analysis of EQUIP and CONQUER (ITT)

	Placebo (n=1477)	PHEN/TPM CR 3.75/23 (n=234)	PHEN/TPM CR 7.5/46 (n=488)	PHEN/TPM CR 15/92 (n=1479)
Age (years)				
Mean (SD)	48.5 (11.4)	43.0 (11.1)	51.1 (10.4)	48.0 (12.0)
Race, n (%)				
Caucasian	1251 (84.7)	189 (80.8)	424 (86.9)	1235 (83.5)
African American	199 (13.5)	35 (15.0)	51 (10.5)	210 (14.2)
Weight (kg)				
Mean (SD)	107.5 (20.2)	118.6 (21.9)	102.8 (18.2)	107.1 (19.6)
Waist circumference (cm)				
Mean (SD)	115.8 (13.3)	121.5 (15.2)	112.7 (12.4)	115.5 (13.5)

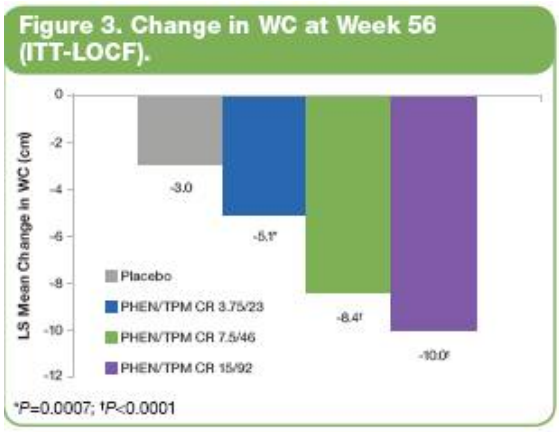
- At Week 56, least-squares (LS) mean percent weight loss was significantly greater in all PHEN/TPM CR groups vs placebo (*P*<0.0001) in both the ITT-LOCF sample and in subjects completing the trials on study drug (completers) (Figure 1).



- Improvements in total adiposity and lean body mass, as measured by DEXA, showed dose-related trends that reached statistical significance at the higher doses (Figure 2).



· In the ITT-LOCF population, WC reduction in all PHEN/TPM CR groups was statistically superior to placebo (*P*<0.001 vs placebo) (Figure 3).



· At Week 56, significant improvements were documented in several cardiometabolic risk parameters which are commonly associated with central adiposity (Table 2).

Table 2. Changes in Cardiometabolic Parameters at Week 56 (ITT-LOCF)

	Placebo	PHEN/TPM CR 3.75/23	PHEN/TPM CR 7.5/46	PHEN/TPM CR 15/92
Lipid Parameters				
Total cholesterol (%)	-3.81	-5.85†	-5.35†	-6.68*
LDL cholesterol (%)	-4.88	-6.94	-4.36	-7.69†
HDL cholesterol (%)	0.39	1.57	4.06*	5.31*
TC/HDL ratio	-0.15	-0.31†	-0.38*	-0.46*
Triglycerides (%)	4.22	-0.00	-9.04*	-10.62*
Glycemic Parameters				
HbA1c (%)	0.03	n/a	-0.08*	-0.10*
Fasting glucose (mg/dL)	-0.43	-2.02	-2.88†	-3.61*

Data represent LS Mean
**P*<0.0001 vs placebo; †*P*<0.05 vs placebo
LDL=low-density lipoprotein; HDL=high-density lipoprotein

· PHEN/TPM CR was generally well tolerated. Of the 3754 randomized subjects, 59.2% completed all study visits on study drug. A higher percentage of subjects in the PHEN/TPM CR groups than in the placebo group completed the study on study drug (63.1% vs 53.4%).

· 13.1% of subjects discontinued study drug due to adverse events (AEs).

· The most commonly reported treatment-emergent AEs are listed in Table 3. The majority of AEs were considered mild or moderate (Table 3).

Table 3. Most Commonly Reported Treatment-Emergent AEs*

Adverse Event (%)	Placebo	PHEN/TPM CR 3.75/23	PHEN/TPM CR 7.5/46	PHEN/TPM CR 15/92
Paresthesia	2.0	4.2	13.7	19.9
Dry mouth	2.9	6.7	13.5	19.5
Constipation	6.2	7.9	15.1	16.3
Upper respiratory tract infection	12.2	15.8	12.2	13.0
Headache	9.4	10.4	7.0	10.8
Dysgeusia	1.1	1.3	7.4	9.7
Nasopharyngitis	8.2	12.5	10.6	9.6

Insomnia	4.8	5.0	5.8	9.4
Dizziness	3.5	2.9	7.2	8.5
Sinusitis	6.3	7.5	6.8	8.1
Nausea	4.4	5.8	3.6	7.0
Diarrhea	4.7	5.0	6.4	5.4
Back pain	5.0	5.4	5.6	6.6
Fatigue	4.4	5.0	4.4	6.0
Blurred vision	3.5	6.3	4.0	5.5

*reported in >5% of subjects receiving PHEN/TPM CR 15/92

- The incidence of treatment-emergent serious AEs was low and similar for all treatment groups: 3.3% of subjects in the placebo group, 2.5% of 3.75/23 group, 2.8% of 7.5/46 group, and 3.5% of 15/92 group. There was one death of a placebo-treated subject in the CONQUER trial.

