### 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) **September 9, 2009** 

#### VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-33389

(Commission File Number)

94-3136179 (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 8.01. Other Events

As previously announced, on September 9, 2009 at 8:00 a.m. Eastern Time, VIVUS, Inc. will host a conference call and webcast discussion of Qnexa Phase 3 results. A copy of the EQUIP and CONQUER study results slides to be presented on the conference call and included with the webcast is attached hereto as Exhibit 99.1. The conference call information is 1-800-967-7185 for domestic callers and 1-719-325-2352 for international callers. The webcast information is http://ir.vivus.com.

The information in this Form 8-K and the exhibit 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 EQUIP & CONQUER Study Results- Slide Presentation

#### **SIGNATURES**

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

VIVUS, INC.

By: /s/ Lee B. Perry

Lee B. Perry

**Vice President and Chief Accounting Officer** 

Date: September 9, 2009

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#### EXHIBIT INDEX

Exhibit No.	Description	
99.1	EQUIP & CONQUER Study Results- Slide Presentation	
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# EQUIP & CONQUER Study Results

September 9, 2009



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### Forward-Looking Statements



VIVUS cautions you that statements included in this presentation that are not a description of historical facts are forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "indicates," "will," "intends," "potential," "suggests," "assuming," "designed" and similar expressions are intended to identify forward-looking statements. These statements are based on the Company's current beliefs and expectations. These forward-looking statements include statements regarding the efficacy and safety of Qnexa@, the potential for, and timing of, an NDA submission for Qnexa, the commercial and therapeutic potential of Qnexa, and the potential to obtain regulatory approval for, and effectively treat obesity with, Qnexa. The inclusion of forward looking statements should not be regarded as a representation by VIVUS that any of its plans will be achieved. Actual results may differ from those set forth in this presentation due to the risk and uncertainties inherent in the VIVUS business, including, without limitation: additional analyses of data from the Qnexa Phase 3 trials and any other clinical trials of Qnexa may produce negative or inconclusive results, or may be inconsistent with previously announced results or previously conducted clinical trials; the FDA may not agree with the Company's interpretation of efficacy and safety results; earlier clinical trials may not be predictive of future results; Qnexa may not receive regulatory approval on a timely basis or at all, and the FDA may require VIVUS to complete additional clinical, non-clinical or other requirements prior to the submission or the approval of NDAs for either product candidate; the potential for adverse safety findings relating to Qnexa to delay or prevent regulatory approval or commercialization, or result in product liability claims, including serious adverse events that are not characterized by clinical investigators as possibly related to Qnexa; the third parties on whom VIVUS relies to assist with the development programs f

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#### Today's Speakers



- Leland Wilson, President & CEO
- Dr. Wesley Day, VP Clinical Development
- Michelle Look, MD, FAAFP, San Diego Sports Medicine and Family Health Center and principal investigator
- Peter Tam, Chief Operating Officer

#### **Qnexa: EQUIP Summary**



### EQUIP (OB-302)

- 1,267 morbidly obese patients
- Weight loss 14.7% or 37 lbs
- Full and Low Dose satisfied FDA efficacy benchmarks
- · Improvement in cardio-metabolic risk factors

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### **Qnexa: CONQUER Summary**



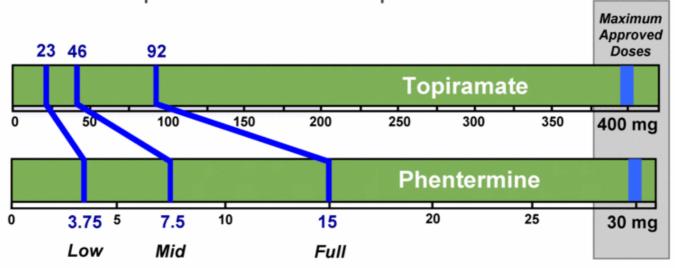
### CONQUER (OB-303)

- 2,487 obese patients with co-morbidities
- Full Dose-Weight loss 13.2% or 30 lbs
- Mid Dose-Weight loss 10.5% or 24 lbs
- Full and Mid Dose satisfied FDA efficacy benchmarks
- Improvement in cardio-metabolic risk factors

