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**VIVUS<sup>®</sup>**

A Pharmaceutical Company

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# Safe Harbor Statement

Certain statements in this presentation are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," "intend," "likely," "may," "plan," "potential," "predict," "opportunity" and "should," among others. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, our lack of commercial experience with Qsymia in the U.S.; the timing of initiation and completion of the clinical studies required as part of the approval of Qsymia by the United States Food and Drug Administration, or FDA; the response from the FDA to the data that VIVUS will submit relating to post-approval clinical studies; the impact of the indicated uses and contraindications contained in the Qsymia label and the REMS requirements; the impact of distribution of Qsymia through a certified pharmacy network; that we may be required to provide further analysis of previously submitted clinical trial data; our response to questions and requests for additional information including additional pre-clinical or clinical studies from the European Medicines Agency, or EMA, and the Committee for Medicinal Products for Human Use, or CHMP, of the Marketing Authorization Application, or MAA, for Qsymia; our ability to successfully commercialize or establish a marketing partnership for avanafil, which will be marketed in the U.S. under the name Stendra, or our partner's ability to obtain and maintain regulatory approval to manufacture and adequately supply avanafil for commercial use; our history of losses and variable quarterly results; substantial competition; risks related to the failure to protect our intellectual property and litigation in which we may become involved; uncertainties of government or third party payer reimbursement; our reliance on sole source suppliers; our limited sales and marketing and manufacturing experience; our reliance on third parties and our collaborative partners; our failure to continue to develop innovative investigational drug candidates and drugs; risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; our ability to demonstrate through clinical testing the safety and effectiveness of our investigational drug candidates; the timing of initiation and completion of clinical trials and submissions to foreign authorities; the volatility and liquidity of the financial markets; our liquidity and capital resources; and our expected future revenues, operations and expenditures. As with any pharmaceutical in development, there are significant risks in the development, the regulatory approval, and commercialization of new products. There are no guarantees that our response to the CHMP's 180-day list of outstanding issues and subsequent meetings and communications will be sufficient to satisfy the CHMP's safety concerns, that the foreign authorities will not require us to conduct any additional prospective studies or retrospective observational studies, or that any product will receive foreign regulatory approval for any indication or prove to be commercially successful. VIVUS does not undertake an obligation to update or revise any forward-looking statements. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ending December 31, 2011, and periodic reports filed with the Securities and Exchange Commission.

# Agenda

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## Leland Wilson, CEO

- General Update
- Manufacturing

## Timothy Morris, SVP and CFO

- Q2 Results
- Intellectual Property

## Barbara Troupin MD, VP

- Qsymia REMS and Label

## Mike Miller, SVP and CCO

- US Launch of Qsymia

# Company Update

## Two FDA Approvals

- Qsymia™
  - Approved by FDA on July 17, 2012
  - Presently manufacturing launch quantities at Catalent
  - Launch in Q4 2012
  - Executed CSO agreement with PDI
  - CHMP oral hearing scheduled September 2012
- STENDRA™
  - Approved by FDA on April 29, 2012
  - Partnering discussions underway
  - MTPC Amendment executed
  - MAA submission under review

# Qsymia Supply Chain in Place

## API Supplier: ScinoPharm

- Leading API manufacturer with >1000 DMF Registrations
- Manufacturing topiramate API
- Excellent FDA track record since 2007

## Manufacturer: Catalent Pharma Solutions

- 75 years of pharmaceutical experience
- 30 facilities in 5 continents

## Distributor: Cardinal Health

- Leading 3PL for pharmaceutical industry





# Commercial Manufacturing Prepared for Launch



## Catalent Pharma Solutions – Headquarters in Somerset, NJ

- Catalent has a proven track record
  - Manufactures many of the most Rx'd drugs
  - Supplied Qsymia since beginning of Phase 3 clinical trials
- Capacity sufficient to meet commercial demand
- Manufacturing of launch quantities underway



# MTPC Amendment

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- Executed August 7, 2012
- Transfers manufacturing rights to VIVUS
- Adds an additional six months to the timing requirements for a major market launch
- Expands field of use for avanafil in all indications



## Q2 Results & IP

**Timothy E. Morris**

Senior Vice President and CFO





# Second Quarter 2012 Financial Update

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**Cash and investment balance 6/30/2012: \$310 million**

**Q2 Net Loss: \$24 million**

**First half 2012 cash used in operations: \$37 million**

**Headcount (FTE and FT consultants) July 31: 107**

# Planned Investor Relations Events

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- UBS Biotech Summer Conference, San Francisco
- Stifel Nicolaus Healthcare Conference 2012, Boston
- Citi Biotech Day, Boston
- BioCentury NewsMakers in the Biotech Industry, New York
- Morgan Stanley Global Healthcare Conference, New York
- Rodman & Renshaw Global Investment Conference, New York
- Bank of America Global Healthcare Conference, London

# Qsymia Protected by Issued Patents

VIVUS has issued patents that protect Qsymia into 2020

- 4 issued US Patents, 166 claims
- EP patent-validated in 19 countries
- Patents in Canada and Australia

Pending patents in the US, Europe, Asia and elsewhere should provide additional protection, if granted

Market exclusivity in the EU for 10 years outside of any patent protection

Lifecycle plan in development seeking to extend product life beyond 2020

# Strong Patent Position

## Validity

- The Shank and McElroy references were considered by the USPTO during prosecution
- The presumption is that the issued claims are valid in view of these references
- The burden is high for a 3<sup>rd</sup> party to challenge validity based on references the PTO already considered

## Freedom to operate

- We have considered both the Shank and McElroy patents with respect to our products
- We are comfortable with our freedom to operate and believe we have a path to successful Qsymia commercialization



# Qsymia REMS and Package Insert

**Barbara Troupin, MD, MBA**

Vice President, Scientific Communication  
and Risk Management



# Qsymia Risk Evaluation and Mitigation Strategy

## Goal

- Inform prescribers and female patients of childbearing potential about the risk, the importance of pregnancy prevention and the need to minimize fetal exposure

## Components

- Medication Guide (patient focused labeling)
- Elements to Assure Safe Use (ETASU)
  - Healthcare Provider (HCP) Training
  - Certified Pharmacies

## Timetable for Assessments

- 6 months, 12 months, annually thereafter

# REMS ETASU – Healthcare Provider Training

## HCP Education and Training

- VIVUS will ensure HCPs are offered training on Qsymia
- Training Program available online and in hard copy
  - Takes about 15-20 minutes to complete online
- VIVUS will maintain a database of trained HCPs
- The data base will be compared to prescriber level prescription data provided by Certified Pharmacies
- Not yet trained HCPs will be contacted via emails over a 3 month period, after first prescription, to offer training