· Conclusions

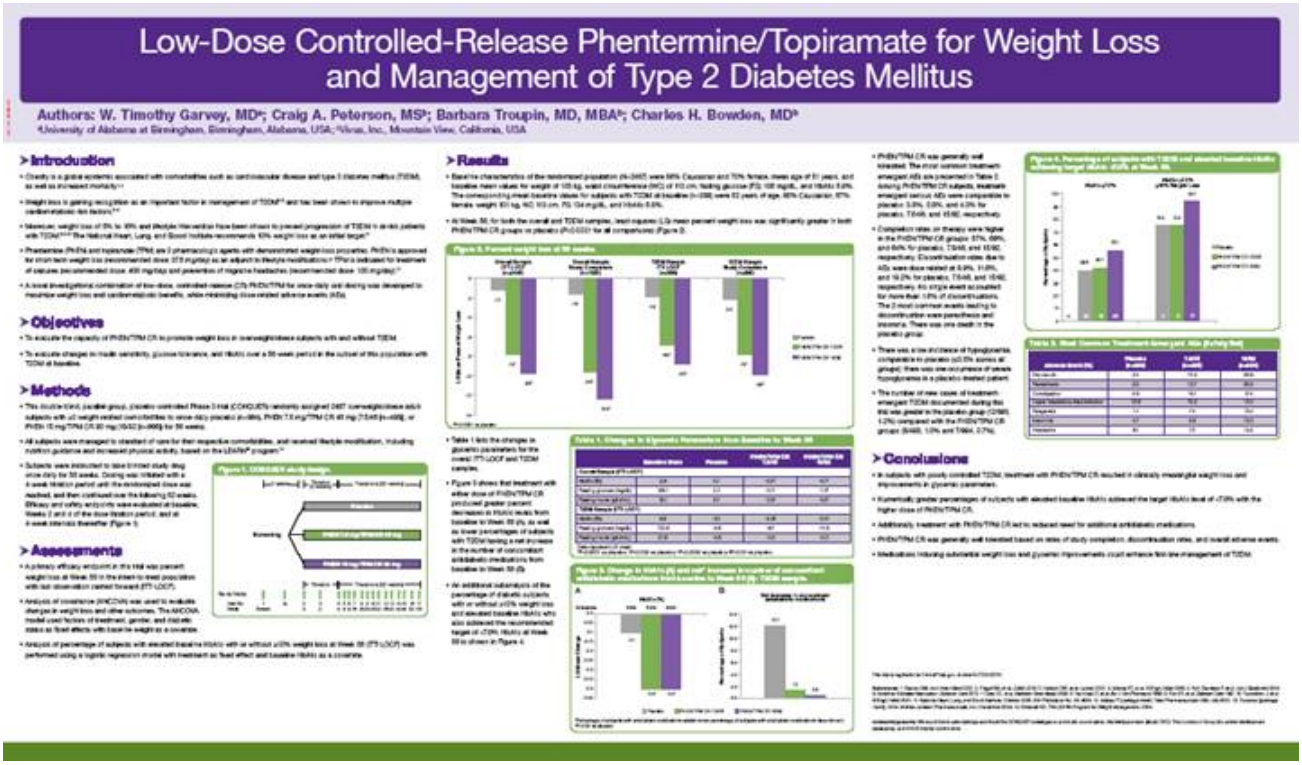
- PHEN/TPM CR led to significant, clinically meaningful weight loss at 56 weeks.
- PHEN/TPM CR reduces total and central adiposity and improves metabolic risk markers associated with increased adiposity.
- PHEN/TPM CR was generally well tolerated based on rates of study completion, discontinuation rates, and overall AEs.
- This large, pooled analysis of two Phase 3 trials suggests that weight reduction that addresses cardiometabolic risk may have significant benefits in terms of preventing future weight-related morbidity and mortality.

These trials are registered at ClinicalTrials.gov, number NCT00554216 (EQUIP) and number NCT00553787 (CONQUER).

References: (1) Reaven GM. *Ann Intern Med* 2003. (2) Flegal KM, et al. *JAMA* 2010. (3) Haslam DW, et al. *Lancet* 2005. (4) Adams KF, et al. *N Engl J Med* 2006. (5) Carey VJ, et al. *Am J Epidemiol* 1997. (6) Després JP, et al. *BMJ* 2001. (7) American Diabetes Association. *Diabetes Care* 2010. (8) Pi-Sunyer X. *Postgrad Med* 2009. (9) National Heart, Lung, and Blood Institute Obesity Education Initiative. October 2000. NIH Publication Number 00-4084. (10) Adipex-P [package insert]. Teva Pharmaceuticals USA; July 2005. (11) Topamax [package insert]. Ortho-McNeil-Janssen Pharmaceuticals, Inc.; December 2009. (12) Bray GA, et al. *Obes Res* 2003. (13) Wilding J, et al. *Int J Obes Relat Metab Disord* 2004. (14) Tonstad S, et al. *Am J Cardiol* 2005. (15) Stenlöf K, et al. *Diabetes Obes Metab* 2007. (16) Toplak H, et al. *Int J Obes (Lond)* 2007. (17) Rosenstock J, et al. *Diabetes Care* 2007. (18) Brownell KD. *The LEARN Program for Weight Management*. 2004.

Acknowledgements: We would like to acknowledge and thank the EQUIP and CONQUER investigators and study coordinators, the Medpace team (study CRO), St. Luke-Roosevelt's Imaging Center, The Lockwood Group (for poster development assistance), and VIVUS internal contributors.

Below is a graphical representation of the poster entitled “Low-Dose Controlled-Release Phentermine/Topiramate for Weight Loss and Management of Type 2 Diabetes Mellitus”:



Below is a reproduction of the contents of the poster entitled “Low-Dose Controlled-Release Phentermine/Topiramate for Weight Loss and Management of Type 2 Diabetes Mellitus”:

Authors: W. Timothy Garvey, MD(a); Craig A. Peterson, MS(b); Barbara Troupin, MD, MBA(b); Charles H. Bowden, MD(b)

(a)University of Alabama at Birmingham, Birmingham, Alabama, USA; (b)Vivus, Inc., Mountain View, California, USA

· Introduction

· Obesity is a global epidemic associated with comorbidities such as cardiovascular disease and type 2 diabetes mellitus (T2DM), as well as increased mortality.(1)-(4)

· Weight loss is gaining recognition as an important factor in management of T2DM(5)-(6) and has been shown to improve multiple cardiometabolic risk factors.(6)-(8)

· Moreover, weight loss of 5% to 10% and lifestyle intervention have been shown to prevent progression of T2DM in at-risk patients with T2DM.(6),(9),(10) The National Heart, Lung, and Blood Institute recommends 10% weight loss as an initial target.(11)

· Phentermine (PHEN) and topiramate (TPM) are 2 pharmacologic agents with demonstrated weight-loss properties. PHEN is approved for short-term weight loss (recommended dose: 37.5 mg/day) as an adjunct to lifestyle modifications.(12) TPM is indicated for treatment of seizures (recommended dose: 400 mg/day) and prevention of migraine headaches (recommended dose: 100 mg/day).(13)

· A novel investigational combination of low-dose, controlled-release (CR) PHEN/TPM for once-daily oral dosing was developed to maximize weight loss and cardiometabolic benefits, while minimizing dose-related adverse events (AEs).

· Objectives

· To evaluate the capacity of PHEN/TPM CR to promote weight loss in overweight/obese subjects with and without T2DM.

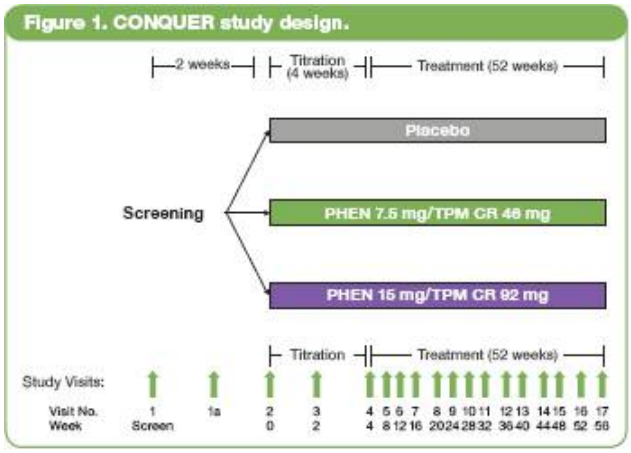
· To evaluate changes in insulin sensitivity, glucose tolerance, and HbA1c over a 56-week period in the subset of this population with T2DM at baseline.

· Methods

· This double-blind, parallel-group, placebo-controlled Phase 3 trial (CONQUER) randomly assigned 2487 overweight/obese adult subjects with ≥2 weight-related comorbidities to once-daily placebo (n=994), PHEN 7.5 mg/TPM CR 46 mg (7.5/46 [n=498]), or PHEN 15 mg/TPM CR 92 mg (15/92 [n=995]) for 56 weeks.