### Qnexa: Proprietary Treatment for Obesity



 Once a day oral controlled release formulation of low dose phentermine and topiramate



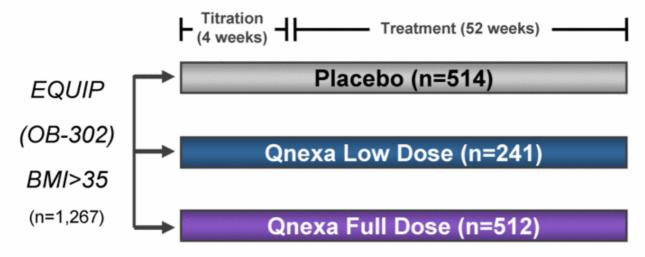
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### **EQUIP: Morbidly Obese Subjects**



#### **Study Design**



#### Study Visits:

- Every other week during titration
- · Monthly thereafter

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### **EQUIP**: Baseline Demographics



Baseline					
Age	43				
Female	83%				
Baseline BMI	42.1				
Weight (lbs)	256				
Waist Circumference (in)	48				
History of Hypertension	25%				
Blood Pressure (mmHg)	122/77				
History of Dyslipidemia	19%				
Total Cholesterol (mg/dL)	194				
History of Psychiatric Disorders	26%				

### **EQUIP: High Completion Rates**



Patients	Placebo	Qnexa Low	Qnexa Full
Randomized	514	241	512
ITT Population <sup>1</sup> (% of randomized)	498	234	498
	97%	97%	97%
Completers <sup>2</sup> (% of randomized)	241	138	301
	47%	57%*	59%*

Statistically greater number of patients completing study on Qnexa vs. placebo, p<0.0001</li>

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# EQUIP: Primary Efficacy Endpoints Satisfies FDA Efficacy Benchmarks at Both Doses



ITT-LOCF	Placebo (n=498)	Qnexa Low (n=234)	Qnexa Full (n=498)
Percent weight loss	1.6%	5.1%*	11.0%*
% Patients ≥ 5% weight loss	17%	45%*	67%*

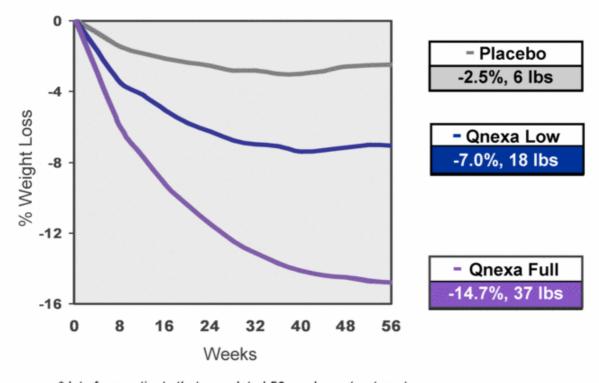
<sup>\*</sup>p<0.0001 vs. placebo

<sup>1</sup> ITT Population = randomized patients with at least one dose of therapy and one post randomization assessment

<sup>2</sup> Completers = randomized patients completing 56-week study on drug therapy

# EQUIP: Continuing Weight Loss Over Time Completers\* Lost 14.7% Body Weight

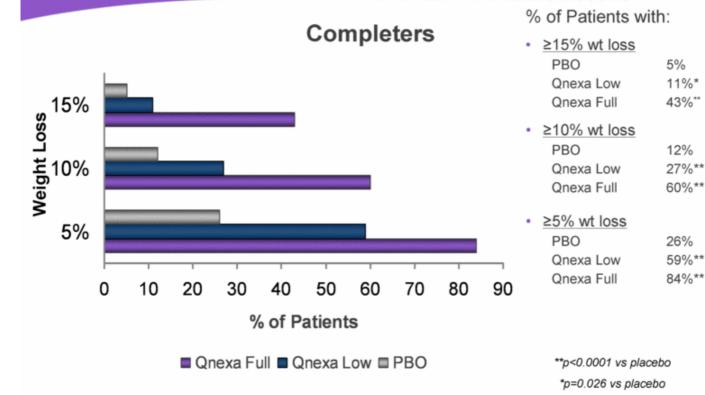




\*data from patients that completed 56 weeks on treatment

# EQUIP: Significant Categorical Weight Loss at Both Doses





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### EQUIP: Improved Cardiovascular Risk Factors



