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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): March 11, 2015**

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**EVOKE PHARMA, INC.**

(Exact Name of Registrant as Specified in its Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-36075**  
(Commission  
File Number)

**20-8447886**  
(IRS Employer  
Identification No.)

**505 Lomas Santa Fe Drive, Suite 270**  
**Solana Beach, California**  
(Address of Principal Executive Offices)

**92075**  
(Zip Code)

**Registrant's telephone number, including area code: (858) 345-1494**

**(Former Name or Former Address, if Changed Since Last Report.)**

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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):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 7.01 Regulation FD Disclosures**

The Company met with investors and presented materials regarding the Company at the 27<sup>th</sup> Annual Roth Conference held March 9-11, 2015. The Company's materials used in the presentation are attached hereto as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Roth 2015 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.

EVOKE PHARMA, INC.

Date: March 11, 2015

By: /s/ Matthew J. D'Onofrio  
Name: Matthew J. D'Onofrio  
Title: Executive Vice President,  
Chief Business Officer and Secretary

## Exhibit Index

Exhibit No.	Description
99.1	Roth 2015 Presentation

The logo for Evoke Pharma features the word "EVOKE" in a large, bold, blue sans-serif font. Below it, the word "PHARMA" is written in a smaller, grey sans-serif font, with each letter spaced out. To the right of the text is a stylized graphic consisting of several overlapping, curved lines in shades of blue and grey, resembling a signal or a wave.

**EVOKE**  
P H A R M A

NASDAQ: EVOK

# Forward-Looking Statements



This presentation contains forward-looking statements about Evoke Pharma, Inc. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negatives of these terms or other similar expressions. These statements are based on the company’s current beliefs and expectations. These forward-looking statements include statements regarding the timing of enrollment completion of Evoke’s ongoing Phase 3 clinical trial of EVK-001, the potential approval and commercialization of EVK-001 as a new and effective treatment for gastroparesis and Evoke’s completed and ongoing trials and studies serving as a basis for submission of a New Drug Application. The inclusion of forward-looking statements should not be regarded as a representation by Evoke that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risk and uncertainties inherent in Evoke’s business, including, without limitation: Evoke is entirely dependent on the success of EVK-001, for which it has commenced a Phase 3 clinical trial and male companion trial, and Evoke cannot be certain that it will be able to obtain regulatory approval for, or successfully commercialize, EVK-001; the results observed in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in Evoke’s Phase 2b clinical trial of EVK-001 may not be predictive of the safety and efficacy results in the Phase 3 clinical trial; the inherent risks of clinical development of EVK-001, including potential delays in enrollment and completion of the Phase 3 trial as well as potential delays in any other clinical trials and studies; Evoke will require substantial additional funding to complete the Phase 3 clinical trial and potentially commercialize EVK-001 as well as to finance additional development requirements, and may be unable to raise capital when needed, including to fund ongoing operations; the potential for adverse safety findings relating to EVK-001 to delay or prevent regulatory approval or commercialization; Evoke’s reliance on outsourcing arrangements for many of its activities, including clinical development and supply of EVK-001; the ability of Evoke to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of its product candidate and the ability to operate its business without infringing the intellectual property rights of others; competition from other pharmaceutical or biotechnology companies; and other risks detailed in prior press releases and in the periodic reports it files with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Evoke undertakes no obligation to revise or update this presentation to reflect events or circumstances after the date hereof.

All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended. Information included herein is based on clinical data Evoke has received to date and its evaluation of such data. All conclusions contained herein are subject to and contingent upon additional clinical data being generated by Evoke as well as the evaluation of such data by the FDA and other regulatory agencies



# Investment Highlights



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**Product Candidate**

- EVK-001: novel intranasal delivery of metoclopramide
- Symptomatic relief of acute and recurrent diabetic gastroparesis in women

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**Differentiation**

- By-passes dysfunctional stomach for predictable dosing
- Critical to patients with compromised gastrointestinal motility or experiencing symptoms of nausea/vomiting
- Improves current standard of care

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**Large, Growing and Unsatisfied Market**

- 12-16 million US gastroparesis patient population; 2-3 million estimated receiving therapeutic treatment
- Only 1 FDA approved oral product, metoclopramide (4 million Rx's written each year)
- Improved recognition and rising diabetic population increasing incidence and hospitalizations

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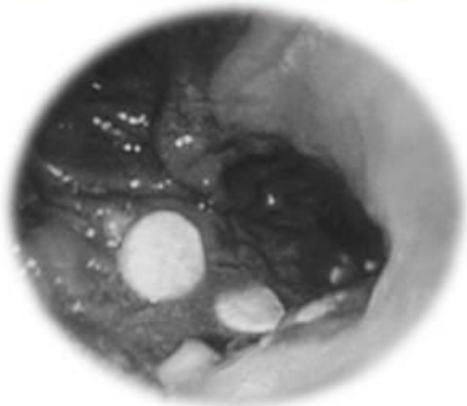
**Clear FDA Pathway**

- 505(b)(2) NDA filing allowing simplified submission
  - Phase 3 enrollment expected 2H 2015
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# Gastroparesis Overview



## Undissolved drug tablets in a stomach



Simpson, S.E., *Clinical Toxicology*, 2011

- Disorder in which the stomach is delayed in emptying contents to small intestine (in the absence of an obstruction)
- Interferes with GI absorption of medications and food due to unpredictable gastric emptying and vomiting
- Characteristic symptom flares of: nausea, vomiting, abdominal pain, early satiety, and bloating