· All subjects were managed to standard of care for their respective comorbidities, and received lifestyle modification, including nutrition guidance and increased physical activity, based on the LEARN® program.(14)

· Subjects were instructed to take blinded study drug once daily for 56 weeks. Dosing was initiated with a 4-week titration period until the randomized dose was reached, and then continued over the following 52 weeks. Efficacy and safety endpoints were evaluated at baseline, Weeks 2 and 4 of the dose titration period, and at 4-week intervals thereafter (Figure 1).



· Assessments

· A primary efficacy endpoint in this trial was percent weight loss at Week 56 in the intent-to-treat population with last observation carried forward (ITT-LOCF).

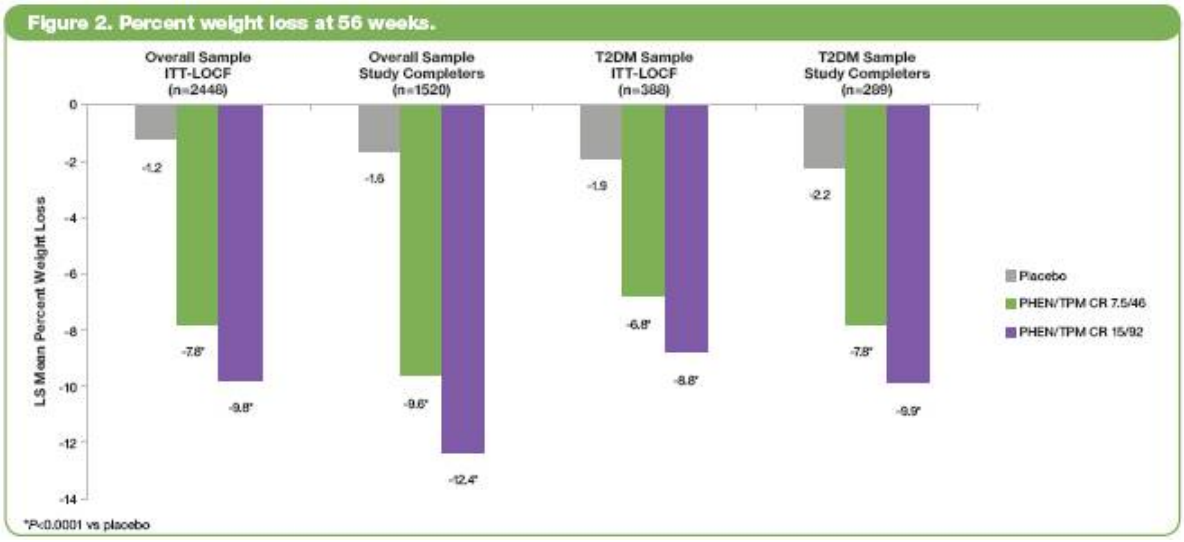
· Analysis of covariance (ANCOVA) was used to evaluate changes in weight loss and other outcomes. The ANCOVA model used factors of treatment, gender, and diabetic status as fixed effects with baseline weight as a covariate.

· Analysis of percentage of subjects with elevated baseline HbA1c with or without ≥10% weight loss at Week 56 (ITT-LOCF) was performed using a logistic regression model with treatment as fixed effect and baseline HbA1c as a covariate.

· Results

· Baseline characteristics of the randomized population (N=2487) were 86% Caucasian and 70% female, mean age of 51 years, and baseline mean values for weight of 103 kg, waist circumference (WC) of 113 cm, fasting glucose (FG) 106 mg/dL, and HbA1c 5.9%. The corresponding mean baseline values for subjects with T2DM at baseline (n=388) were 52 years of age, 85% Caucasian, 67% female, weight 101 kg, WC 113 cm, FG 134 mg/dL, and HbA1c 6.8%.

· At Week 56, for both the overall and T2DM samples, least-squares (LS) mean percent weight loss was significantly greater in both PHEN/TPM CR groups vs placebo (P<0.0001 for all comparisons) (Figure 2).



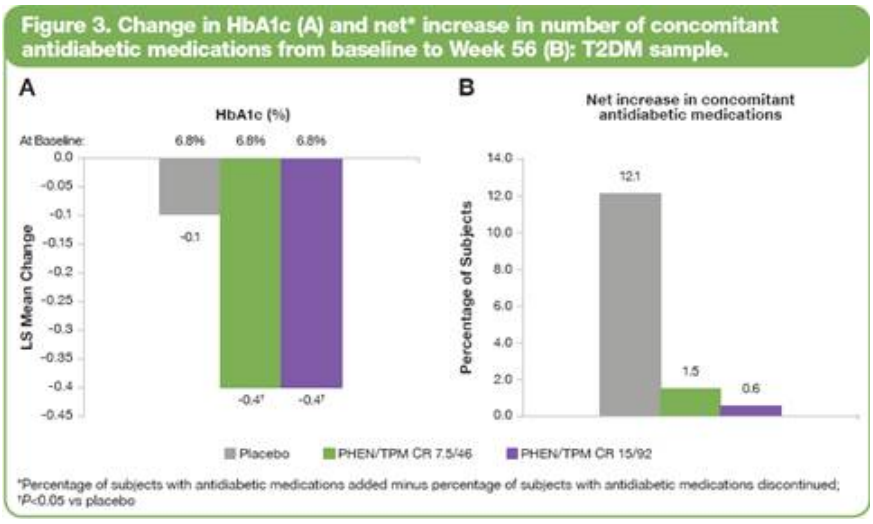
· Table 1 lists the changes in glycemic parameters for the overall ITT-LOCF and T2DM samples.

Table 1. Changes in Glycemic Parameters from Baseline to Week 56

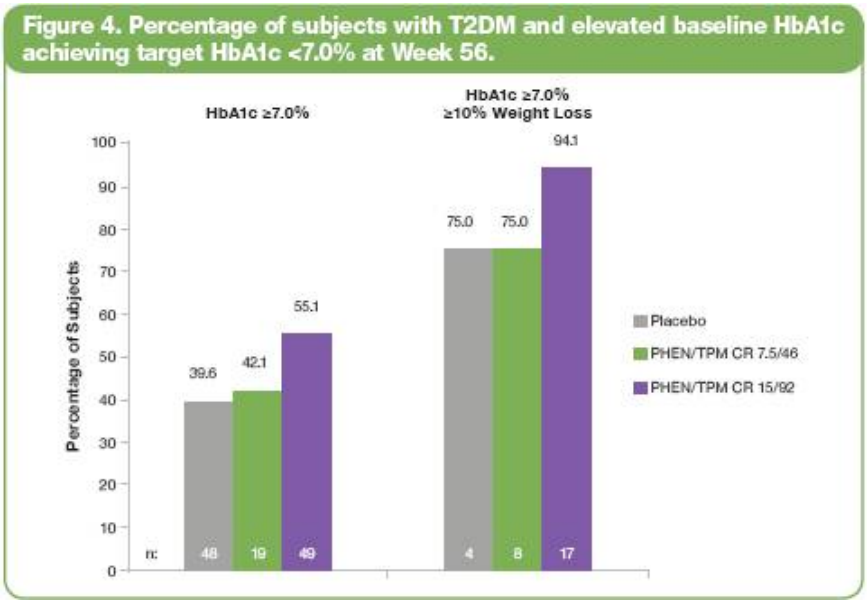
	Baseline Mean	Placebo	PHEN/TPM CR 7.5/46	PHEN/TPM CR 15/92
Overall Sample (ITT-LOCF)				
HbA1c (%)	5.9	0.1	-0.0*	-0.1*
Fasting glucose (mg/dL)	106.1	2.3	-0.1†	-1.3*
Fasting insulin (mIU/mL)	18.1	0.7	-3.5‡	-4.0*
T2DM Sample (ITT-LOCF)				
HbA1c (%)	6.8	-0.1	-0.4§	-0.4†
Fasting glucose (mg/dL)	133.9	-5.6	-9.7	-11.9
Fasting insulin (mIU/mL)	21.6	-4.6	-4.0	-5.3