#### ITT-LOCF Placebo Comparisons

CV Risk Factors	Qnexa Low	p-value*	Qnexa Full	p-value*
Waist Circumference	4	<0.0001	<b>V</b>	<0.0001
Systolic BP	<b>V</b>	0.002	<b>V</b>	<0.0001
Diastolic BP	4	ns	<b>V</b>	0.0002
Triglycerides	$\downarrow$	ns	<b>V</b>	<0.0001
Total Cholesterol/HDL Ratio	<b>V</b>	0.0148	<b>*</b>	<0.0001
Total Cholesterol	4	0.05	<b>V</b>	0.0014
LDL	<b>V</b>	ns	<b>V</b>	0.0157
HDL	<b>1</b>	ns	<b>↑</b>	0.0005

<sup>\*</sup>p-values represent comparisons to placebo

#### **EQUIP: Efficacy Summary**



- 14.7% (37 lbs) weight loss on Qnexa Full Dose\*
- Qnexa Full and Low doses satisfied FDA efficacy benchmarks
- Improvement shown for all cardiovascular risk factors

\* Completer analysis

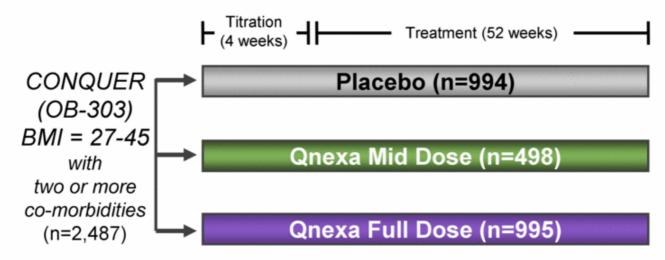
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### CONQUER: Co-morbid Obese Subjects



#### Study Design



#### Study Visits:

- · Every other week during titration
- Monthly thereafter

### CONQUER: Baseline Demographics



Baseline					
Age	51				
Female	70%				
Baseline BMI	36.6				
Weight (lbs)	227				
Waist Circumference (in)	44.5				
History of Hypertension	69%				
Blood Pressure (mmHg)	128/81				
History of Dyslipidemia	57%				
Total Cholesterol	205				
History of Diabetes	16%				
Fasting Blood Glucose (mg/dL)	106				
History of Psychiatric Disorders	30%				

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### CONQUER: High Completion Rates



Patients	Placebo	Qnexa Mid	Qnexa Full
Randomized	994	498	995
ITT Population <sup>1</sup> (% of randomized)	979	488	981
	99%	98%	99%
Completers <sup>2</sup> (% of randomized)	564	344	634
	57%	69%*	64%*

Statistically greater number of patients completed study on Qnexa vs. placebo, p<0.0001</li>

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# CONQUER: Primary Efficacy Endpoints Satisfies FDA Efficacy Benchmarks at Both Doses



ITT-LOCF	Placebo (n=979)	Qnexa Mid (n=488)	Qnexa Full (n=981)
Percent weight loss	1.8%	8.4%*	10.4%*
% Patients ≥ 5% weight loss	21%	62%*	70%*

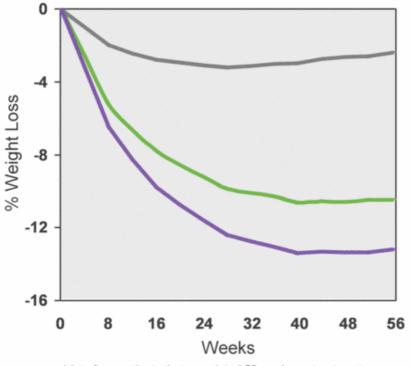
<sup>\*</sup>p<0.0001 vs. placebo

<sup>1</sup> ITT Population = randomized patients with at least one dose of therapy and one post randomization assessment

<sup>2</sup> Completers = randomized patients completing 56-week study on drug therapy