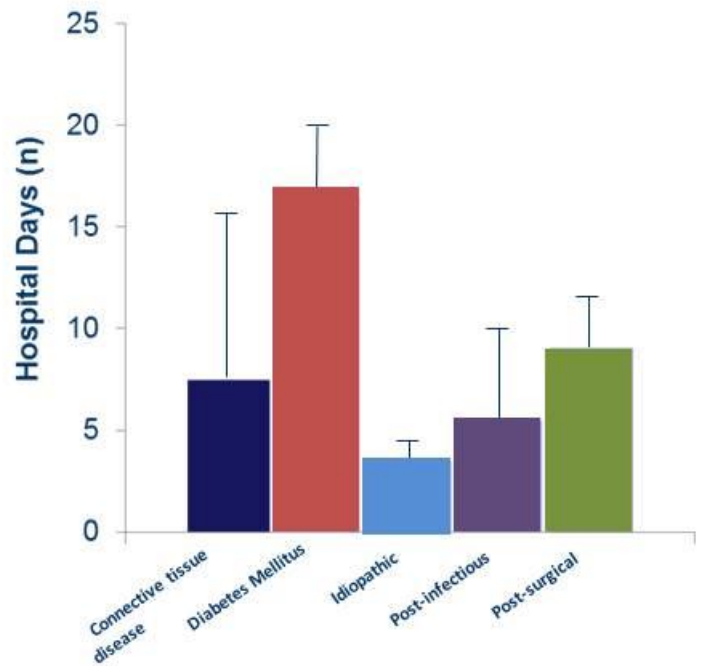
## The Consequences

- Diminished Quality of Life; Malnourishment; Poor diabetes control
- Hospitalization (on average 6+ days)\*

\* Wang, YM. *Am J of Gastroenterol* 2008; 103:313-322

# Gastroparesis: Significant Hospital Costs

- Since 2006, emergency room visits for gastroparesis increased 44.6%<sup>1</sup>
- Hospitalizations for gastroparesis as primary or secondary diagnosis increased:
  - 138% from 1995-2004<sup>2</sup>
  - 300% 1997-2009<sup>1</sup>
- Gastroparesis-related hospitalization costs<sup>2</sup>
  - \$3.5B in 2004
  - \$20K per patient per admission
- Gastroparetics utilize<sup>3</sup>
  - 3-16 hospital days per year
  - ~6 hospital days per stay
  - Diabetics require most care



<sup>1</sup> DDW, May 2012

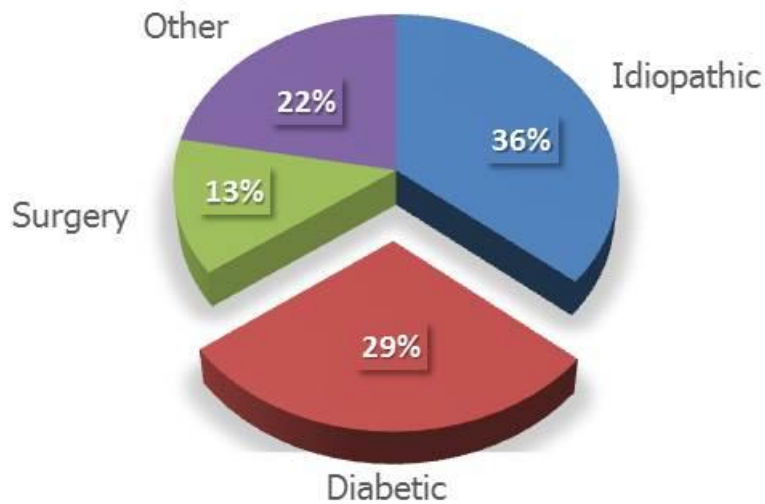
<sup>2</sup> Wang, YM. Am J of Gastroenterol 2008; 103:313-322

<sup>3</sup> Dudekula, A. J Gastroenterol Hepatol. 2011;26(8):1275-1282

# US Gastroparesis Population is Large and Growing



- Potentially 12-16 million patients with symptoms of gastroparesis
- Increasing prevalence due to growing diabetes rate and disease awareness/recognition



80% of all patients are women



• Samsom M, Roelofs J. "Prevalence of Delayed Gastric Emptying in Diabetic Patients and Relationship to Dyspeptic Symptoms." *Diabetes Care*, Vol. 26, No. 11, Nov. 2003, 3116-3122.

• Hasler WL. *Current Gastro Reports* 2007;9: 261-269/2007;9: 270-279

• Intagliato NJ, Koch KL. *Current Gastro Reports*

• Soykan I, Sivri B, Sarosiek I, Kiernan B, McCallum RW. Demography, clinical characteristics, psychological and abuse profiles, treatment, and long-term follow-up of patients with gastroparesis. *Dig Dis Sci* 1998;43:2398-404.