# REMS ETASU – Certified Pharmacies

## Certified Home Delivery Pharmacy Network

- Qsymia will only be distributed to Certified Home Delivery Pharmacies for launch
  - Unable to resell or distribute Qsymia outside of the certified pharmacy network
- Must dispense Med Guide and patient brochure with every prescription
- Must train pharmacy staff on REMS requirements
- Pharmacies must maintain databases of REMS-required prescriber level Rx data and make available to VIVUS
- Approval letter included request for REMS Modification to broaden pharmacy network to include retail
  - Will submit REMS Modification request prior to launch

## What Elements are not in the Qsymia REMS?

- It does not have a patient registry
- It does not require any type of patient enrollment
- There are not “hard stops” for the ability to prescribe and dispense
- Pregnancy tests are recommended and not required; so no pharmacy lockout and no stipulations on prescription dispensing relative to pregnancy test
- Monitoring of patients is recommended but is not a “hard stop” for prescribing
- Topiramate, for epilepsy and migraine prevention, does not have a REMS requirement and is not included in the Qsymia REMS



## Qsymia Approved Indication

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For use as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with BMI of 30 (obese) or 27 or greater (overweight) with at least one weight related co-morbidity such as hypertension, type 2 diabetes, or dyslipidemia

Contraindications include pregnancy, glaucoma, hyperthyroidism, patients receiving MAOIs (within 14 days) or in patients with hypersensitivity to phentermine or topiramate



# Tolerability and Safety

- Warnings and precautions include increased risk of orofacial clefts in infants exposed in first trimester of pregnancy, increase in resting heart rate, mood changes including depression, cognitive impairment, acute angle glaucoma, and metabolic acidosis
- Most common side effects include paraesthesia, dizziness, insomnia, constipation and dry mouth
- Drop out due to AEs in clinical studies was 11.6% to 17.4% for Qsymia vs. 8.4% for placebo

# Dosing and Administration

- Once daily in the morning with or without food
- Start with Qsymia 3.75 mg/23 mg - 14 days
- Increase to Qsymia 7.5 mg/46 mg – 12 weeks
- <3% weight loss, discontinue or escalate the dose

**84% of patients on Qsymia 7.5 mg/46 mg for 12 weeks achieved  $\geq$  3% weight loss**

- To escalate: Increase to Qsymia 11.25 mg/69 - 14 days
- Qsymia 15 mg/92 mg – 12 weeks
- <5% weight loss, discontinue

**89% of patients on Qsymia 15 mg/92 mg for 28 weeks achieved  $\geq$  5% weight loss**



# Two Simple Ways to Rx Qsymia for Patients

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1. HCP can complete the Qsymia Rx form and fax to the patient's home delivery pharmacy of choice
2. HCP hands Rx to patient and patient calls pharmacy of choice for fulfillment

The Qsymia Certified Home Delivery Pharmacy Network (with contact information and forms) will be available on [www.Qsymia.com](http://www.Qsymia.com) and in all HCP and patient materials

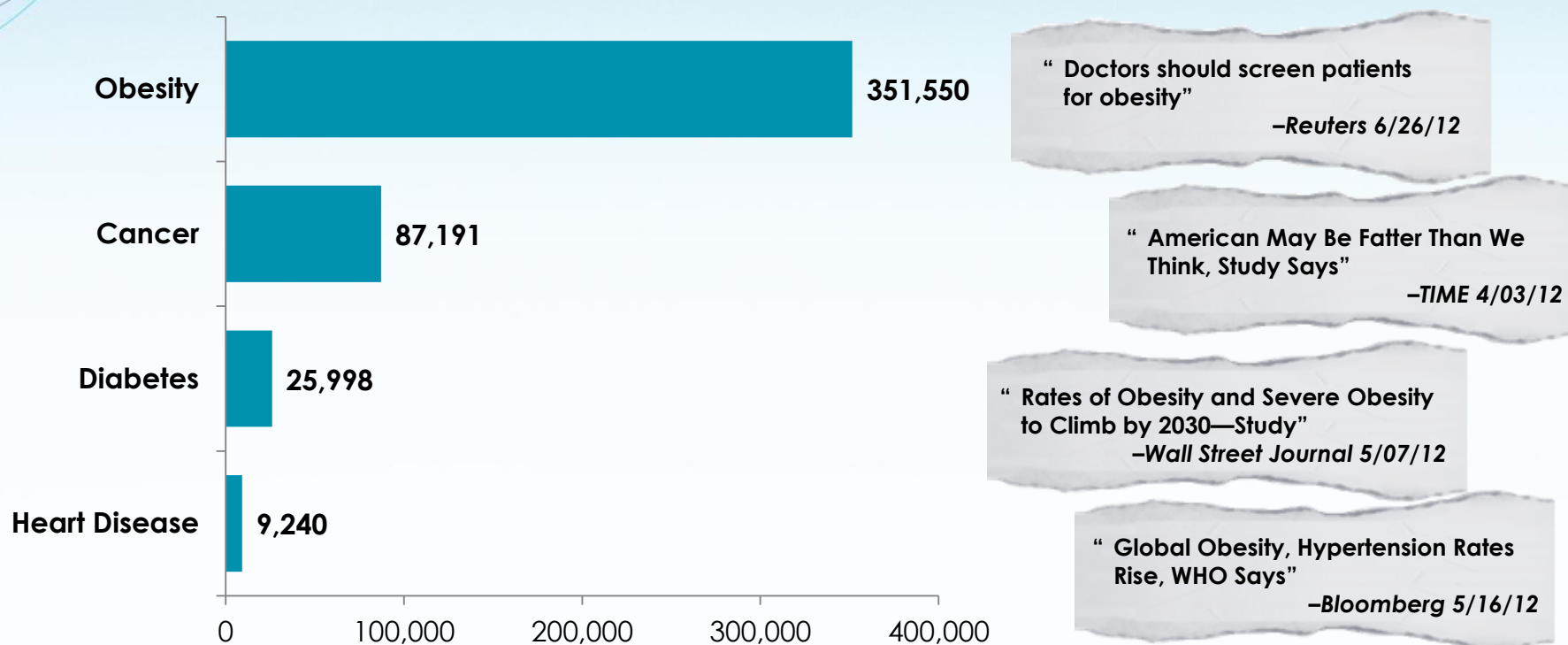


# Qsymia US Launch Plan

**Michael P. Miller**

Senior Vice President  
and Chief Commercial Officer

# Obesity is Headline News



\*Number of stories in major news and business publications from January through June 2012