### **CONQUER: Weight Loss Over Time** Completers\* Lost 13.2% Body Weight





- Placebo -2.4%, 6 lbs

Qnexa Mid -10.5%, 24 lbs

Qnexa Full -13.2%, 30 lbs

73% excess weight lost \*\*

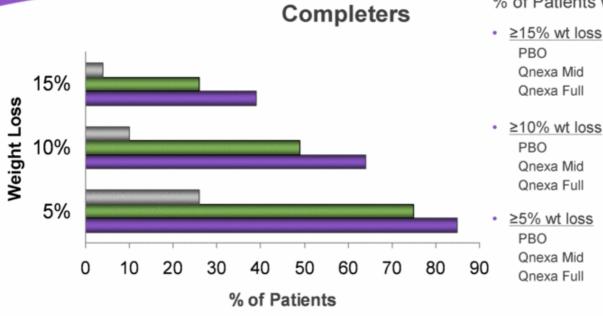
\*data from patients that completed 56 weeks on treatment "based upon BMI goal of 30

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### **CONQUER: Significant Categorical** Weight Loss at Both Doses



4%



■ Qnexa Full ■ Qnexa Mid ■ PBO

#### % of Patients with:

**PBO** 

Qnexa Mid 26%\*\* Qnexa Full 39%\*\* ≥10% wt loss PBO 10% Qnexa Mid 49%\*\* Qnexa Full 64%\*\* ≥5% wt loss PBO 26% Qnexa Mid 75%\*\* Qnexa Full 85%\*\*

\*\*p<0.0001 vs placebo

# CONQUER: Improved Cardiovascular Risk Factors



### ITT-LOCF Placebo Comparisons

Risk Factors	Qnexa Mid	p-value	Qnexa Full	p-value
Waist Circumference	$\downarrow$	<0.0001	$\downarrow$	<0.0001
Systolic BP	<b>\</b>	<0.0001	<b>\</b>	<0.0001
Diastolic BP	$\downarrow$	ns	<b>V</b>	0.0031
Triglycerides	$\downarrow$	<0.0001	<b>V</b>	<0.0001
Total Cholesterol/ HDL Ratio	<b>V</b>	<0.0001	<b>V</b>	<0.0001
Total Cholesterol	$\downarrow$	0.0345	$\downarrow$	<0.0001
LDL	$\downarrow$	ns	$\downarrow$	0.0069
HDL	<b>↑</b>	<0.0001	<b>↑</b>	<0.0001

p-values represent comparisons to placebo

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#### ITT-LOCF Placebo Comparisons

Risk Factors	Qnexa Mid	p-value	Qnexa Full	p-value
Hemoglobin A1c	<b>\</b>	<0.0001	<b>\</b>	<0.0001
Fasting Blood Glucose	<b>\</b>	0.0047	<b>\</b>	<0.0001
OGTT Insulin	<b>\</b>	<0.0001	<b>\</b>	<0.0001
Insulin Resistance (HOMA)	<b>\</b>	0.0007	<b>\</b>	<0.0001

p-values represent comparisons to placebo

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# CONQUER: Improved Inflammatory Risk Factors



#### ITT-LOCF Placebo Comparisons

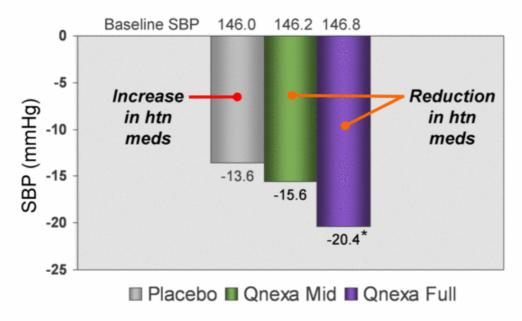
Risk Factors	Qnexa Mid	p-value	Qnexa Full	p-value
CRP	$\downarrow$	<0.0001	$\downarrow$	<0.0001
Fibrinogen	$\downarrow$	0.023	$\downarrow$	0.048
Adiponectin	<b>1</b>	< 0.0001	<b>1</b>	< 0.0001