## Motility & Symptoms

- Metoclopramide (1<sup>st</sup> line)
- Domperidone (not approved in the US)

## Motility

- Erythromycin (not indicated)

## Symptoms

- Ondansetron, promethazine
- PPI's
- Narcotics



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## The Consequences

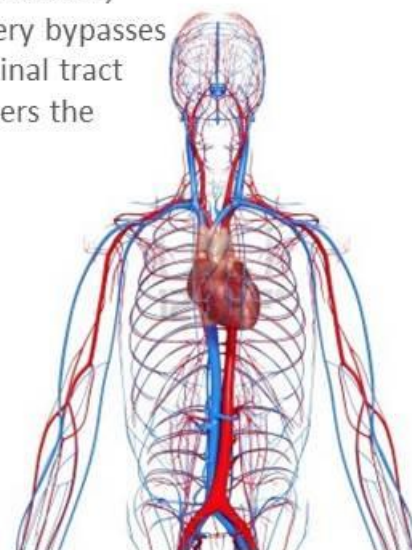
- Potential for erratic absorption (significant delay, multi-dose dumping or no absorption due to vomiting)
- Unpredictable efficacy and possible safety concerns for any oral medications taken by these patients who typically have comorbidities

# A novel approach for symptomatic relief for acute and recurrent diabetic gastroparesis in women

Sites of drug spray and absorption



Unlike oral medications, intranasal delivery bypasses the gastrointestinal tract and directly enters the bloodstream



EVK-001  
(Intranasal Metoclopramide)

Provides predictable absorption regardless of gastric emptying delays; Provides symptom relief even during flares



Product	Class	Route	Company	Development Status
EVK-001	Dopamine antagonist & mixed 5-HT <sub>3</sub> antagonist/5-HT <sub>4</sub> agonist	Intranasal	Evoke Pharma	<b>Phase 3 (enrolling)</b> <b>Phase 2b (n=287) results:</b> <b>Met prespecified symptomatic efficacy endpoint in both doses</b>
RM-131	Ghrelin agonist	Sub Cutaneous	Actavis/Rhythm Therapeutics	Phase 2b (early 2015) Phase 2a (n=204) results: Failed to meet secondary composite symptom endpoint with either dose
GSK962040	Motilin agonist	Oral	Glaxo	<b>Phase 2b (enrolling)</b> Phase 2a (n=79) results: No composite symptom endpoint results reported; effect seen for fullness only
TD-5108	5-HT <sub>4</sub> agonist	Oral	Theravance	<b>Phase 2 (end of 2014)</b> Phase 2a (n=34) results: No results reported for symptom relief
IW-9179	GC-C agonist	Oral	Ironwood	<b>Phase 2a (end of 2014)</b>
TC-6499	NNR	Oral	Targacept	<b>Exploratory Phase 1/2 (enrolling) for gastric emptying</b>

## Summary

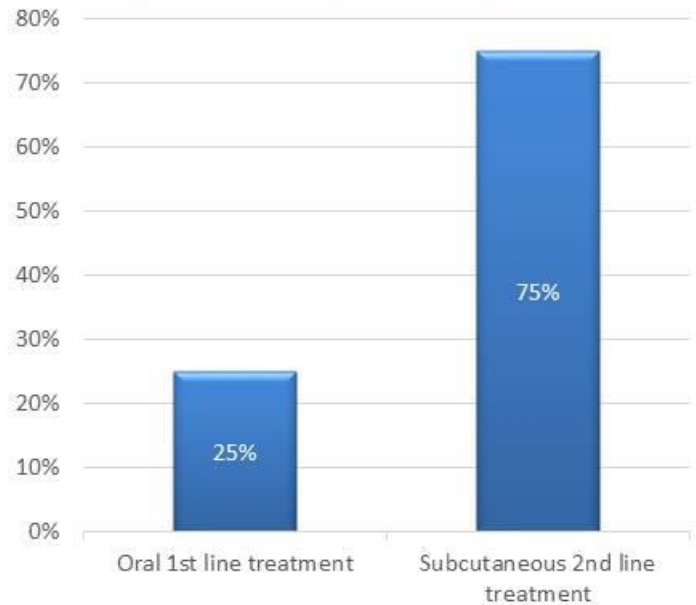
- FDA requires symptom relief as the primary endpoint for gastroparesis clinical trials
- Only EVK-001 has shown symptomatic efficacy in a primary endpoint

# Commercial Opportunity

# Oral treatments may be less optimal for patients with gastroparesis

“...in patients who had apparently failed oral metoclopramide trials, yet had no limiting side effect, the subcutaneous route could result in success. This route generates a **constant plasma level** of the drug when **vomiting and unpredictable absorption** limit the value of any orally administered agent.”

Success rates with different delivery routes of metoclopramide at a gastroenterology motility clinic





# EVK-001: Compelling Commercial Opportunity



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<b>Significant Unmet Need</b>	<ul style="list-style-type: none"><li>Physicians and patients report extensive interest in non-oral treatment alternatives to address unpredictable absorption (via compromised motility or vomiting)</li></ul>
<b>Ready-made Market</b>	<ul style="list-style-type: none"><li>4 Million prescriptions of oral metoclopramide prescribed per year</li><li>20-50% of patients use off-label treatments or go untreated</li></ul>
<b>Potential for Premium Pricing</b>	<ul style="list-style-type: none"><li>10 national plans indicate limited reimbursement impediments based upon various pricing scenarios</li></ul>
<b>Appropriate for Specialty Salesforce</b>	<ul style="list-style-type: none"><li>~7,200 metoclopramide prescribing gastroenterologists; allows for specialty representative salesforce</li><li>Significant specialist referral for diagnosis/treatment recommendation</li></ul>
<b>Rapid Uptake Possible</b>	<ul style="list-style-type: none"><li>No expected competitive sales force for several years after launch</li><li>Market research shows rapid incorporation into treatment regime</li></ul>