Data represent LS mean
*P<0.0001 vs placebo; †P<0.005 vs placebo; ‡P<0.0005 vs placebo; §P<0.05 vs placebo

· Figure 3 shows that treatment with either dose of PHEN/TPM CR produced greater percent decreases in HbA1c levels from baseline to Week 56 (A), as well as lower percentages of subjects with T2DM having a net increase in the number of concomitant antidiabetic medications from baseline to Week 56 (B).



· An additional subanalysis of the percentage of diabetic subjects with or without ≥10% weight loss and elevated baseline HbA1c who also achieved the recommended target of <7.0% HbA1c at Week 56 is shown in Figure 4.



· PHEN/TPM CR was generally well tolerated. The most common treatment-emergent AEs are presented in Table 2. Among PHEN/TPM CR subjects, treatment-emergent serious AEs were comparable to placebo: 3.8%, 2.8%, and 4.3% for placebo, 7.5/46, and 15/92, respectively.

Table 2. Most Common Treatment-Emergent AEs (Safety Set)

Adverse Event (%)	Placebo (n=993)	7.5/46 (n=498)	15/92 (n=994)
Dry mouth	2.4	13.5	20.8
Paresthesia	2.0	13.7	20.5
Constipation	5.9	15.1	17.4
Upper respiratory tract infection	12.9	12.2	13.4
Dysgeusia	1.1	7.4	10.4
Insomnia	4.7	5.8	10.3
Headache	9.1	7.0	10.2

· Completion rates on therapy were higher in the PHEN/TPM CR groups: 57%, 69%, and 64% for placebo, 7.5/46, and 15/92, respectively. Discontinuation rates due to AEs were dose related at 8.9%, 11.6%, and 19.2% for placebo, 7.5/46, and 15/92, respectively. No single event accounted for more than 1.6% of discontinuations. The 2 most common events leading to discontinuation were paresthesia and insomnia. There was one death in the placebo group.

· There was a low incidence of hypoglycemia, comparable to placebo (≤0.5% across all groups); there was one occurrence of severe hypoglycemia in a placebo-treated patient.

· The number of new cases of treatment-emergent T2DM documented during this trial was greater in the placebo group (12/993, 1.2%) compared with the PHEN/TPM CR groups (5/498, 1.0% and 7/994, 0.7%).

· Conclusions

- In subjects with poorly controlled T2DM, treatment with PHEN/TPM CR resulted in clinically meaningful weight loss and improvements in glycemic parameters.
- Numerically greater percentages of subjects with elevated baseline HbA1c achieved the target HbA1c level of <7.0% with the higher dose of PHEN/TPM CR.
- Additionally, treatment with PHEN/TPM CR led to reduced need for additional antidiabetic medications.
- PHEN/TPM CR was generally well tolerated based on rates of study completion, discontinuation rates, and overall adverse events.
- Medications inducing substantial weight loss and glycemic improvements could enhance first-line management of T2DM.

This trial is registered at ClinicalTrials.gov, number NCT00553787.

References: (1) Reaven GM. *Ann Intern Med* 2003. (2) Flegal KM, et al. *JAMA* 2010. (3) Haslam DW, et al. *Lancet* 2005. (4) Adams KF, et al. *N Engl J Med* 2006. (5) Koh-Banerjee P, et al. *Am J Epidemiol* 2004. (6) American Diabetes Association. *Diabetes Care* 2010. (7) Case CC, et al. *Diabetes Obes Metab* 2002. (8) Van Gaal LF, et al. *Eur J Clin Pharmacol* 1998. (9) Pan XR, et al. *Diabetes Care* 1997. (10) Tuomilehto J, et al. *N Engl J Med* 2001. (11) National Heart, Lung, and Blood Institute. October 2000. NIH Publication No. 00-4084. (12) Adipex-P [package insert]. Teva Pharmaceuticals USA; July 2005. (13) Topamax [package insert]. Ortho-McNeil-Janssen Pharmaceuticals, Inc.; December 2009. (14) Brownell KD. *The LEARN Program for Weight Management*. 2004.

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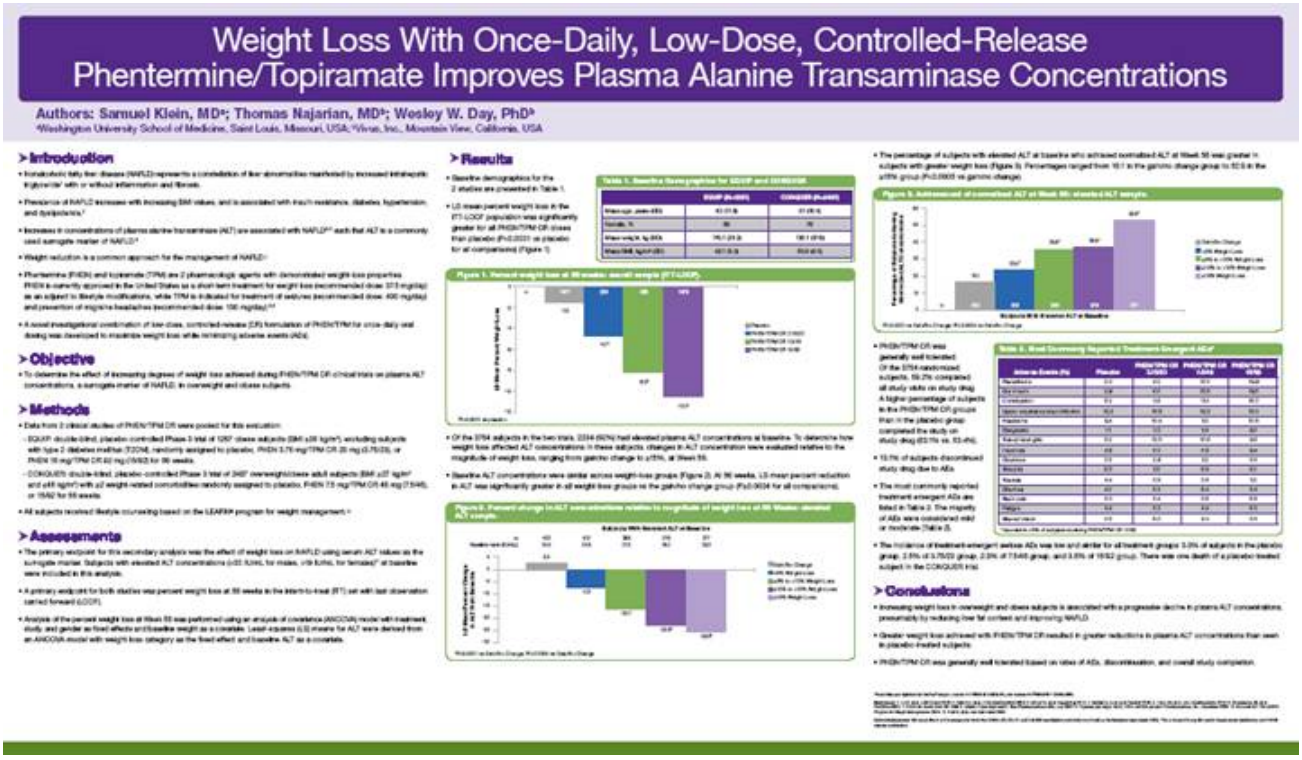
Below is a graphical representation of the poster entitled “Weight Loss With Once-Daily, Low-Dose, Controlled-Release Phentermine/Topiramate Improves Plasma Alanine Transaminase Concentrations”:



