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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): January 9, 2017**

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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 2.02 Results of Operations and Financial Condition.**

On January 9, 2017, Evoke Pharma, Inc. (the “Company” or “Evoke”), announced that its preliminary unaudited cash and cash equivalents as of December 31, 2016 were approximately \$9.0 million.

The preliminary unaudited cash position discussed above is subject to the completion of financial closing procedures and other developments that may arise between now and the time the financial results for the fourth quarter are finalized, as well as the completion of the audit of the 2016 financial statements. Therefore, actual results may differ materially from these estimates. In addition, the above estimates do not present all information necessary for an understanding of Evoke’s financial condition as of December 31, 2016.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form

**Item 7.01 Regulation FD Disclosure.**

Beginning on January 9, 2017, representatives of Evoke will be attending meetings with investors, analysts and other parties in connection with the J.P. Morgan 34th Annual Healthcare Conference in San Francisco, California. During these meetings, Evoke will present the slides attached as Exhibit 99.1 to this Current Report on Form 8-K, which are incorporated by reference.

The information in this Item 7.01, including Exhibit 99.1, is being furnished pursuant to Item 7.01 and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this item of this report.

**Forward Looking Statements.**

The Company cautions you that statements included in this Current Report on Form 8-K that are not a description of historical facts are forward-looking statements. 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 the pharmacokinetic (“PK”) study of Gimoti and submission of a new drug application (“NDA”), the potential approval and commercialization of Gimoti as a new and effective treatment for gastroparesis, the potential market size for Gimoti, the potential for Gimoti to be the only product that has shown symptomatic efficacy in an endpoint, Evoke’s protection of its intellectual property and Evoke’s belief that the PK study may serve as a basis for submission of a NDA. The inclusion of forward-looking statements should not be regarded as a representation by the Company that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in the Company’s business, including, without limitation: the statistically-significant data from the Phase 3 clinical trial of Gimoti only includes a portion of the patients in trial and that the Phase 3 trial failed to reach its primary endpoint; risks associated with successfully commencing and receiving favorable results from the planned PK study; later developments with the Food and Drug Administration (“FDA”) that may be inconsistent with the already completed pre-NDA meetings, including that the FDA will not accept selected data from our Phase 3 clinical trial; the FDA may change its recommendations regarding evaluation of drugs for the treatment of gastroparesis; the inherent risks of clinical development of Gimoti; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that it will be able to submit an NDA for Gimoti or obtain regulatory approval for or successfully commercialize Gimoti; risks associated with manufacturing new formulations of Gimoti for use in the PK trial; Evoke’s dependence on third parties for the manufacture of Gimoti as well as the conduct of the PK trial; Evoke may require additional funding to complete the PK study and submit the NDA, and will require substantial additional funding to commercialize Gimoti, and may be unable to raise capital when needed, including to fund ongoing operations; Evoke may not be able to successfully commercialize Gimoti, if approved, as a result of risks associated with market acceptance, coverage and reimbursement and competing products; and other risks detailed in the periodic reports Evoke 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 the Company undertakes no obligation to revise or update this report 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 the Private Securities Litigation Reform Act of 1995.

**Item 9.01. Financial Statements and Exhibits.**

*(d) Exhibits.*

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Exhibit  
No.

Description

99.1

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.

EVOKE PHARMA, INC.

Date: January 9, 2017

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



**EVOKE**  
P H A R M A

Exh. 99.1

NASDAQ: EVOK  
January 2017

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 the pharmacokinetic (PK) study of Gimoti and submission of a new drug application (NDA), the potential approval and commercialization of Gimoti as a new and effective treatment for gastroparesis, the potential market size for Gimoti, the potential for Gimoti to be the only product that has shown symptomatic efficacy in an endpoint, Evoke’s protection of its intellectual property and Evoke’s belief that the PK study may serve as a basis for submission of a NDA. 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: the statistically-significant data from the Phase 3 clinical trial of Gimoti only includes a portion of the patients in trial and that the Phase 3 trial failed to reach its primary endpoint; risks associated with successfully commencing and receiving favorable results from the planned PK study; later developments with the Food and Drug Administration (FDA) that may be inconsistent with the already completed pre-new drug application (NDA) meetings, including that the FDA will not accept selected data from our Phase 3 clinical trial; the FDA may change its recommendations regarding evaluation of drugs for the treatment of gastroparesis; the inherent risks of clinical development of Gimoti; Evoke is entirely dependent on the success of Gimoti, and Evoke cannot be certain that it will be able to submit an NDA for Gimoti or obtain regulatory approval for or successfully commercialize Gimoti; risks associated with manufacturing new formulations of Gimoti for use in the PK trial; Evoke’s dependence on third parties for the manufacture of Gimoti as well as the conduct of the PK trial; Evoke may require additional funding to complete the PK study and submit the NDA, and will require substantial additional funding to commercialize Gimoti, and may be unable to raise capital when needed, including to fund ongoing operations; Evoke may not be able to successfully commercialize Gimoti, if approved, as a result of risks associated with market acceptance, coverage and reimbursement and competing products; and other risks detailed in the periodic reports Evoke 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.