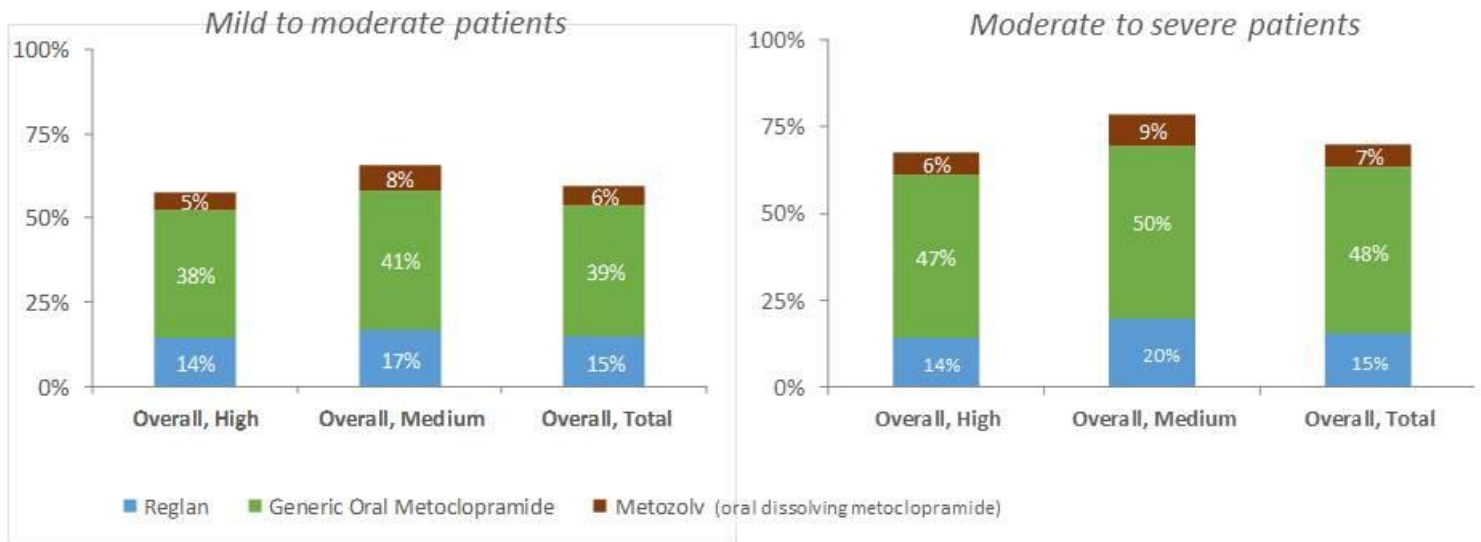
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# Metoclopramide: An Established Compound



50% - 80% of Patients Treated with Metoclopramide,  
Trending Higher in Moderate to Severe Patients



Source: ZS Associates Gastroparesis quantitative survey (n=121), Questions 3Q30 and 3Q37: What percent of your mild to moderate / moderate to severe gastroparesis patients are being managed with each of the following options? Your percentage can sum to over 100% if patients are receiving more than one therapy. Totals weighted based on average metoclopramide TRx's per high/medium segment.

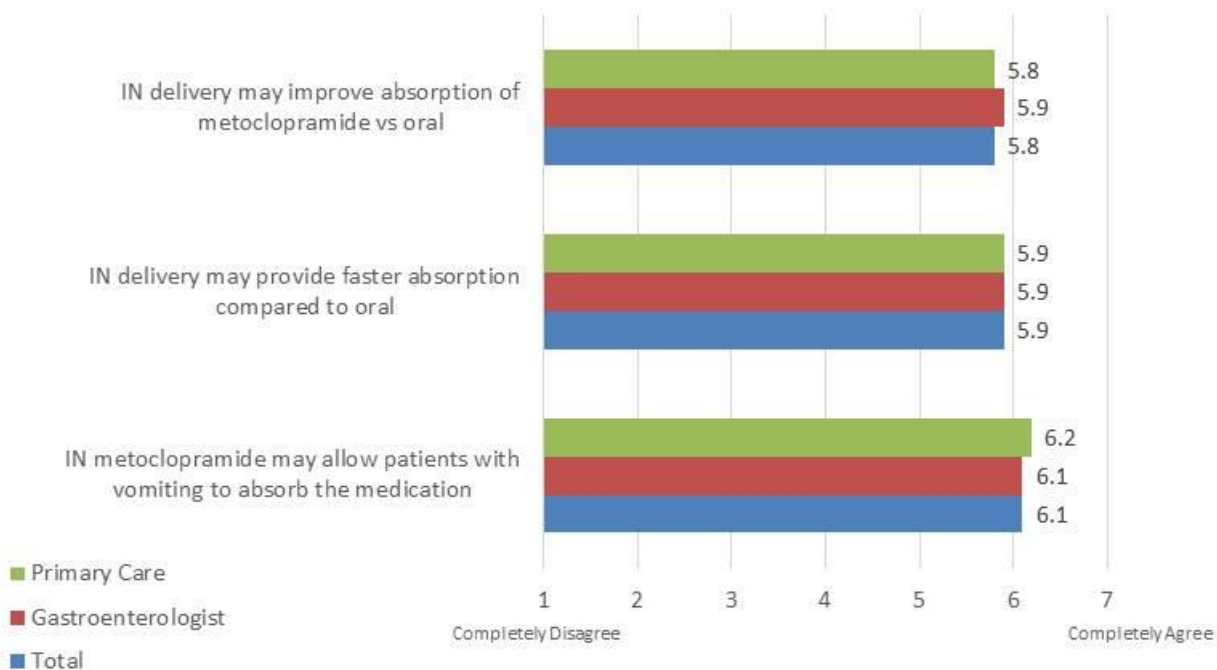
- Pasricha (2015)
  - “Delayed gastric emptying may also be important in explaining hypoglycemia, and possibly, erratic response to medications in patients with diabetes.”
- Rao and Camilleri (2010)
  - “Patients with gastroparesis have erratic emptying of solids from the stomach, making plasma drug levels unpredictable with an oral medication.”
- Lee and Kuo (2010)
  - “Alternative formulations may be beneficial in providing more consistent absorption of the medication and may potentially allow for the lowest efficacious dose to be used.”
  - “An intranasal formulation of metoclopramide may have advantages including rapid onset of delivery and circumvention of first pass metabolism compared with oral formulations.”