Source: Dow Jones Factiva



# Qsymia Interest

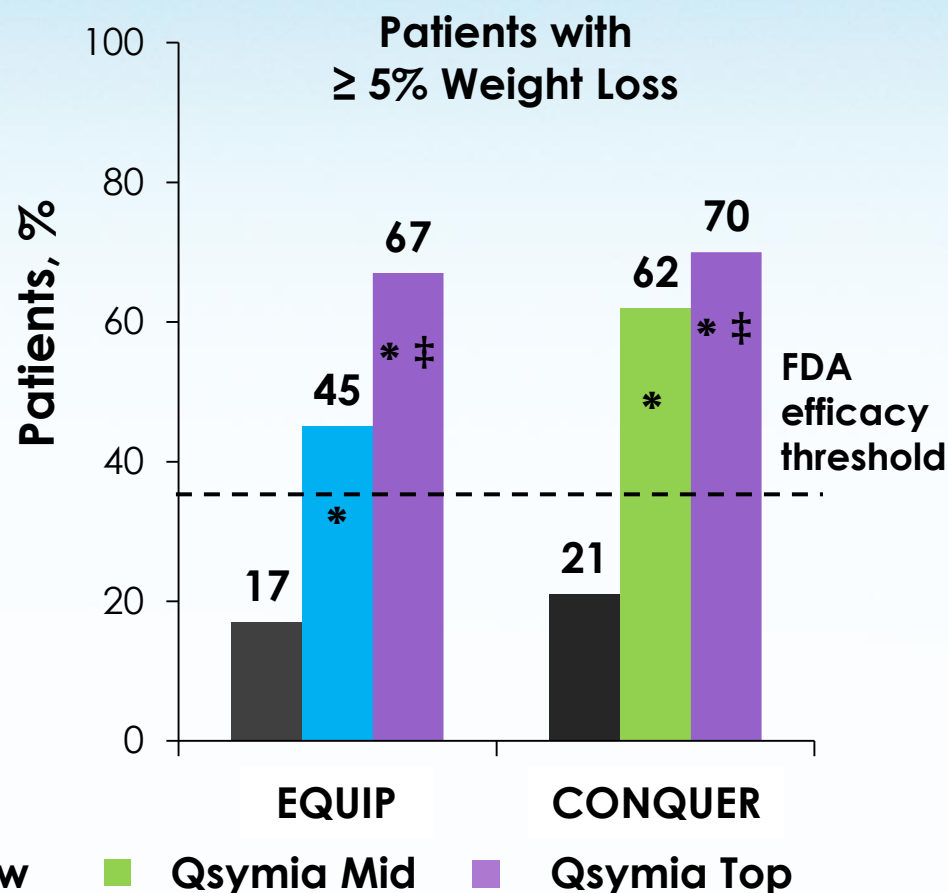
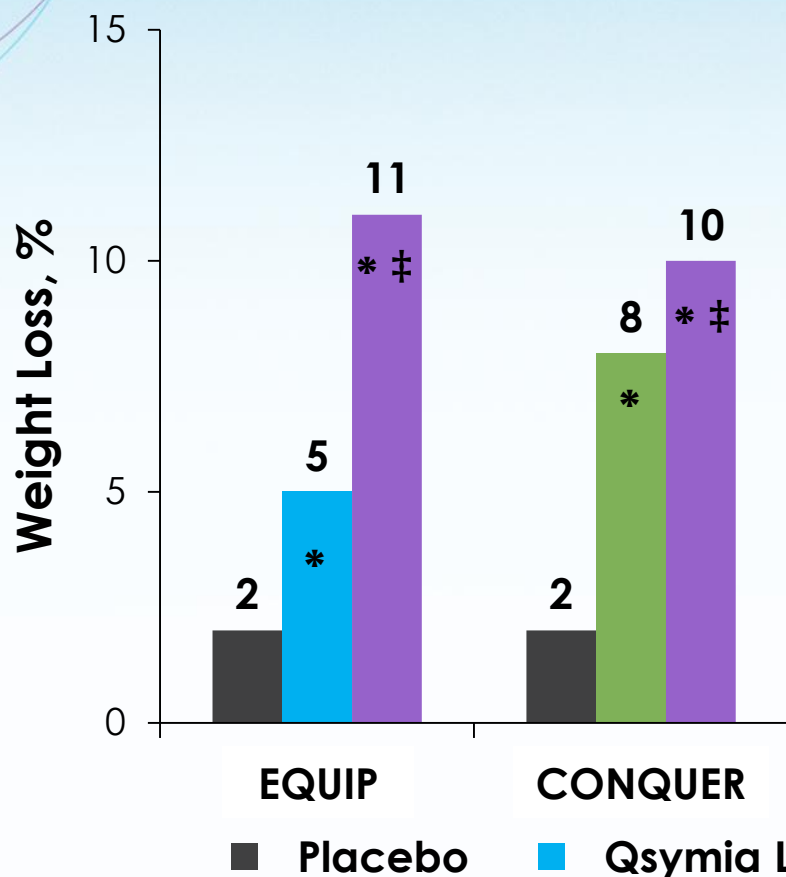
- Very significant media coverage of approval
  - Almost 500,000,000 impressions based on print, online, broadcast and social media since approval
- Qsymia website “live” at approval
  - In July, over 91,000 unique visitors to [www.Qsymia.com](http://www.Qsymia.com)
  - Almost 13,000 have registered for more information on the product
    - 87% identified themselves as patients
    - 12% were HCPs
    - Less than 1% were media or investors
- Qsymia HCP Training “live” at approval at [www.QsymiaREMS.com](http://www.QsymiaREMS.com) with several hundred HCPs completed to date

# Qsymia – Key Messages

- First pharmacotherapy with the proven potential of allowing patients to achieve and maintain  $\geq 10\%$  weight loss
  - For completers in pivotal studies, categorical weight loss after one year of tx was 64% at  $>10\%$ , and 43% at  $>15\%$  with top dose
- Shown to be well tolerated in clinical trials
- Multiple strengths
- Simple, once-daily dosing