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**Product**

- Gimoti™: a novel nasal delivery of metoclopramide
- Symptomatic relief of acute and recurrent diabetic gastroparesis in women

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**Differentiation versus Oral Medications**

- Predictable absorption despite delayed and erratic stomach emptying
- Absorption not affected by vomiting

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**Large, Growing & Unsatisfied Market**

- 12-16M patients in US, 80% female
- Only 1 FDA-approved product: metoclopramide (oral & IV)
- ~4M prescriptions annually for oral metoclopramide

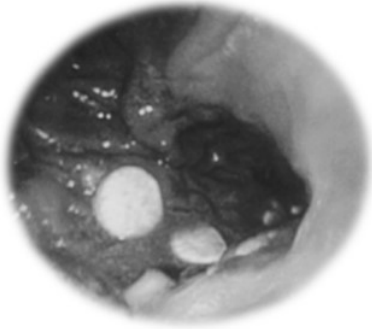
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**Clinical and Regulatory Pathway**

- Phase 3 Efficacy Data: statistical significance demonstrated in patients with moderate to severe gastroparesis symptoms at baseline despite not meeting primary endpoint
- Pre-NDA Meetings Successful: In August and December 2016, obtained positive guidance for Gimoti NDA (include pharmacokinetic (PK) study) and Regulatory, CMC, and Non-clinical plans were agreeable

## Disease severity can cause malnutrition and result in hospitalization

Undissolved drug tablets in stomach



Simpson, S.E, Clinical Toxicology, 2011

- Delayed emptying of stomach contents to small intestine (in the absence of an obstruction) interferes with oral absorption
- Vomiting further complicates effectiveness of oral medications
- Symptoms characteristic of flare:

Nausea	Abdominal Pain	Early Satiety
Bloating	Prolonged Fullness	Vomiting

### Impact on patients:

Diminished Quality of Life • Malnourishment • Poor Diabetes Control • Hospitalizations (Avg. 6+ days\*)

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





- **Estimated \$3-4B prescription market**
- **\$3.5B in additional hospitalization costs in 2004**
- ~2-3M patients currently receive treatment
- Under-diagnosed in part due to lack of awareness
- Diabetes is number one known cause
- Increasing prevalence due to growing diabetes rate
- **80% of diabetic gastroparesis patients are women**

1. Wang, Parkman. "Gastroparesis Related Hospitalizations in the United States: Trends, Characteristics and Outcomes 1995-2004" *AM J Gastroenterol* 2008; 103:313-322
2. 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
3. Hasler WL. *Current Gastro Reports* 2007; 9: 261-269/2007; 9: 270-279
4. Intagliato NI, Koch KL. *Current Gastro Reports*
5. 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

## Current oral treatment options lack predictable delivery

- **Motility & Symptoms**
  - Metoclopramide (1<sup>st</sup> line)
  - Domperidone (not FDA-approved)
- **Motility**
  - Erythromycin (not indicated)
- **Symptoms**
  - Ondansetron, promethazine (N & V)
  - PPI's (Abdominal pain)
  - Narcotics (Abdominal pain)