# MDs' Concerns Regarding Absorption of Medication Are Addressed by EVK-001's Product Profile

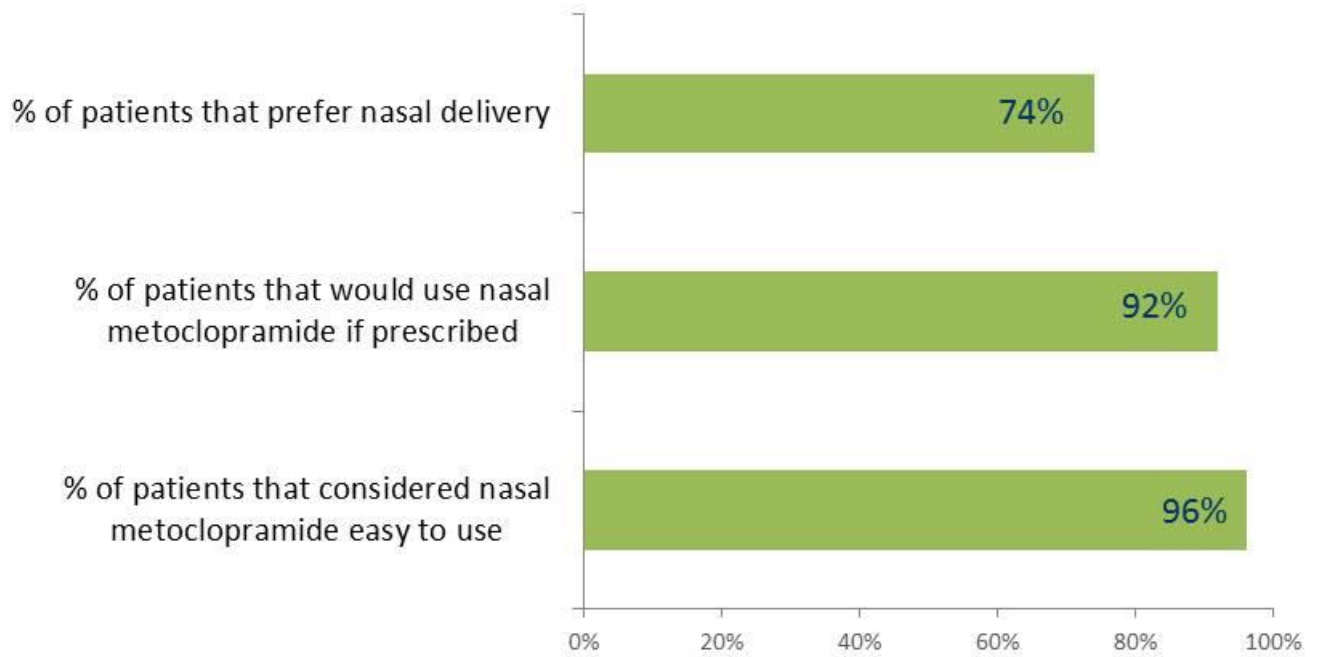


## Mode of Delivery Attributes



Source: ZS Associates Gastroparesis quantitative survey (n=121), Question 4Q5: How much do you agree with each of the following statements?  
Totals weighted based on average metoclopramide TRx's per high/medium segment