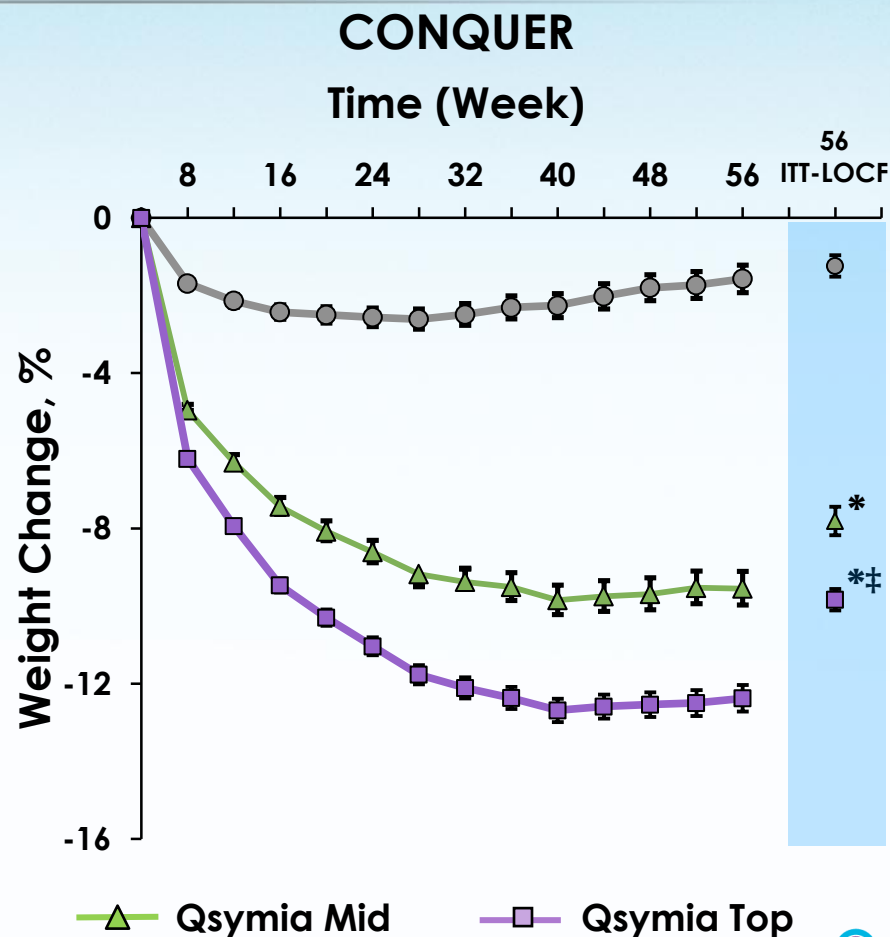
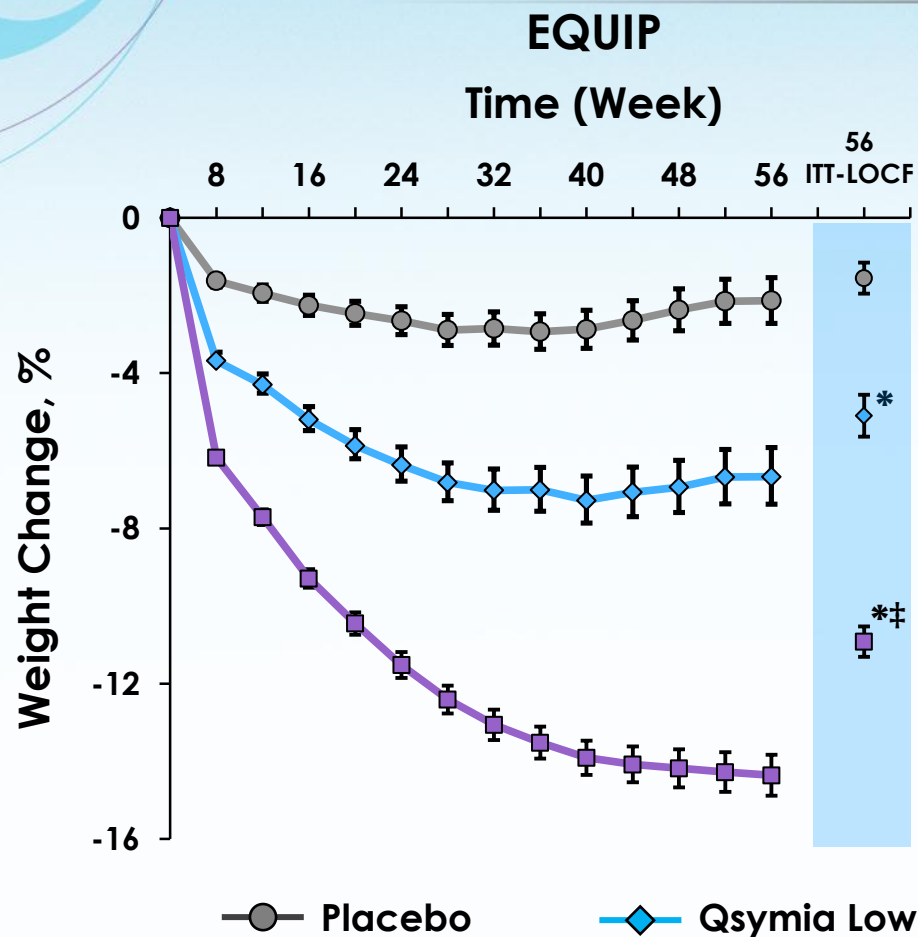


# Pivotal 1-Year Studies: Co-Primary Endpoints (ITT LOCF at Week 56)



\*p<0.0001 vs placebo; ‡p<0.002 vs. low/mid dose

# Pivotal 1-Year Studies: Weight Loss Over Time (Observed Data)



All observed data; \* $p < 0.0001$  vs placebo; † $p < 0.0001$  vs. Qsymia Mid or Low



# Pivotal Studies Published in Top Tier Journals

Lancet

Obesity

American Journal of Clinical Nutrition

## Effects of low-dose, controlled-release, phentermine plus topiramate combination on weight and associated comorbidities in overweight and obese adults (CONQUER): a randomised, placebo-controlled, phase 3 trial

Kishore M Gadde, David B Allison, Donna H Ryan, Craig A Peterson, Barbara Troupin, Michael L Schwiers, Wesley W Day

**Summary**  
Background Obesity is associated with a reduction in life expectancy and an increase in mortality from cardiovascular diseases, cancer, and other causes. We therefore assessed the efficacy and safety of two doses of phentermine plus topiramate controlled-release combination as an adjunct to diet and lifestyle modification for weight loss and metabolic risk reduction in individuals who were overweight and obese, with two or more risk factors.

**Methods** In this 56-week phase 3 trial, we randomly assigned overweight or obese adults (aged 18–70 years), with a body-mass index of 27–45 kg/m<sup>2</sup> and two or more comorbidities (hypertension, dyslipidaemia, diabetes or prediabetes, or abdominal obesity) to placebo, once-daily phentermine 7.5 mg plus topiramate 46.0 mg, or once-daily phentermine 15.0 mg plus topiramate 92.0 mg in a 2:1:2 ratio in 51 centres in the USA. Drugs were administered orally. Patients were randomly assigned by use of a computer-generated algorithm that was implemented through an interactive voice response system, and were stratified by sex and diabetic status. Investigators, patients, and study sponsors were masked to treatment. Primary endpoints were the percentage change in bodyweight and the proportion of patients achieving at least 5% weight loss. Analysis was by intention to treat. This study is registered with Clinical Trials.gov, number NCT00553787.