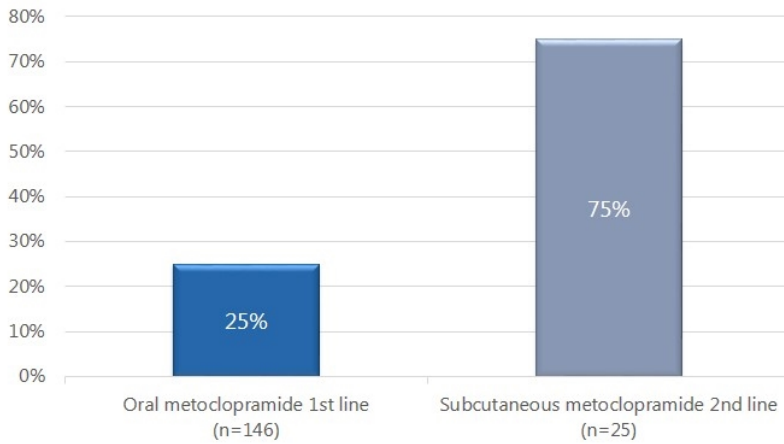
### **Ineffective Treatments and Inadequate Response**

- Erratic absorption of oral drugs\* (significant delay, multi-dose dumping) or no absorption due to vomiting
- Unpredictable efficacy and potential safety concerns
- Lack of compliance due to nausea and other GI symptoms

\* Gastroparesis: Clinical Evaluation of Drugs for Treatment FDA Guidance for Industry, July 2015

## Success rate for alternative administration shown to be 3x higher than oral

Metoclopramide gastroparesis success rates by delivery route at a GI motility clinic



- “This non-oral route generates a constant plasma level of the metoclopramide when:
  - Patients are vomiting
  - Unpredictable absorption limits the value of any orally administered agent”
- Clinical study only: Subcutaneous metoclopramide not commercially available and not FDA approved

Soykan. et al Digestive Diseases and Sciences, Vol. 43, No. 11 (November 1998)

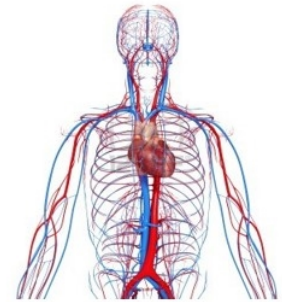
## Novel approach for symptomatic relief of acute & recurrent diabetic gastroparesis in women

Sites of nasal spray delivery and absorption

**Gimoti**  
(metoclopramide nasal spray)



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



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

- Efficacy
  - Primary endpoint not met (N = 205,  $p = 0.881$ )
  - Statistically significant results demonstrated in patients with moderate to severe gastroparesis symptoms at baseline at multiple time points
  - Significant placebo effect in mild patients
- Safety
  - Gimoti was well-tolerated
  - Similar or fewer adverse events of special interest (CNS, nasal) for Gimoti compared to placebo
  - No Serious Adverse Events (SAE) related to study drug

- Randomized double-blind, placebo-controlled, parallel-group, 28-day US study evaluated the efficacy, safety and population pharmacokinetics in adult female subjects with diabetic gastroparesis and delayed gastric emptying
- Two treatment arms: Gimoti or placebo, one spray before meals and at bedtime
- Primary endpoint: Change in GSA total score from Baseline to Week 4 of treatment
- 205 total patients



- Patients with moderate to severe symptoms (N = 105, 51% of subjects) responded statistically significantly better to Gimoti than placebo
  - Analysis of patients with higher symptom severity consistent with FDA Draft Guidance (July 2015)

	Population	Time Period	Placebo <sup>1</sup>	Gimoti <sup>1</sup>	p-value <sup>2</sup>
Estimated Mean Change from Baseline in Mean Daily GSA Total Scores: Moderate to Severe Study Populations	<b>Intent-to-Treat</b>	Week 1	(N = 53) -0.387	(N = 52) -0.588	0.036
		Week 2	-0.614	-0.950	0.025
		Week 3	-0.749	-1.096	0.039
		Week 4	-0.856	-1.220	0.085*
	<b>Per Protocol</b>	Week 1	(N = 40) -0.362	(N = 38) -0.623	0.019
		Week 2	-0.625	-1.040	0.015
		Week 3	-0.714	-1.286	0.003
		Week 4	-0.841	-1.373	0.014

<sup>1</sup>LSMean from ANCOVA

<sup>2</sup>p-value is obtained from an ANCOVA model with fixed effect for treatment group and the baseline value as a covariate. If the normality assumption was not met, the p-value was obtained from a rank ANCOVA test and denoted with an \*.