# Gastroparesis Patients Prefer Nasal Delivery

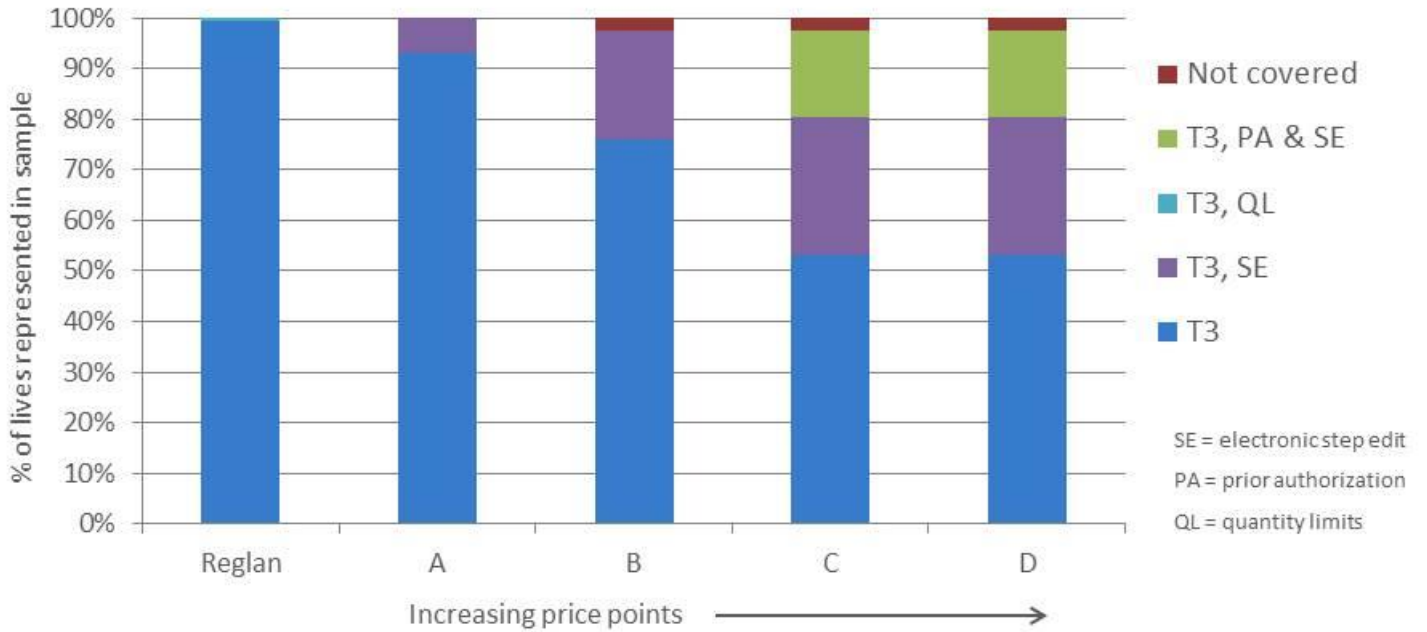


Source: G&S Research, May 2011 (n = 98). All previously diagnosed with diabetic gastroparesis and enrolled in METO-IN-002. Questions: 31, 35, 37, 38

# EVK-001 Payer Reimbursement Landscape



Commercial Predicted Formulary Access of EVK-001  
(n = 10; 104M total US lives represented)



## Summary

- As the majority of patients are already on generic metoclopramide, a step edit is projected to have minimal market share loss at the highest price point tested



## U.S. Granted Patents

<b>Patent #</b>	U.S. 6,770,262	U.S. 8,334,281
<b>Title</b>	Nasal Administration of Agents for the Treatment of Gastroparesis	Nasal Formulations of Metoclopramide
<b>Expires</b>	2021	2030

## PCT Application

<b>Application #</b>	PCT/US2012/052096
<b>Title</b>	Treatment of Symptoms Associated with Female Gastroparesis
<b>Expires</b>	2032 (if granted)

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### Summary

Current patents provide protection against:

- Delivering metoclopramide into the nose to treat symptoms associated with gastroparesis; and
- Using a spectrum of stable liquid formulations containing metoclopramide

# Clinical Development



# Phase 2b Study Design (METO-IN-002)

- US multicenter, randomized, double-blind, placebo-controlled, parallel group, dose-ranging clinical study of EVK-001 in diabetic subjects with gastroparesis
- 3 treatment arms (placebo, 10 mg and 14 mg)
- 4-week safety and efficacy study
- Primary Endpoint
  - Patient Reported Outcome (PRO)
    - modified Gastroparesis Cardinal Symptom Index - Daily Diary (mGCSI-DD)
    - Four symptom composite: nausea, early satiety, bloating, upper abdominal pain
  - Total score change from baseline to week 4

Currently the largest diabetic gastroparesis study ever conducted with metoclopramide (n=287)

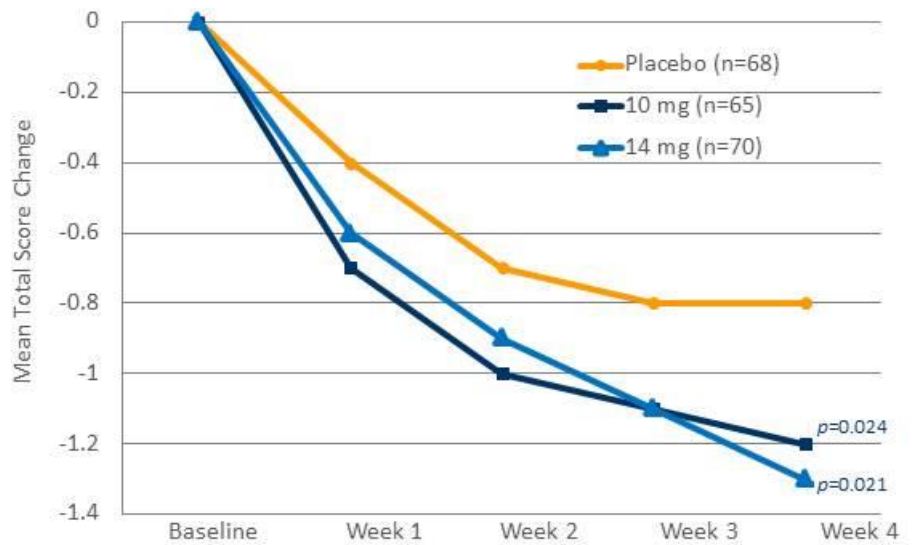
# Phase 2b Efficacy Results: Statistically Significant & Clinically Meaningful Improvement of Symptoms of Gastroparesis in Women