p-values represent comparisons to placebo

# CONQUER: Decreased BP in Obese Hypertensive Patients (Subgroup Analysis)



#### SBP Change at Week 56 (upper quartile)



\*p<0.0001 vs. placebo

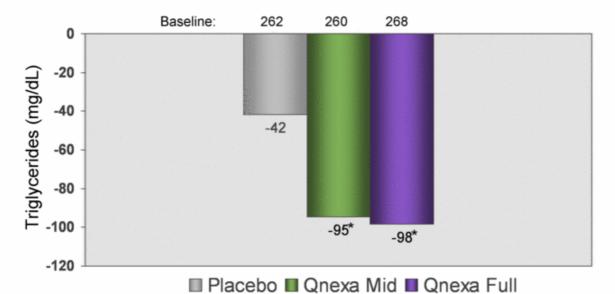
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# CONQUER: Decreased Triglyceride in Obese Dyslipidemic Patients (Subgroup Analysis)

# **V**ivus

#### Total Triglycerides Change at Week 56 (upper quartile)

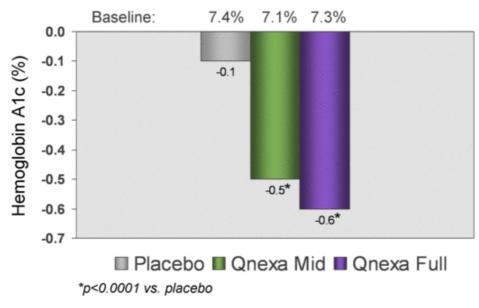


\*p<0.0001 vs placebo

# CONQUER: Decreased HbA1c in Obese Diabetic Patients (Subgroup Analysis)



#### HbA1c Change at Week 56 (upper quartile)



Rates of hypoglycemia were comparable to placebo (<0.5%)</li>

### **CONQUER: Efficacy Summary**



- 13.2% (30 lbs) weight loss on Qnexa Full Dose\*
- 10.5% (24 lbs) weight loss on Qnexa Mid Dose\*
- Both doses exceed FDA efficacy benchmarks
- Clinically meaningful improvement in cardiovascular, diabetes and inflammatory risk factors compared to placebo
- Patients at higher risk experienced greater improvements in blood pressure, triglycerides, and HbA1c

\* Completer analysis

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# Treatment-Emergent Adverse Events >5%: EQUIP & CONQUER



	EQUIP (N=1,264)		CON	QUER (N=2	,485)	
% of Patients (N=3,749)	Placebo	Qnexa Low	Qnexa Full	Placebo	Qnexa Mid	Qnexa Full
Dry Mouth	3.7	6.7	17.0	2.4	13.5	20.8
Tingling	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
Altered Taste	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
Headache	10.1	10.4	11.9	9.1	7.0	10.2
Dizziness	4.1	2.9	5.7	3.1	7.2	10.0
Common Cold	7.2	12.5	9.0	8.7	10.6	9.9
Sinus Infection	5.5	7.5	7.2	6.7	6.8	8.6
Back Pain	5.1	5.4	5.5	4.9	5.6	7.2
Nausea	4.7	5.8	7.2	4.2	3.6	6.8
Blurred Vision	3.1	6.3	4.5	3.6	4.0	6.0
Bronchitis	4.3	6.7	5.5	4.3	4.4	5.2
Diarrhea	4.5	5.0	4.7	4.8	6.4	5.8
Urinary Tract Infection	3.5	3.3	4.7	3.7	5.2	5.4
Cough	3.5	3.3	5.1	3.0	3.8	4.8
Influenza	4.7	7.5	5.1	4.3	4.6	3.5

# Low Discontinuation Rate in All Doses Studied



#### Study Completion & Discontinuation for AE by Dose\*

	Placebo	Qnexa Low	Qnexa Mid	Qnexa Full
Number of Subjects	1,508	241	498	1,507
Study Completion	53%	57%	69%	62%
Discontinuation due to AEs	9%	12%	12%	18%
Blurred Vision	0.5%	2.1%	0.8%	0.7%
Headache	0.7%	1.7%	0.2%	0.9%
Insomnia	0.4%	0.0%	0.4%	1.7%
Depression	0.2%	0.0%	0.8%	1.4%
Tingling	0.0%	0.4%	1.0%	1.2%
Irritability	0.1%	0.8%	0.8%	1.2%
Anxiety	0.3%	0.0%	0.2%	1.1%
Dizziness	0.2%	0.4%	1.2%	0.8%