- Patients with moderate to severe symptoms had a statistically significant improvement in nausea and abdominal pain consistent with previous studies

Mean Change from Baseline to Week 4 in Mean Daily Nausea and Upper Abdominal Pain Score in ITT Population with Moderate to Severe Symptoms

Symptom	Time Period	Placebo <sup>1</sup> (N = 53)	Gimoti <sup>1</sup> (N = 52)	p-value <sup>2</sup>
Nausea	Week 1	-0.370	-0.859	0.001
	Week 2	-0.696	-1.149	0.032*
	Week 3	-0.818	-1.242	0.043
	Week 4	-0.905	-1.404	0.027
Upper Abdominal Pain	Week 1	-0.394	-0.641	0.025
	Week 2	-0.554	-0.990	0.016
	Week 3	-0.690	-1.194	0.008
	Week 4	-0.791	-1.218	0.047

<sup>1</sup>LSMean from ANCOVA

<sup>2</sup>p-value is obtained from an ANCOVA model with fixed effect for treatment group and the baseline value as a covariate. If the normality assumption was not met, the p-value was obtained from a rank ANCOVA test and denoted with an \*.

## Statistically Significant & Clinically Meaningful Improvement in Women

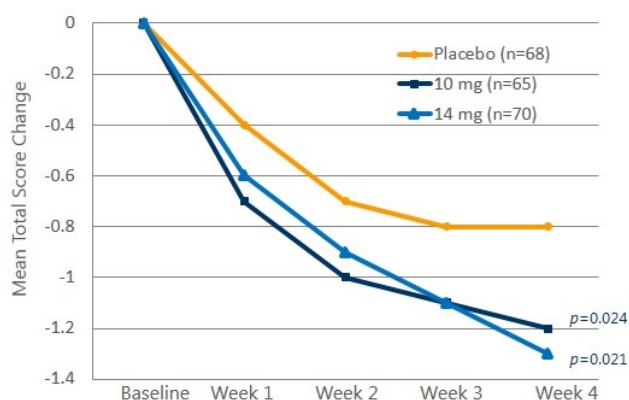
- Summary of Phase 2b Study

- Statistically significant difference between Gimoti and placebo ( $p < 0.02$ ) for pre-specified analysis group of females ( $n = 203$ )
- Results not significant for ITT population due to lack of statistical differentiation from placebo in males ( $n = 84$ )

- Other Considerations

- METO-IN-002 revealed 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 female-only indications

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



\*Revicki 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.

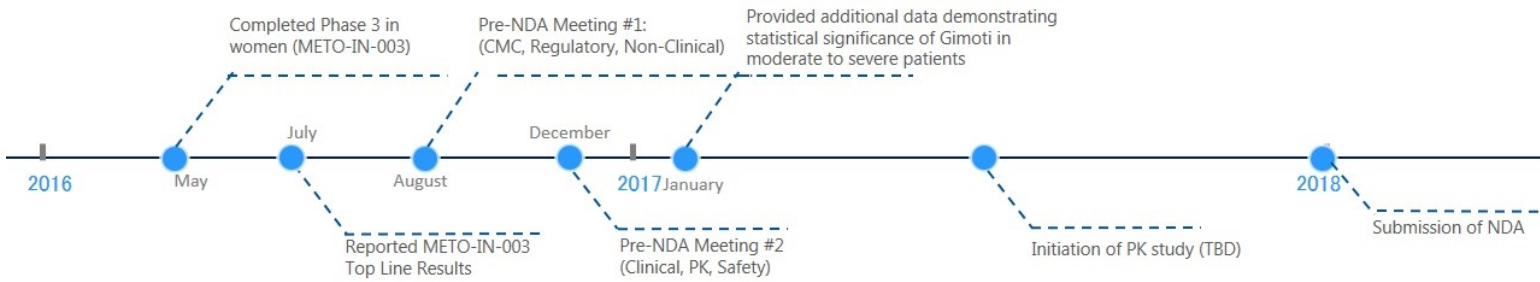


	Phase 2			Phase 3	
	Placebo (N=95)	10 mg (N=95)	14 mg (N=95)	Placebo (N=103)	10 mg (N=102)
Adverse Events (AEs)					
Nervous System	12%	25%	30%	12%	10%
Respiratory System	8%	13%	18%	12%	7%
Epistaxis	2%	2%	3%	2%	1%
Nasal discomfort	0	3%	2%	4%	1%
Serious Adverse Events (n)	4	0	2	2	3