## Summary of Phase 2b Study

- Statistically significant difference between EVK-001 and placebo ( $p < 0.02$ ) for the **pre-specified** analysis group of females ( $n = 203$ )
- Results not significant for ITT population due to lack of statistical differentiation from placebo in males
- A treatment difference of .40 - .50 points is considered the minimally important (absolute) difference for GCSI total scores\*

**Mean mGCSI-DD Total Score Change from Baseline to Week 4 for Females**



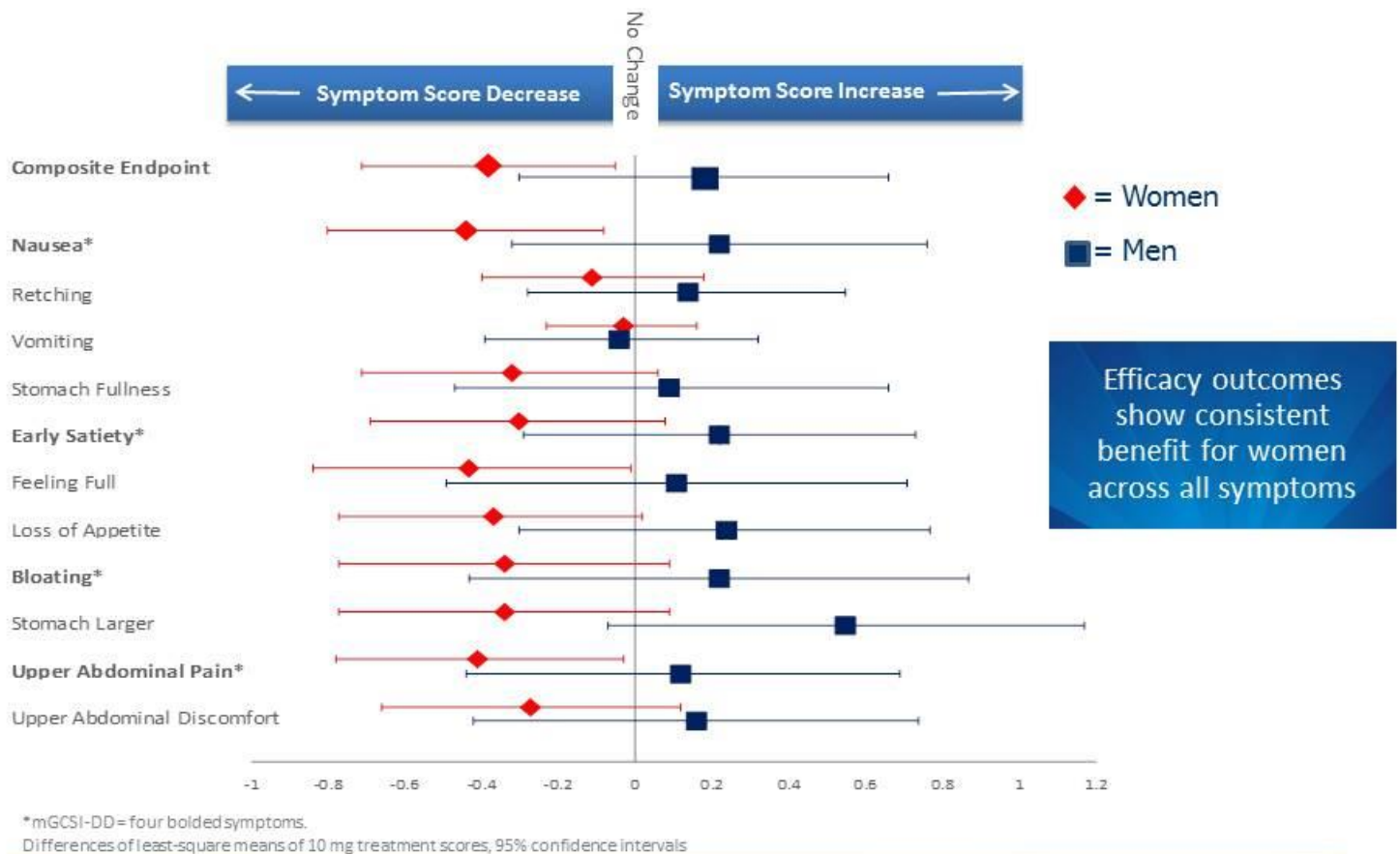
## Other Considerations

- METO-IN-002 revealed a gender difference not previously detected in smaller gastroparesis studies
- Gender effects have been reported in drug studies for other GI motility disorders, such as IBS, and products approved for women only indications

\*Revidi et al. (2004) Gastroparesis Cardinal Symptom Index (GCSI): development and validation of a patient reported assessment of severity of gastroparesis symptoms. *Qual Life Res.* 2004;13(4):833-44.