**Findings** Of 2487 patients, 994 were assigned to placebo, 498 to phentermine 7.5 mg plus topiramate 46.0 mg, and 995 to phentermine 15.0 mg plus topiramate 92.0 mg; 979, 488, and 981 patients, respectively, were analysed. At 56 weeks, change in bodyweight was -3.4 kg (least-squares mean -1.2%, 95% CI -1.8 to -0.7), -8.1 kg (-7.8%, -8.5 to -7.7, *p* < 0.001), and -10.2 kg (-9.8%, -10.4 to -9.9, *p* < 0.001) in the patients assigned to placebo, phentermine 7.5 mg plus topiramate 46.0 mg, and phentermine 15.0 mg plus topiramate 92.0 mg, respectively. 204 (21%) patients achieved at least 5% weight loss with placebo, 303 (62%, odds ratio 6.3, 95% CI 4.4 to 8.6; *p* < 0.001) with phentermine 7.5 mg plus topiramate 46.0 mg, and 487 (70%, *p* < 0.001) with phentermine 15.0 mg plus topiramate 92.0 mg; for 45% weight loss, the corresponding numbers were 72 (7%), 182 (37%, *p* < 0.001), and 467 (48%, *p* < 0.001). The most common adverse events were dry mouth (24 [2.4%], 67 [13%], and 207 [21%] in the groups assigned to placebo, phentermine 7.5 mg plus topiramate 46.0 mg, and phentermine 15.0 mg plus topiramate 92.0 mg, respectively), paraesthesia (20 [2.0%], 68 [14%], and 204 [21%], respectively), constipation (59 [6%], 75 [15%], and 173 [17%], respectively), insomnia (41 [4%], 20 [4%], and 102 [10%], respectively), dizziness (31 [3%], 46 [9%], 90 [9%], respectively), and depression (11 [1%], 37 [7%], and 113 [11%], respectively). 38 (4%) patients assigned to placebo, 19 (4%) to phentermine 7.5 mg plus topiramate 46.0 mg, and 73 (7%) to phentermine 15.0 mg plus topiramate 92.0 mg had depression-related adverse events, and 28 (3%), 24 (5%), and 77 (8%), respectively, had antiepileptic adverse events.

**Interpretation** The combination of phentermine and topiramate, with office-based lifestyle interventions, might be a valuable treatment for obesity that can be provided by family doctors.

**Funding** Vivus.

**Introduction**  
Obesity is associated with reduced life expectancy and increased mortality from cardiovascular disease, cancer, and other causes.<sup>1,2</sup> About 50% of cases of type 2 diabetes are attributable to excess weight, and there is a two-to-six times increase in hypertension among obese individuals compared with those with normal weight.<sup>3,4</sup>

In patients with normal weight, a weight reduction of 5–10% improves obesity-related risk factors and comorbidities,<sup>5</sup>

with substantial improvements in glycaemia, blood pressure, and lipid concentrations.<sup>6</sup> Intensive lifestyle-modification programmes that produce significant weight loss, and concomitant benefits, in obese patients with prediabetes or diabetes have to be implemented by trained counsellors during frequent office visits, and are not readily incorporated into the family doctor.<sup>7,8</sup> An effective pharmacological intervention that can produce 5–10% greater weight loss than does brief office-based

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Articles



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ARTICLES  
INTERVENTION AND PREVENTION

## Controlled-Release Phentermine/Topiramate in Severely Obese Adults: A Randomized Controlled Trial (EQUIP)

David B. Allison<sup>1,2</sup>, Kishore M. Gadde<sup>3</sup>, William Timothy Garvey<sup>4,5</sup>, Craig A. Peterson<sup>6</sup>, Michael L. Schwiers<sup>4</sup>, Thomas Najarian<sup>7</sup>, Peter Y. Tam<sup>8</sup>, Barbara Troupin<sup>9</sup> and Wesley W. Day<sup>1</sup>

A 56-week randomized controlled trial was conducted to evaluate safety and efficacy of a controlled-release combination of phentermine and topiramate (PHE/TPM CR) for weight loss (WL) and metabolic improvements. Men and women with class II and III obesity (BMI ≥ 35 kg/m<sup>2</sup>) were randomized to placebo, PHE/TPM CR 3.75/23 mg, or PHE/TPM CR 15/92 mg, added to a reduced-energy diet. Primary end points were percent WL and proportions of patients achieving 5% WL. Secondary end points included waist circumference (WC), systolic and diastolic blood pressure (BP), fasting glucose, and lipid measures. In the primary analysis (randomized patients with at least one postbaseline weight measurement who took at least one dose of assigned drug or placebo), patients in the placebo, 3.75/23, and 15/92 groups lost 1.8%, 5.1%, and 10.0% of baseline body weight (BW), respectively, at 56 weeks (*p* < 0.0001). In categorical analysis, 17.3% of placebo patients, 44.9% of 3.75/23 patients, and 66.7% of 15/92 patients, lost at least 5% of baseline BW at 56 weeks (*p* < 0.0001). The 15/92 group had significantly greater changes relative to placebo for WC, systolic and diastolic BP, fasting glucose, triglycerides, total cholesterol, low-density lipoprotein (LDL), and high-density lipoprotein (HDL). The most common adverse events were paraesthesia, dry mouth, constipation, dyspnea, and insomnia. Dropout rate from the study was 47.1% for placebo patients, 30.0% for 3.75/23 patients, and 33.6% of 15/92 patients. PHE/TPM CR demonstrated dose-dependent effects on weight and metabolic variables in the direction expected to be beneficial with no evidence of serious adverse events induced by treatment.

Obesity 2012;116:1015–1024 | DOI:10.1038/s12225-012-9300-7

### INTRODUCTION

Obesity, a highly prevalent public health problem, is associated with increased mortality and morbidity, including an increased risk of type 2 diabetes mellitus and cardiovascular disease, physical disabilities, sleep apnea, and reduced quality of life (1). When achieved by medically recommended procedures, weight loss (WL) is associated with reduced morbidity in obese persons (2). Beyond surgery, long-term weight reductions much greater than 3–6 kg remain elusive (3). Hence, generating additional medical treatment options is a priority.