### Favorable Safety Profile in Phase 1 ,2, 3 and TQT studies

- No deaths, few SAE's and no SAE's related to study drug
- Dropouts
  - Phase 2 = 10% (includes 5% due to AE)
  - Phase 3 = 7% (includes 2% due to AE)
- TQT study: No QT prolongation at supratherapeutic dose (80 mg)

- FDA guidance provided at Pre-NDA Meetings
- Currently developing strategy for healthy volunteer pharmacokinetic (PK) study
- In discussions with
  - Manufacturing organizations
  - Phase I clinical study sites
- NDA development in parallel with PK trial



Clinical Development

**Significant Unmet Need**

- Physicians and patients report broad interest in non-oral treatment alternatives to address unpredictable absorption
- No new therapies for gastroparesis since 1980

**Ready-made Market**

- 4M prescriptions of oral metoclopramide annually
- 20-50% of patients use off-label treatments or go untreated

**Potential for Premium Pricing**

- 30 national and regional plans indicate limited reimbursement impediments based upon various pricing scenarios

**Appropriate for Specialty Salesforce**

- ~7,200 metoclopramide prescribing gastroenterologists allows for small, targeted salesforce
- Significant referrals for diagnosis/treatment from specialists

**Rapid Uptake Possible**

- No expected competitive sales force for several years after launch
- Market research shows rapid incorporation into treatment regime

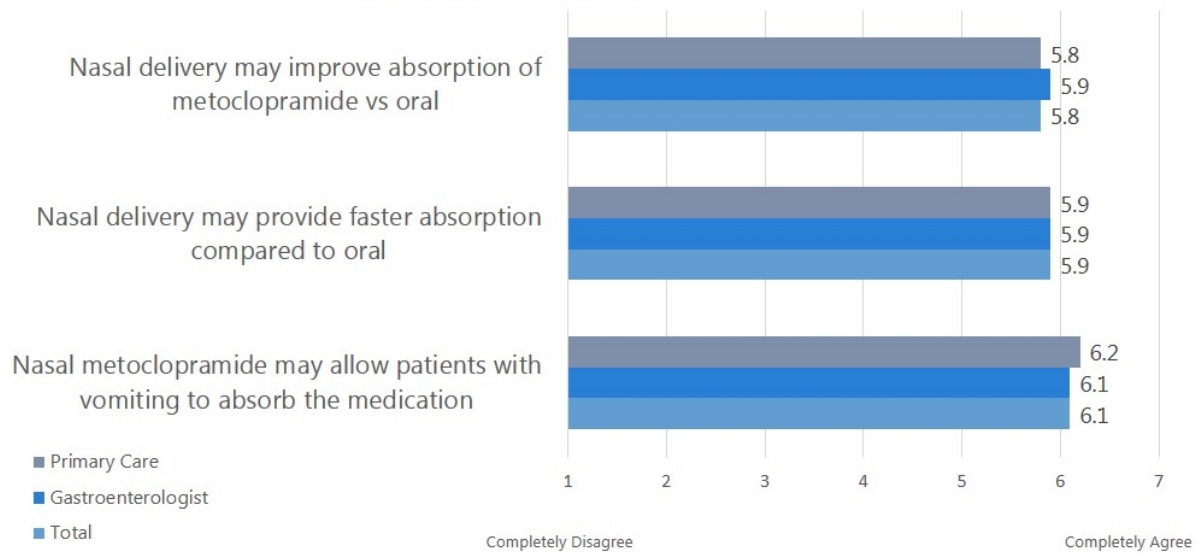
## Strong competitive advantages

- FDA requires symptom relief for any new chemical entity as the primary endpoint for gastroparesis
- Gimoti only known product with statistically significant symptom efficacy in pre-specified endpoint