# Phase 2b Efficacy Results:

## Gender Disparity in Treatment Effects of EVK-001 vs. Placebo



## Favorable Safety Profile

- Majority of AEs were mild/moderate and transient in nature
- <10% dropouts, includes 5% due to adverse events (AEs)
- No significant cardiac changes throughout 28-day treatment period
- No SAEs reported related to study drug

Treatment-Emergent Adverse Events Reported by More than two Subjects in Any Treatment Group

	Placebo (N = 95)	EVK-001 10 mg IN (N = 95)	EVK-001 14 mg IN (N = 95)
Dysgeusia*	4 (4.2%)	12 (12.6%)	13 (13.7%)
Headache	4 (4.2%)	7 (7.4%)	8 (8.4%)
Dizziness	2 (2.1%)	3 (3.2%)	3 (3.2%)
Somnolence	0 (0.0%)	2 (2.1%)	2 (2.1%)
Fatigue	1 (1.1%)	5 (5.3%)	6 (6.3%)
Depression	3 (3.2%)	0 (0.0%)	0 (0.0%)
Diarrhea	9 (9.5%)	3 (3.2%)	2 (2.1%)
Nausea	4 (4.2%)	1 (1.1%)	4 (4.2%)
GERD	1 (1.1%)	4 (4.2%)	0 (0.0%)
Epistaxis	0 (0.0%)	2 (2.1%)	3 (3.2%)
Cough	2 (2.1%)	0 (0.0%)	3 (3.2%)
Nasaldiscomfort	0 (0.0%)	3 (3.2%)	2 (2.1%)
Rhinorrhea	1 (1.1%)	1 (1.1%)	3 (3.2%)
Throat irritation	1 (1.1%)	0 (0.0%)	3 (3.2%)
Upper resp. tract inf.	4 (4.2%)	0 (0.0%)	2 (2.1%)
Nasopharyngitis	1 (1.1%)	3 (3.2%)	1 (1.1%)
Hyperglycemia	1 (1.1%)	1 (1.1%)	3 (3.2%)
Hypoglycemia	1 (1.1%)	1 (1.1%)	3 (3.2%)

\* Of the subjects reporting dysgeusia, 34% were from one site (1 of 60)

# End of Phase 2 FDA Guidance



## Required for NDA Filing

- Single Phase 3 study in women only (ongoing)
  - Dose, regimen, duration (10 mg, QID, and 28 days), and endpoint
- ✓ Thorough QT study (**Completed**)
  - Despite absence of cardiac safety issues with metoclopramide

## Not Required for NDA filing

- Parallel companion study in men
  - Futility stop based on efficacy
  - Safety results will be included in female NDA

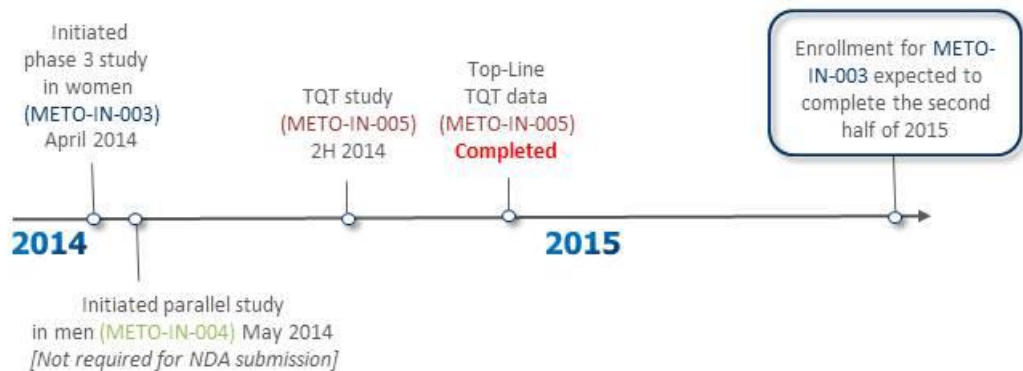


# Phase 3 Study for EVK-001



## Design

- Similar to successful Phase 2b study in women
- Double-blind, placebo-controlled, parallel-group, 28 day-study to evaluate the efficacy, safety and population pharmacokinetics in adult female subjects with diabetic gastroparesis
- Two treatment arms: EVK-001 10 mg or placebo QID (before meals and at bedtime)
- Primary endpoint is the change in the average GSA total score for baseline versus Week 4 of the treatment period
- ~200 subjects in a U.S. study, initiated in April 2014



# Experienced Senior Management & Board



<b>Cam Garner</b> Chairman, Founder	      
<b>Dave Gonyer, R.Ph.</b> President, CEO, Founder, Director	    
<b>Matt D'Onofrio, MBA</b> Chief Business Officer, Founder	  
<b>Marilyn Carlson, D.M.D, M.D., RAC</b> Chief Medical Officer	   

# Selected Financial Data



## Income Statement Data (in US \$)

	3 months ended December 31, 2014
Operating Expense	
Research & Development	\$2.2M
General Administrative	\$0.7M
Total Operating Expense	\$2.9M
Other (Income) Expense	\$0.0M
Net Loss	\$2.9M

## Balance Sheet Data (in US \$)

	December 31, 2014
Cash Balance	\$14.2M
Debt	\$4.5M

## Equity Outstanding at December 31, 2014

6.1M Common Shares
0.1M Warrants
0.7M Stock Options



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