Below is a reproduction of the contents of the poster entitled “Weight Loss With Once-Daily, Low-Dose, Controlled-Release Phentermine/Topiramate Improves Plasma Alanine Transaminase Concentrations”:

Authors: Samuel Klein, MD(a); Thomas Najarian, MD(b); Wesley W. Day, PhD(b)

(a)Washington University School of Medicine, Saint Louis, Missouri, USA; (b)Vivus, Inc., Mountain View, California, USA

· Introduction

· Nonalcoholic fatty liver disease (NAFLD) represents a constellation of liver abnormalities manifested by increased intrahepatic triglyceride(1) with or without inflammation and fibrosis.

· Prevalence of NAFLD increases with increasing BMI values, and is associated with insulin resistance, diabetes, hypertension, and dyslipidemia.(2)

· Increases in concentrations of plasma alanine transaminase (ALT) are associated with NAFLD(3)-(5) such that ALT is a commonly used surrogate marker of NAFLD.(6)

· Weight reduction is a common approach for the management of NAFLD.(7)

· Phentermine (PHEN) and topiramate (TPM) are 2 pharmacologic agents with demonstrated weight-loss properties. PHEN is currently approved in the United States as a short-term treatment for weight loss (recommended dose: 37.5 mg/day) as an adjunct to lifestyle modifications, while TPM is indicated for treatment of seizures (recommended dose: 400 mg/day) and prevention of migraine headaches (recommended dose: 100 mg/day).(8),(9)

· A novel investigational combination of low-dose, controlled-release (CR) formulation of PHEN/TPM for once-daily oral dosing was developed to maximize weight loss while minimizing adverse events (AEs).

· Objective

· To determine the effect of increasing degrees of weight loss achieved during PHEN/TPM CR clinical trials on plasma ALT concentrations, a surrogate marker of NAFLD, in overweight and obese subjects.

· Methods

· Data from 2 clinical studies of PHEN/TPM CR were pooled for this evaluation:

  · EQUIP: double-blind, placebo-controlled Phase 3 trial of 1267 obese subjects (BMI $\geq$35 kg/m^2), excluding subjects with type 2 diabetes mellitus (T2DM), randomly assigned to placebo, PHEN 3.75 mg/TPM CR 23 mg (3.75/23), or PHEN 15 mg/TPM CR 92 mg (15/92) for 56 weeks.

  · CONQUER: double-blind, placebo-controlled Phase 3 trial of 2487 overweight/obese adult subjects (BMI $\geq$27 kg/m^2 and $\leq$45 kg/m^2) with $\geq$2 weight-related comorbidities randomly assigned to placebo, PHEN 7.5 mg/TPM CR 46 mg (7.5/46), or 15/92 for 56 weeks.

· All subjects received lifestyle counseling based on the LEARN® program for weight management.(10)

· Assessments

- The primary endpoint for this secondary analysis was the effect of weight loss on NAFLD using serum ALT values as the surrogate marker. Subjects with elevated ALT concentrations (>30 IU/mL for males, >19 IU/mL for females)(11) at baseline were included in this analysis.
- A primary endpoint for both studies was percent weight loss at 56 weeks in the intent-to-treat (ITT) set with last observation carried forward (LOCF).
- Analysis of the percent weight loss at Week 56 was performed using an analysis of covariance (ANCOVA) model with treatment, study, and gender as fixed effects and baseline weight as a covariate. Least-squares (LS) means for ALT were derived from an ANCOVA model with weight loss category as the fixed effect and baseline ALT as a covariate.

· Results

- Baseline demographics for the 2 studies are presented in Table 1.

Table 1. Baseline Demographics for EQUIP and CONQUER

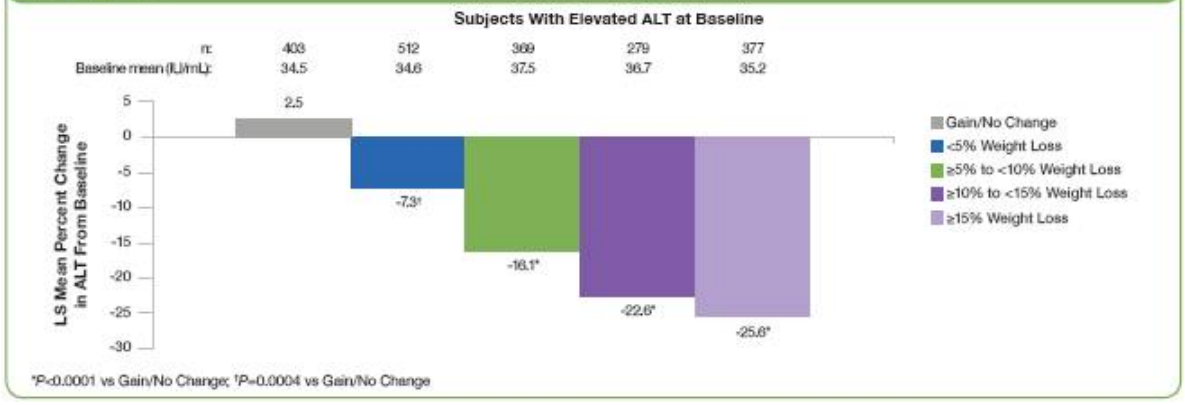
	EQUIP (N=1267)	CONQUER (N=2487)
Mean age, years (SD)	43 (11.8)	51 (10.4)
Female, %	83	70
Mean weight, kg (SD)	116.1 (21.2)	103.1 (17.9)
Mean BMI, kg/m^2 (SD)	42.1 (6.2)	36.6 (4.5)

- LS mean percent weight loss in the ITT-LOCF population was significantly greater for all PHEN/TPM CR doses than placebo (*P*<0.0001 vs placebo for all comparisons) (Figure 1).