Phentermine hydrochloride is a sympathomimetic amine approved by the US Food and Drug Administration (FDA) in 1959 with a dose range of up to 37.5 mg/day for short-term obesity treatment. Phentermine stimulates increased hypothalamic release of norepinephrine with no detectable effect on serotonin (4). Topiramate, a fructose monosaccharide

derivative with sulphamate functionality, was approved for the treatment of epilepsy in 1996 and the prevention of migraine in 2004. Randomized controlled trials (RCTs) show that topiramate monotherapy produces WL among obese individuals of ~6–8 kg at 24 weeks and improvements in lipids, glycemic control, and blood pressure (5) (1–5). However, topiramate has been associated with adverse events (AEs) that may limit its use as a single agent at optimal doses for WL. With respect to possible mechanisms for the WL effects of topiramate, animal experiments suggest that topiramate-induced WL results from increased energy expenditure, decreased energetic efficiency, and decreased caloric intake (6–10). A significant factor associated with topiramate-induced WL in humans appears to be decreased caloric intake (11–13). However, consistent with animal findings, reduction in caloric intake does not appear to fully explain the observed WL (11,12); thus, as suggested

<sup>1</sup>Department of Biostatistics, School of Public Health and Nutrition Obesity Research Center, University of Alabama at Birmingham, Birmingham, Alabama, USA; <sup>2</sup>Department of Nutrition Sciences, School of Health Professions and Nutrition Obesity Research Center, University of Alabama at Birmingham, Birmingham, Alabama, USA; <sup>3</sup>Obesity Clinical Trials Program, Duke University Medical Center, Durham, North Carolina, USA; <sup>4</sup>Department of Medicine, School of Health Professions and Medicine and Nutrition Obesity Research Center, University of Alabama at Birmingham, Birmingham, Alabama, USA; <sup>5</sup>NVUS, Inc., Mountain View, California, USA; <sup>6</sup>Medscape, Cincinnati, Ohio, USA; <sup>7</sup>Compendex, Seattle, WA, USA; <sup>8</sup>Alkermes, Boston, Massachusetts, USA; <sup>9</sup>Alkermes, Boston, Massachusetts, USA

Received 27 January 2012; accepted 24 September 2012; advance online publication 2 November 2012; doi:10.1038/s12225-012-9300-7

OBESITY

## Two-year sustained weight loss and metabolic benefits with controlled-release phentermine/topiramate in obese and overweight adults (SEQUEL): a randomized, placebo-controlled, phase 3 extension study

W Timothy Garvey, Donna H Ryan, Michelle Look, Kishore M Gadde, David B Allison, Craig A Peterson, Michael Schwiers, Wesley W Day, and Charles H Boden

**ABSTRACT**  
Background: Obesity is a serious chronic disease. Controlled-release phentermine/topiramate (PHE/TPM CR), as an adjunct to lifestyle modification, has previously shown significant weight loss compared with placebo in a 56-week study in overweight and obese subjects with ≥2 weight-related comorbidities.  
Objective: This study evaluated the long-term efficacy and safety of PHE/TPM CR in overweight and obese subjects with cardiometabolic disease.

**Design:** This was a placebo-controlled, double-blind, 52-wk extension study; volunteers at selected sites continued with original randomized assigned treatment (placebo, 7.5 mg phentermine/46 mg controlled-release topiramate (5/46), or 15 mg phentermine/92 mg controlled-release topiramate (15/92)) to complete a total of 108 wk. All subjects participated in a lifestyle-modification program.  
**Results:** Of 866 eligible subjects, 676 (78%) elected to continue in the extension. Overall, 84.0% of subjects completed the study, with similar completion rates between treatment groups. At week 108, PHE/TPM CR was associated with significant, sustained weight loss (intent-to-treat with last observation carried forward; *P* < 0.0001) compared with placebo; least-squares mean percentage changes from baseline in body weight were -1.8%, -9.5%, and -10.5% for placebo, 7.5/46, and 15/92, respectively. Significantly more PHE/TPM CR-treated subjects at each dose achieved ≥5%, ≥10%, ≥15%, and ≥20% weight loss compared with placebo (*P* < 0.001). PHE/TPM CR improved cardiovascular and metabolic variables and decreased rates of incident diabetes in comparison with placebo. PHE/TPM CR was well tolerated over 108 wk, with reduced rates of adverse events occurring between weeks 56 and 108 compared with rates between weeks 0 and 56.

**Conclusion:** PHE/TPM CR in conjunction with lifestyle modification may provide a well-tolerated and effective option for the sustained treatment of obesity complicated by cardiometabolic disease. This trial was registered at clinicaltrials.gov as NCT00796807. *Am J Clin Nutr* 2012;95:297–308.

### INTRODUCTION

Obesity is a global epidemic (1, 2). This chronic disease increases morbidity and mortality, in large part due to associated comorbidities, including T2D, CVD, metabolic syndrome, liver

disease, and cancer (1–7). The first-line strategy for the treatment of obesity and prevention of cardiometabolic disease is achieving weight loss through lifestyle interventions, which consist of reductions in caloric intake (by 500–1000 calories/day), increases in physical activity, and changes in health behaviors (8). However, adherence to lifestyle changes can be challenging for a wide variety of reasons, such as a lack of readiness for change on the part of the patient, physical restrictions that limit activity, and a shortage of therapeutic venues that include a multidisciplinary health care team essential to treatment effectiveness. When lifestyle changes alone do not provide the desired weight loss, the addition of pharmacotherapy or bariatric surgery provides a viable option for patients meeting eligibility criteria. However, effective pharmacologic options are limited, and indication for bariatric surgery is limited to patients with a high BMI due to the inherent risks of invasive procedures (9, 10). Thus, it is imperative that effective, long-term pharmacologic strategies are identified that may be used in conjunction with lifestyle changes to combat the obesity epidemic.

<sup>1</sup>From the Departments of Nutrition Sciences and Medicine, UAB Diabetes Research and Training Center, University of Alabama at Birmingham, Birmingham, AL; <sup>2</sup>UAB Medical Center, Birmingham, AL; <sup>3</sup>UAB, Pennington Biomedical Research Center, Baton Rouge, LA; <sup>4</sup>UAB, San Diego State Medical Center, San Diego, CA; <sup>5</sup>UAB, The Obesity Clinical Trials Program, Duke University Medical Center, Durham, NC; <sup>6</sup>UAB, The Department of Biostatistics, UAB Nutrition and Obesity Research Center, University of Alabama at Birmingham, Birmingham, AL; <sup>7</sup>UAB, NVUS Inc., Mountain View, CA; <sup>8</sup>UAB, Wadsworth and CIBR; and <sup>9</sup>Medpace, Cincinnati, OH (MS).