<sup>\*</sup> Includes adverse events by dose for EQUIP & CONQUER, which lead to discontinuation in >1% of patients

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# EQUIP & CONQUER: Depression Assessment



	Placebo	Qnexa Low	Qnexa Mid	Qnexa Full
Moderate or severe AEs Depression/Depressed Mood	1.7%	1.7%	1.2%	1.9%

- No difference between Qnexa and placebo for incidence of moderate or severe depression/depressed mood
- No serious adverse events (SAE) reported for depression/depressed mood

### Patient Health Questionnaire (PHQ-9)



- PHQ-9 is a validated tool for diagnosing and assessing severity of depression.
- 38,000 PHQ-9 assessments taken in EQUIP and CONQUER
- Conclusion: No signal for depression
- Significant improvement in depression scores

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# EQUIP & CONQUER: Suicidality Assessments



- C-SSRS (Columbia Suicide Severity Rating Scale) developed to assess suicidality
- Over 38,000 C-SSRS assessments taken in EQUIP and CONQUER
- Results:
  - No suicides
  - · No suicide attempts
  - No suicidal behavior
  - · No signal for suicidal ideation
- Conclusion: No signal for suicidal risk

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#### **Overall Safety Assessments**



- Serious Adverse Event Assessment (EQUIP & CONQUER)
  - Total SAE not different between Qnexa (3.3%) and placebo (3.3%)
  - Drug Related SAE not different between Qnexa (0.4%) and placebo (0.4%)
  - · One death on placebo
- · Cognitive Function
  - · Studies completed, no clinically relevant effects
- Psychomotor Testing
  - · Study completed, no clinically relevant effects
- Thorough QT Study
  - Study completed, no signal for QT prolongation
- · Drug interactions
  - · Studies completed, no findings of concern
- Special populations
  - · Studies completed, no findings of concern

# Quality of Life and Health & Physical Function



- Impact of Weight on Quality of Life (IWQOL)
- · Significant improvement in (ITT-LOCF vs. placebo):
  - · Quality of Life
  - Self-Esteem
  - Public Distress
  - Physical Function
  - · Work Score
  - · Sexual Life Score
- Short Form Health Survey (SF-36)
- · Significant improvement in (ITT-LOCF vs. placebo) :
  - · General Health
  - · Physical Function
  - · Physical Role
  - Bodily Pain Score
  - Vitality Score

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# What can a hypothetical at-risk patient expect from Qnexa?



#### **Typical At-risk Patient**

- 51 year old female
- 250 lbs
- Hypertension (BP: 147/92 mmHg)
- Diabetes (HbA1c: 7.3%)
- HDL: 33 mg/dL
- LDL: 171 mg/dL
- TG: 268 mg/dL

Framingham 10-yr CHD risk: 27%

# What can a hypothetical at-risk patient expect from Qnexa?



#### **Typical At-risk Patient**

- 51 year old female
- 250 lbs
- Hypertension (BP: 147/92 mmHg)
- Diabetes (HbA1c: 7.3%)
- · HDL: 33 mg/dL
- LDL: 171 mg/dL
- TG: 268 mg/dL

Framingham 10-yr CHD risk: 27%

#### After 1 year on Qnexa

- → Lost 37 lbs
- → Normal (BP: 126/81 mmHg)
- → Below ADA goal (6.7%)
- → 21% increase
- → 18% decrease
- 37% decrease

10-yr CHD risk: 7%\* (4-fold decrease)

<sup>\*</sup> Achieved while using fewer medications for the management of co-morbidities

### **Qnexa: EQUIP and CONQUER Summary**



- Unprecedented weight loss 14.7% (37 lbs)\*
- Clinically meaningful improvements across cardiovascular, metabolic and inflammatory risk factors
- All three doses of Qnexa exceeded FDA efficacy benchmarks
- Well tolerated with completion rates significantly higher than placebo
- Compelling benefit/risk profile supporting approval, reimbursement & commercial success
  - \* Completers at 1 year in EQUIP

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