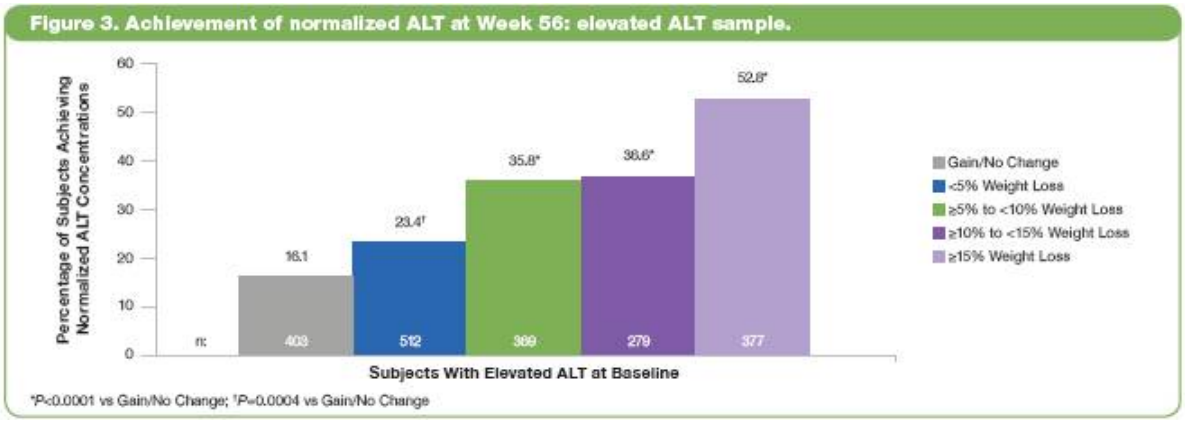
Figure 1. Percent weight loss at 56 weeks: overall sample (ITT-LOCF).

- Of the 3754 subjects in the two trials, 2234 (60%) had elevated plasma ALT concentrations at baseline. To determine how weight loss affected ALT concentrations in these subjects, changes in ALT concentration were evaluated relative to the magnitude of weight loss, ranging from gain/no change to ≥15%, at Week 56.
- Baseline ALT concentrations were similar across weight-loss groups (Figure 2). At 56 weeks, LS mean percent reduction in ALT was significantly greater in all weight-loss groups vs the gain/no change group (*P*≤0.0004 for all comparisons).

Figure 2. Percent change in ALT concentrations relative to magnitude of weight loss at 56 Weeks: elevated ALT sample.



- The percentage of subjects with elevated ALT at baseline who achieved normalized ALT at Week 56 was greater in subjects with greater weight loss (Figure 3). Percentages ranged from 16.1 in the gain/no change group to 52.8 in the ≥15% group (*P*<0.0005 vs gain/no change).



· PHEN/TPM CR was generally well tolerated. Of the 3754 randomized subjects, 59.2% completed all study visits on study drug. A higher percentage of subjects in the PHEN/TPM CR groups than in the placebo group completed the study on study drug (63.1% vs. 53.4%).

· 13.1% of subjects discontinued study drug due to AEs.

· The most commonly reported treatment-emergent AEs are listed in Table 2. The majority of AEs were considered mild or moderate (Table 2).

Table 2. Most Commonly Reported Treatment-Emergent AEs*

Adverse Events (%)	Placebo	PHEN/TPM CR 3.75/23	PHEN/TPM CR 7.5/46	PHEN/TPM CR 15/92
Paresthesia	2.0	4.2	13.7	19.9
Dry mouth	2.9	6.7	13.5	19.5
Constipation	6.2	7.9	15.1	16.3
Upper respiratory tract infection	12.2	15.8	12.2	13.0
Headache	9.4	10.4	7.0	10.8
Dysgeusia	1.1	1.3	7.4	9.7
Nasopharyngitis	8.2	12.5	10.6	9.6
Insomnia	4.8	5.0	5.8	9.4
Dizziness	3.5	2.9	7.2	8.5
Sinusitis	6.3	7.5	6.8	8.1
Nausea	4.4	5.8	3.6	7.0
Diarrhea	4.7	5.0	6.4	5.4
Back pain	5.0	5.4	5.6	6.6
Fatigue	4.4	5.0	4.4	6.0
Blurred vision	3.5	6.3	4.0	5.5

*reported in >5% of subjects receiving PHEN/TPM CR 15/92

· The incidence of treatment-emergent serious AEs was low and similar for all treatment groups: 3.3% of subjects in the placebo group, 2.5% of 3.75/23 group, 2.8% of 7.5/46 group, and 3.5% of 15/92 group. There was one death of a placebo-treated subject in the CONQUER trial.

· Conclusions

· Increasing weight loss in overweight and obese subjects is associated with a progressive decline in plasma ALT concentrations, presumably by reducing liver fat content and improving NAFLD.

· Greater weight loss achieved with PHEN/TPM CR resulted in greater reductions in plasma ALT concentrations than seen in placebo-treated subjects.

· PHEN/TPM CR was generally well tolerated based on rates of AEs, discontinuation, and overall study completion.

These trials are registered at ClinicalTrials.gov, number NCT00554216 (EQUIP), and number NCT00553787 (CONQUER).

References: (1) Li ZZ, et al. *J Biol Chem* 2009. (2) Patel AA, et al. *J Clin Gastroenterol* 2009. (3) Ghouri N, et al. *Hepatology* 2010. (4) Radetti G, et al. *Acta Paediatr* 2006. (5) Clark JM, et al. *Am J Gastroenterol*. 2003. (6) Schwimmer JB, et al. *Pediatrics* 2005. (7) Diehl AM. *Semin Liver Dis* 1999. (8) Adipex-P [package insert]. Teva Pharmaceuticals USA; July 2005. (9) Topamax [package insert]. Ortho-McNeil-Janssen Pharmaceuticals, Inc.; December 2009. (10) Brownell KD. *The LEARN Program for Weight Management*. 2004. (11) Prati D, et al. *Ann Intern Med* 2002.