<sup>10</sup>Vivus Inc provided funding and essential materials for this study. <sup>11</sup>Address correspondence and requests for reprints to W T Garvey, Department of Nutrition Sciences, University of Alabama at Birmingham, 1615, 1615 University Boulevard, Birmingham, AL 35294-3360. E-mail: ggarvey@uab.edu

<sup>12</sup>Abbreviations used: AE, adverse event type; bpm per minute; C-SIBS, Columbia-Sibers Severity Rating Scale; CVD, cardiovascular disease; IDA, glycated hemoglobin; ITT, intent-to-treat; LOCF, last observation carried forward; LS, least-squares; PHE/TPM CR, controlled-release phentermine/topiramate; SAS, statistical software; T2DM, treatment emergent adverse event; T2D, type 2 diabetes; T5/46, 7.5 mg phentermine/46 mg controlled-release topiramate; T15/92, 15 mg phentermine/92 mg controlled-release topiramate.

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Am J Clin Nutr 2012;95:297–308. Printed in USA. © 2012 American Society for Nutrition

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Supplemental Materials can be found at: <http://ajcn.nutrition.org/content/95/3/297/suppl/1>

VIVUS

**Osymia**  
(phentermine and topiramate extended-release) capsules

# Healthcare Provider Strategies at Launch

- Generate awareness of Qsymia
- Convert currently written weight loss prescriptions (in appropriate patients) with specialists
- Educate PCPs on the importance of treating obesity
- Provide tools to providers to help counsel and engineer successful new starts





# Healthcare Provider Marketing Launch Tactics

## Direct Mail

- Announcement Letter – Physicians and Medical Societies

## Journal Advertising

- Now Approved
- Branded Launch Ad – Upon Product Availability

## Digital Marketing

- Qsymia Website
- Qsymia Webcasts
- Medical Site Promotion
- Qsymia Video Education
- Downloadable Patient Educational Materials

## Medical Society Meetings

- Convention Booth
- Convention Advertising

## Sales Force Support

- Qsymia Detail Aid (print & iPad)
- Qsymia Titration Card
- Back office mgmt kit
- Obesity counseling tool
- Patient brochure/ waiting room brochure

## Medical Education

- Qsymia Speakers Bureau
- Qsymia Slide Set
- Speakers Resource Portal



# Patient Strategies at Launch

- Create awareness of the approval of new and effective prescription product for obesity
- Elevate health risks of obesity beyond cosmetic treatment
- Facilitate meaningful discussions with HCP
- Engineer patient success and compliance with tools and support



# Patient Marketing Tactics at Launch

## Public Relations

- Obesity Epidemic and Co-morbidities
- Qsymia availability

## Qsymia Patient Support Program

- Support Program Website
- Educational Tips – Email
- Progress Tracking
- Downloadable Applications
- Educational Video Segments
- Patient Database

## Digital Marketing

- Qsymia Website  
Patient Education Area
- Health Site Promotion/  
Partnerships
- Disease State Education
- Social Media
- Unbranded Banner  
Advertising
- Health Links



# Marketing, Market Access and Medical Talent Acquisition

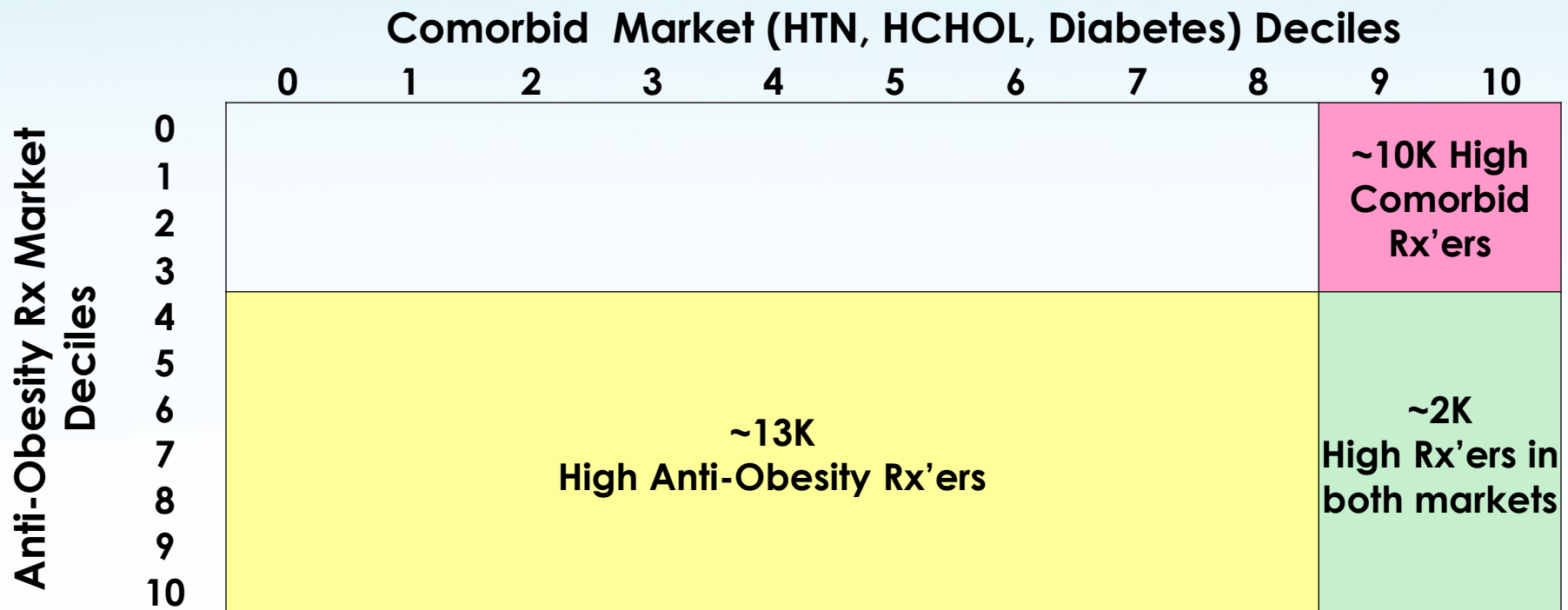
**In last six months, 50 new hires  
into Commercial and Medical Affairs**

Amgen  
Amylin  
Bristol-Myers Squibb  
Daiichi-Sankyo  
Dendreon  
Elan  
Gilead  
GlaxoSmithKline  
Ipsen  
Johnson & Johnson

Lilly  
Merck  
Novartis  
Novo Nordisk  
Roche Genentech  
Sanofi  
Takeda  
TAP  
MedImmune  
Astra Zeneca