Product	Class	Route	Company	Development Status
<b>Gimoti</b>	<b>Dopamine antagonist &amp; mixed 5-HT<sub>3</sub> antagonist/5-HT<sub>4</sub> agonist</b>	<b>Nasal</b>	<b>Evoke Pharma</b>	Phase 3 (n=205): Statistical significance achieved in patients with moderate to severe gastroparesis. Did not meet primary endpoint for ITT. FDA agreed NDA could be submitted with additional PK study as a portion of Gimoti filing
Relamorelin	Ghrelin agonist	Sub Cutaneous	Allergan/Motus/Rhythm Therapeutics	<b>Phase 2b</b> Phase 2b results: Failed to meet primary endpoint in symptomatic relief of vomiting reduction. Phase 2a results: Failed to meet secondary symptom endpoint with either dose
Velusetrag	5-HT <sub>4</sub> agonist	Oral	Theravance	<b>Phase 2b (enrolling)</b> Phase 2a (n=34) results: No results reported for symptom relief
Tradipitant	NK-1 antagonist	Oral	Vanda	<b>Phase 2 (enrolling):</b> No prior results in gastroparesis
Renzapride	5-HT <sub>4</sub> agonist and 5HT-3 antagonist	Oral	EndoLogic	<b>Phase 2a (completed 2008)</b> No results reported for symptom relief (gastric emptying only)
ATC-1906	D2/D3 receptor antagonist	Oral	Takeda	<b>Phase 1 (ongoing):</b> No known results

## Commercial Opportunity

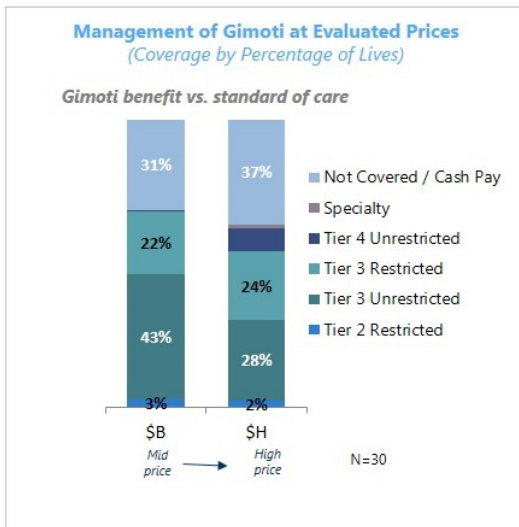
## Mode of Delivery Attributes



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

Commercial Opportunity

## Anticipate Gimoti to be widely available to commercial plan members



- Ample commercial insurance reimbursement expected
  - Prices similar to (\$B) or higher than (\$H) than current branded GI products
  - Similar regardless of label (profile) differentiation
- Mostly Tier 3 “Unrestricted” or “Restricted” coverage projected (typical for branded products)
- Expecting relatively less reimbursement issues due to
  - Lack of competitive products
  - Large unmet need
  - Significant current medical costs for hospitalization

Source: Campbell Alliance Web-based surveys with 18 pharmacy directors and 12 medical directors. April 29 through May 26, 2015.



## 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

U.S. Granted Patents			PCT Application	
Patent #	U.S. 6,770,262	U.S. 8,334,281	Application #	PCT/US2012/052096
Title	Nasal Administration of Agents for the Treatment of Gastroparesis	Nasal Formulations of Metoclopramide	Title	Treatment of Symptoms Associated with Female Gastroparesis
Expires	2021	2030	Expires	2032 (if granted)

## Income Statement Data (in USD)

3Q 2016	(Ended September 30, 2016)
Operating Expense	
Research & Development	\$1.3M
General Administrative	\$0.8M
Total Operating Expense	\$2.1M
Other (Income) Expense	\$0.8M
Net Loss	\$3.0M

## Cash (in USD) and Equity Data

	September 30, 2016
Cash Balance	\$10.4M
Common Shares Outstanding	12.4M
Warrants	3.3M
Stock Options	1.3M

	December 31, 2016
Cash Balance	\$9.0M



- **Gimoti™**: novel nasal delivery of metoclopramide for the symptomatic relief of acute and recurrent diabetic gastroparesis in women
- **Only one FDA-approved therapy for gastroparesis**: Metoclopramide (oral & IV) which has ~4M million prescriptions of the oral medication annually
- **Serves unmet clinical need**: Provides predictable absorption despite gastroparesis symptoms
- **Large market opportunity**: 12-16M patients in US (80% women)
- **Positive additional data from Phase 3 trial**: Gimoti demonstrated a statistically significant benefit in patients with moderate to severe gastroparesis demonstrated
- **Received positive NDA guidance from FDA**: A PK trial could serve as portion of an NDA for Gimoti