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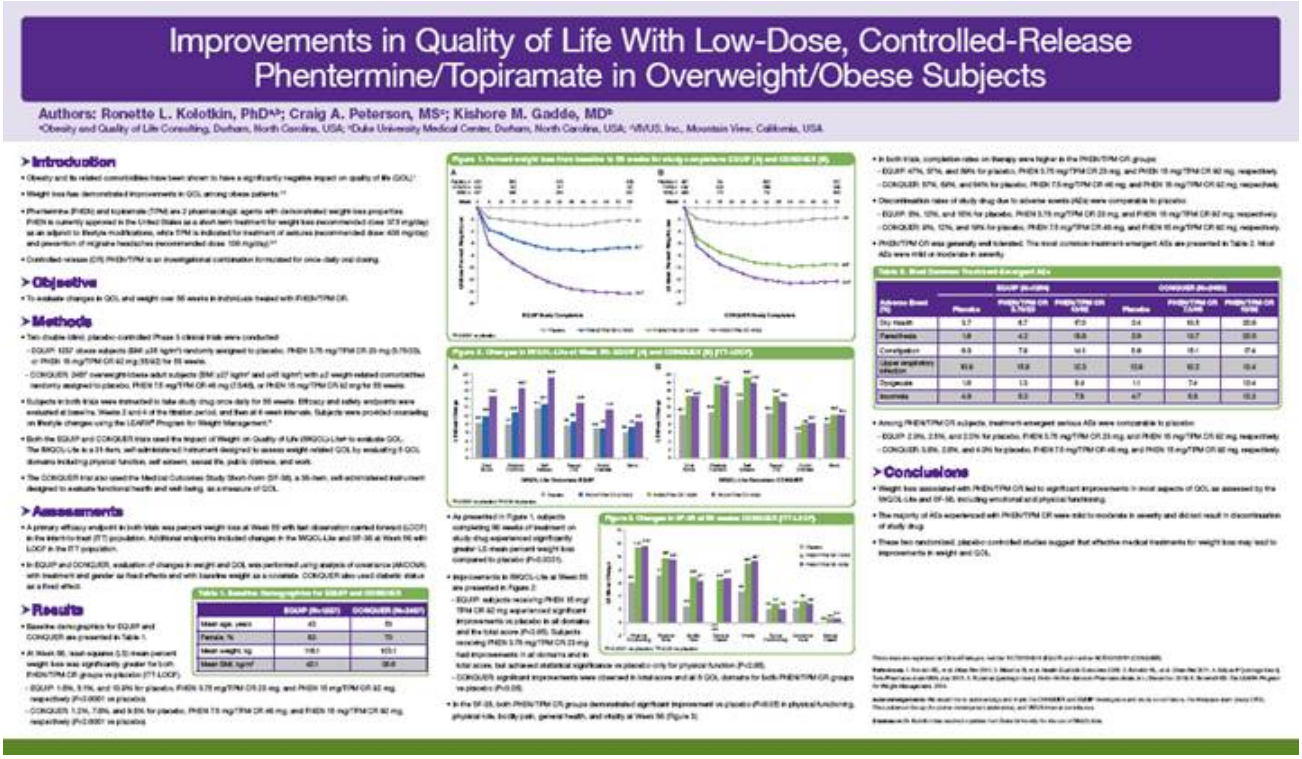
Below is a graphical representation of the poster entitled “Improvements in Quality of Life With Low-Dose, Controlled-Release Phentermine/Topiramate in Overweight/Obese Subjects”:



Below is a reproduction of the contents of the poster entitled “Improvements in Quality of Life With Low-Dose, Controlled-Release Phentermine/Topiramate in Overweight/Obese Subjects”:

Authors: Ronette L. Kolotkin, PhD(a),(b); Craig A. Peterson, MS(c); Kishore M. Gadde, MD(b)

(a)Obesity and Quality of Life Consulting, Durham, North Carolina, USA; (b)Duke University Medical Center, Durham, North Carolina, USA; (c)VIVUS, Inc., Mountain View, California, USA

· Introduction

· Obesity and its related comorbidities have been shown to have a significantly negative impact on quality of life (QOL).(1)

· Weight loss has demonstrated improvements in QOL among obese patients.(1)-(3)

· Phentermine (PHEN) and topiramate (TPM) are 2 pharmacologic agents with demonstrated weight-loss properties. PHEN is currently approved in the United States as a short-term treatment for weight loss (recommended dose: 37.5 mg/day) as an adjunct to lifestyle modifications, while TPM is indicated for treatment of seizures (recommended dose: 400 mg/day) and prevention of migraine headaches (recommended dose: 100 mg/day).(4),(5)

· Controlled-release (CR) PHEN/TPM is an investigational combination formulated for once-daily oral dosing.

· Objective

· To evaluate changes in QOL and weight over 56 weeks in individuals treated with PHEN/TPM CR.

· Methods

· Two double-blind, placebo-controlled Phase 3 clinical trials were conducted:

  · EQUIP: 1267 obese subjects (BMI $\geq$35 kg/m^2) randomly assigned to placebo, PHEN 3.75 mg/TPM CR 23 mg (3.75/23), or PHEN 15 mg/TPM CR 92 mg (15/92) for 56 weeks.

  · CONQUER: 2487 overweight/obese adult subjects (BMI $\geq$27 kg/m^2 and $\leq$45 kg/m^2) with $\geq$2 weight-related comorbidities randomly assigned to placebo, PHEN 7.5 mg/TPM CR 46 mg (7.5/46), or PHEN 15 mg/TPM CR 92 mg for 56 weeks.

· Subjects in both trials were instructed to take study drug once daily for 56 weeks. Efficacy and safety endpoints were evaluated at baseline, Weeks 2 and 4 of the titration period, and then at 4-week intervals. Subjects were provided counseling on lifestyle changes using the LEARN® Program for Weight Management.(6)

· Both the EQUIP and CONQUER trials used the Impact of Weight on Quality of Life (IWQOL)-Lite© to evaluate QOL. The IWQOL-Lite is a 31-item, self-administered instrument designed to assess weight-related QOL by evaluating 5 QOL domains including physical function, self esteem, sexual life,

public distress, and work.

- The CONQUER trial also used the Medical Outcomes Study Short-Form (SF-36), a 36-item, self-administered instrument designed to evaluate functional health and well-being, as a measure of QOL.

· Assessments

- A primary efficacy endpoint in both trials was percent weight loss at Week 56 with last observation carried forward (LOCF) in the intent-to-treat (ITT) population. Additional endpoints included changes in the IWQOL-Lite and SF-36 at Week 56 with LOCF in the ITT population.

- In EQUIP and CONQUER, evaluation of changes in weight and QOL was performed using analysis of covariance (ANCOVA) with treatment and gender as fixed effects and with baseline weight as a covariate. CONQUER also used diabetic status as a fixed effect.

· Results

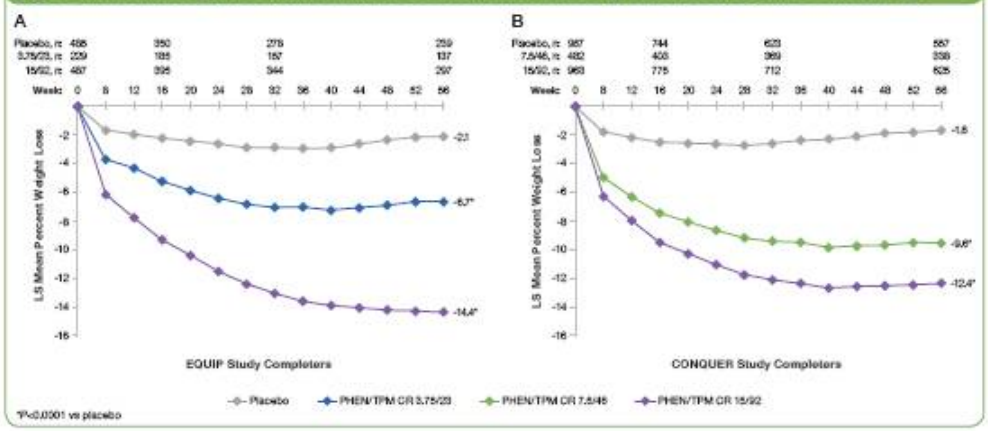
- Baseline demographics for EQUIP and CONQUER are presented in Table 1.