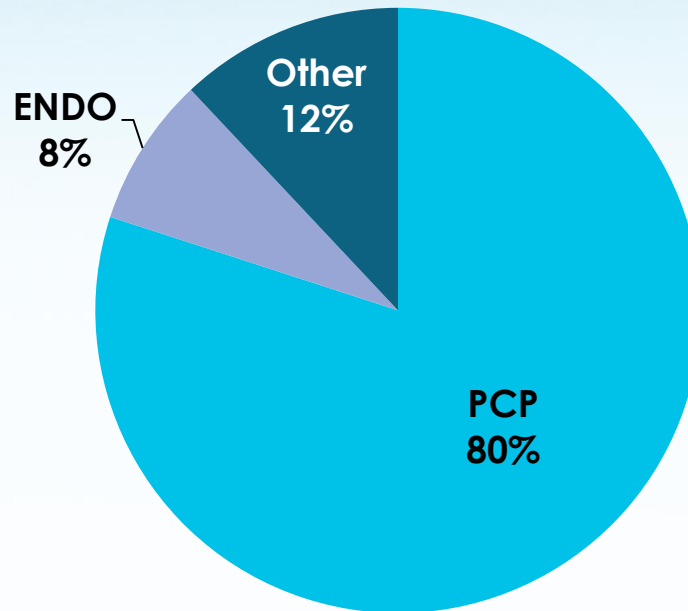


# Prescriber Target Identification for Launch



# 25K Targets by Specialty and Prioritization

## Specialties Targeted



Targeting scheme prioritizes for current volume and opportunity, early adopters and affiliation efficiencies



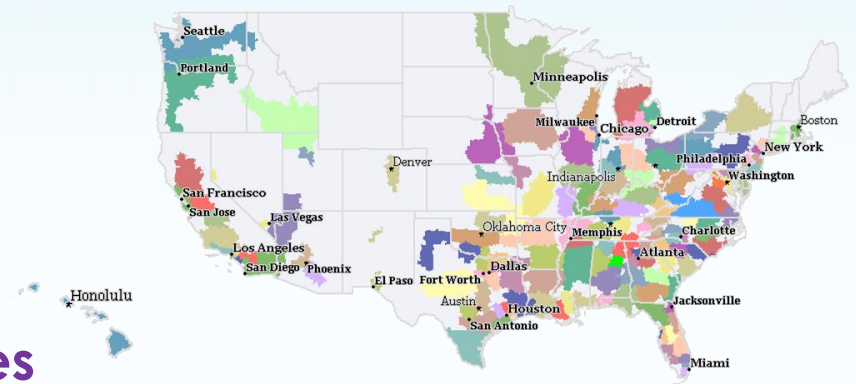
# Sales Force Deployment

## Sales Management Team are VIVUS employees

- National Sales Director
- 2 Regional Sales Directors
- Director, Sales Training
- Director, Sales Operations
- 16 District Managers

## 150 Territory Representatives

- PDI Partnership
- Recruited PCP Sales Reps with Cardio-Metabolic Experience in those geographies
- 134 offers (out of 150) extended and 114 accepted



# Unlike Bariatric Surgery, Insurance Coverage of Drugs to Treat Obesity is Not Widely Available at Present

- Medicare Part D** Pharmacological agents used for weight loss are an excluded category, even if used for a non-cosmetic purpose (i.e., severe obesity)
- Medicaid** States have the option of providing coverage for pharmacological agents used for weight loss; currently ten states
- Private Payers** Approximately one-third of prescriptions for weight management drugs are currently reimbursed

<sup>1</sup>Lee et al. Coverage of Obesity Treatment: A State-by-State Analysis of Medicaid and State Insurance Laws. *Pub Health Rep* 2010.

# Future Coverage Potential

## Commercial Payers: “On the cusp of addressing a policy change”

- Payer's indicate that Qsymia's approval will push Plans/PBMs to consider formulary placement, most predicted a policy decision within 6 – 12 months

## Employers: “Already addressing obesity and wellness in the workplace”

- Recent employer advisory input suggests that obesity is not ideally addressed in already existing wellness programs

## Medicare Part D

- Pursue legislative and federal policy changes in an attempt to remove the statutory exclusion for the entire category of drugs indicated for chronic weight management

# Key Payer/Employer Launch Activities

- Qsymia approval notifications being sent to Plan/PBM Medical Directors and Pharmacy Directors, Business Health Coalition Executive Directors, and State Medicaid Directors
- AMCP Dossier will be available to fulfill unsolicited payer requests by mid-August
- Seasoned group of National Account Managers will begin calling on target accounts with an educational focus on the health impacts/costs of obesity
- Pharmacoeconomic research is underway for publication to support the value proposition of Qsymia



# Qsymia Certified Home Delivery Pharmacy Network

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**In final stages of contracting with large, nationally known Mail Order and PBM pharmacies**

- CVS
- Express Scripts
- Kaiser
- Walgreens
- Walmart

# Significant Barriers to Off-label Generic Prescribing

## FDA approved REMS and category X label

- Primary research with specialists and PCPs indicated this strongly discourages off-label prescribing of generics
- Concerns for liability
- Quantitative research indicates generic phentermine Rx'ing (with and without topiramate) will decline after availability of Qsymia

## No true equivalent

- Comparable ER formulation or dosage strengths not available
- No longer have QD dosing convenience or simplicity

## No switching at Certified Home Delivery Pharmacies



# Commercial Timeline

**2009**

- ✓ KOL Identification and Advocacy Development
- ✓ PIII Publication Planning
- ✓ Government Relations Strategy Development
- ✓ Market Assessment
  - ✓ Current Landscape and Potential Barriers
- ✓ Define key customer groups
- ✓ Initial Product Perceptions
- ✓ Pharmacoeconomic Planning

**2010**

- ✓ Brand Development
  - ✓ Core Value
  - ✓ Positioning
  - ✓ Messaging
  - ✓ Strategic Plan
  - ✓ Concept Development
- ✓ Hallmark Creation
  - ✓ Color, Typeface, Logo, Tagline
- ✓ Hire Core Launch Team
- ✓ Expanded Advocacy Development
- ✓ PIII Secondary Publication Planning and Submissions
- ✓ CME Support

**2011**

- ✓ Marketing Campaign
  - ✓ Creation of Tactical Promotional Programs
- ✓ Concept and Message Testing
- ✓ Pricing Research
- ✓ Commercial Build Up
- ✓ Expanded PR Efforts
- ✓ Implementation of Pharmacoeconomic Plan
- ✓ Training Materials Development
- ✓ Call Audience Deciling and Targeting
- ✓ Public policy efforts

**Launch Q4 2012**

- ✓ Product Promotion
- ✓ Program Implementation and Tracking
- ❑ Final Phase IV Program
- ❑ Deploy Employer and Payer Tactics
- ✓ Hire sales management team
- ✓ CSO selection
- ✓ CME Initiatives to PCP
- ❑ Obesity Awareness Campaign
- ✓ Patient Support Program
- ❑ Promotion Effectiveness Measurements



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A Pharmaceutical Company

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