Table 1. Baseline Demographics for EQUIP and CONQUER

	EQUIP (N=1267)	CONQUER (N=2487)
Mean age, years	43	51
Female, %	83	70
Mean weight, kg	116.1	103.1
Mean BMI, kg/m^2	42.1	36.6

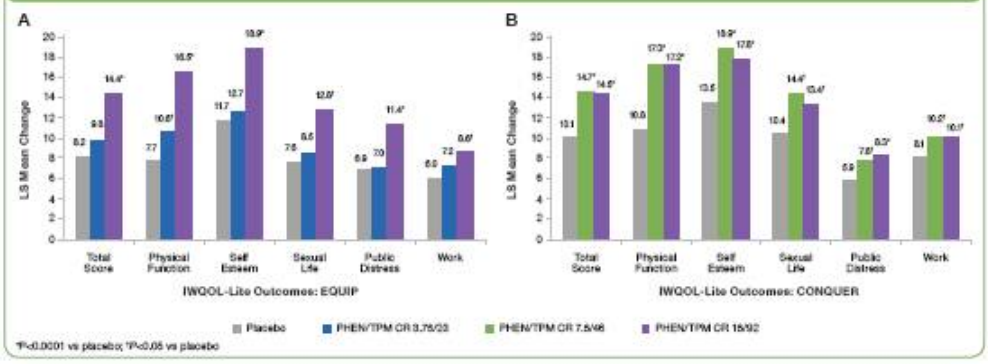
- At Week 56, least-squares (LS) mean percent weight loss was significantly greater for both PHEN/TPM CR groups vs placebo (ITT-LOCF).
  - EQUIP: 1.6%, 5.1%, and 10.9% for placebo, PHEN 3.75 mg/TPM CR 23 mg, and PHEN 15 mg/TPM CR 92 mg, respectively (P<0.0001 vs placebo).
  - CONQUER: 1.2%, 7.8%, and 9.8% for placebo, PHEN 7.5 mg/TPM CR 46 mg, and PHEN 15 mg/TPM CR 92 mg, respectively (P<0.0001 vs placebo).
- As presented in Figure 1, subjects completing 56 weeks of treatment on study drug experienced significantly greater LS mean percent weight loss compared to placebo (P<0.0001).

Figure 1. Percent weight loss from baseline to 56 weeks for study completers: EQUIP (A) and CONQUER (B).



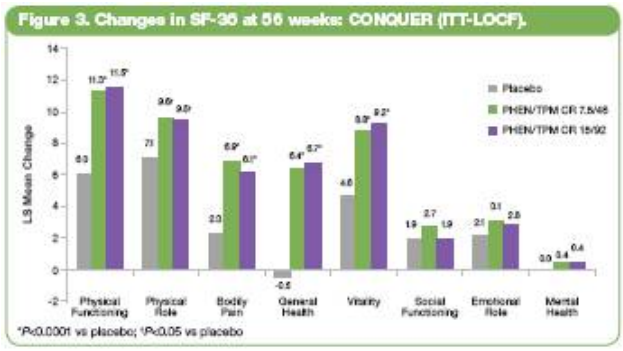
- Improvements in IWQOL-Lite at Week 56 are presented in Figure 2:

Figure 2. Changes in IWQOL-Lite at Week 56: EQUIP (A) and CONQUER (B) (ITT-LOCF).



- EQUIP: subjects receiving PHEN 15 mg/TPM CR 92 mg experienced significant improvements vs placebo in all domains and the total score (P<0.05). Subjects receiving PHEN 3.75 mg/TPM CR 23 mg had improvements in all domains and in total score, but achieved statistical significance vs placebo only for physical function (P<0.05).
- CONQUER: significant improvements were observed in total score and all 5 QOL domains for both PHEN/TPM CR groups vs placebo (P<0.05).

- In the SF-36, both PHEN/TPM CR groups demonstrated significant improvement vs placebo ($P<0.05$) in physical functioning, physical role, bodily pain, general health, and vitality at Week 56 (Figure 3).



- In both trials, completion rates on therapy were higher in the PHEN/TPM CR groups:
  - EQUIP: 47%, 57%, and 59% for placebo, PHEN 3.75 mg/TPM CR 23 mg, and PHEN 15 mg/TPM CR 92 mg, respectively.
  - CONQUER: 57%, 69%, and 64% for placebo, PHEN 7.5 mg/TPM CR 46 mg, and PHEN 15 mg/TPM CR 92 mg, respectively.
- Discontinuation rates of study drug due to adverse events (AEs) were comparable to placebo:
  - EQUIP: 8%, 12%, and 16% for placebo, PHEN 3.75 mg/TPM CR 23 mg, and PHEN 15 mg/TPM CR 92 mg, respectively.
  - CONQUER: 9%, 12%, and 19% for placebo, PHEN 7.5 mg/TPM CR 46 mg, and PHEN 15 mg/TPM CR 92 mg, respectively.
- PHEN/TPM CR was generally well tolerated. The most common treatment-emergent AEs are presented in Table 2. Most AEs were mild or moderate in severity.

Table 2. Most Common Treatment-Emergent AEs

	EQUIP (N=1264)			CONQUER (N=2485)		
Adverse Event (%)	**Placebo**	**PHEN/TPM CR 3.75/23**	**PHEN/TPM CR 15/92**	**Placebo**	**PHEN/TPM CR 7.5/46**	**PHEN/TPM CR 15/92**
Dry mouth	3.7	6.7	17.0	2.4	13.5	20.8
Paresthesia	1.9	4.2	18.8	2.0	13.7	20.5
Constipation	6.8	7.9	14.1	5.9	15.1	17.4
Upper respiratory infection	10.9	15.8	12.3	12.9	12.2	13.4
Dysgeusia	1.0	1.3	8.4	1.1	7.4	10.4
Insomnia	4.9	5.0	7.8	4.7	5.8	10.3

- Among PHEN/TPM CR subjects, treatment-emergent serious AEs were comparable to placebo:
  - EQUIP: 2.3%, 2.5%, and 2.0% for placebo, PHEN 3.75 mg/TPM CR 23 mg, and PHEN 15 mg/TPM CR 92 mg, respectively.
  - CONQUER: 3.8%, 2.8%, and 4.3% for placebo, PHEN 7.5 mg/TPM CR 46 mg, and PHEN 15 mg/TPM CR 92 mg, respectively.

· Conclusions

- Weight loss associated with PHEN/TPM CR led to significant improvements in most aspects of QOL as assessed by the IWQOL-Lite and SF-36, including emotional and physical functioning.
- The majority of AEs experienced with PHEN/TPM CR were mild to moderate in severity and did not result in discontinuation of study drug.
- These two randomized, placebo-controlled studies suggest that effective medical treatments for weight loss may lead to improvements in weight and QOL.

These trials are registered at ClinicalTrials.gov, number NCT00554216 (EQUIP) and number NCT00553787 (CONQUER).

References: (1) Kolotkin RL, et al. *Obes Rev* 2001. (2) Blissmer B, et al. *Health Qual Life Outcomes* 2006. (3) Kolotkin RL, et al. *Obes Res* 2001. (4) Adipex-P [package insert]. Teva Pharmaceuticals USA; July 2005. (5) Topamax [package insert]. Ortho-McNeil-Janssen Pharmaceuticals, Inc.; December 2009. (6) Brownell KD. *The LEARN Program for Weight Management*. 2004.

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