

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

# Corporate Presentation

December 2024

NASDAQ: EVOK

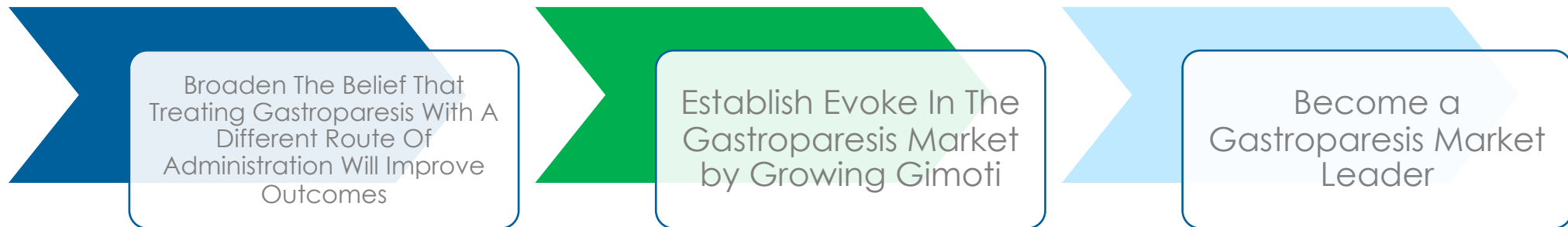


# Disclaimers

Evoke cautions you that statements included in this presentation 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 Company’s commercialization plans, including its plans to increase awareness and access to GIMOTI, and commercial activities to be conducted by EVERSANA; the potential of GIMOTI to provide an important new alternative to current treatment options; the potential commercial opportunity for GIMOTI including the potential pricing and reimbursement coverage; potential future prescribing trends for GIMOTI based on market surveys of healthcare providers or the Company’s marketing efforts; projected cash runway and expected intellectual property protection and regulatory exclusivity for GIMOTI. 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 risks and uncertainties inherent in Evoke’s business, including, without limitation: Evoke’s and EVERSANA’s ability to successfully drive market demand for GIMOTI; the results of market surveys may not predict prescribing trends by doctors or acceptance by patients, and are not intended to reflect or imply actual prescriptions or sales to date; Evoke’s ability to obtain additional financing as needed to support its operations; Evoke is dependent on EVERSANA to commercialize GIMOTI and EVERSANA has the right to terminate the commercialization agreement in certain circumstances, including a quarterly termination right because net profit has been negative for two consecutive quarters; Evoke’s dependence on third parties for the manufacture of GIMOTI; Evoke is entirely dependent on the success of GIMOTI; inadequate efficacy or unexpected adverse side effects relating to GIMOTI that could harm commercialization, or that could result in recalls or product liability claims; Evoke may use its capital resources sooner than expected; Evoke’s ability to obtain and maintain intellectual property protection and regulatory exclusivity for GIMOTI; and other risks detailed in Evoke’s periodic reports it files with the Securities and Exchange Commission (SEC). 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 the Private Securities Litigation Reform Act of 1995. This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

# Who We Are

- Evoke Pharma is a commercial-stage gastroenterology company dedicated to fulfilling a significantly unmet health need for patients with gastroparesis
- Our FDA-approved product, Gimoti® (metoclopramide HCl) nasal spray was developed to offer health care professionals and patients a direct and unique approach to treat symptoms associated with gastroparesis
- Exclusively focused on the commercial growth of Gimoti
- Headquartered in San Diego, CA

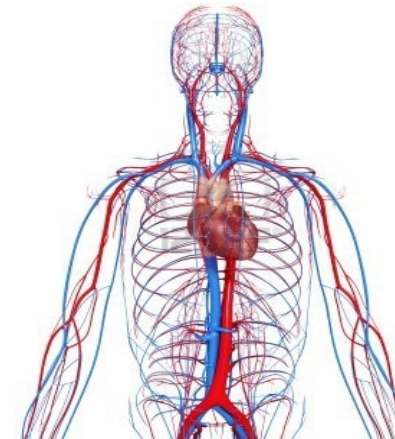
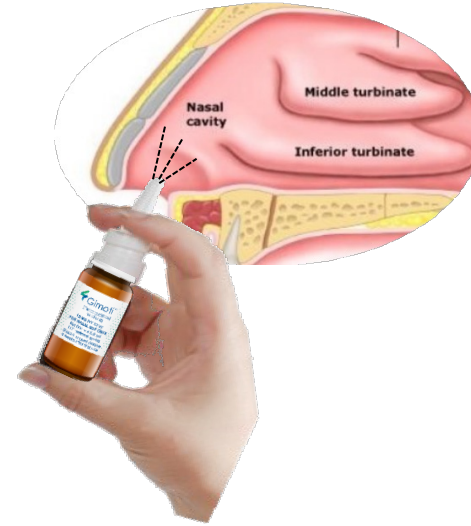


# Gimoti is the first and only FDA-approved non-oral outpatient treatment for gastroparesis



## Nasal Route of Administration

- Designed to:
  - Provide absorption regardless of gastric emptying delays
  - Deliver symptom relief during flares (nausea and vomiting)
  - Bypass the GI tract to directly enter the bloodstream, unlike oral medications



# Limitations of Current Oral Treatments

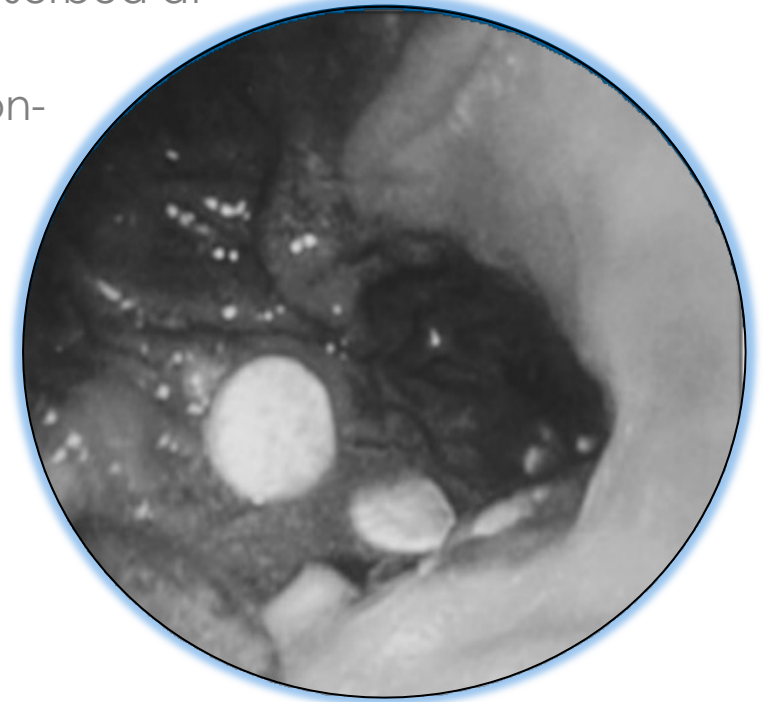
*Vomiting and/or unpredictable gastric emptying can interfere with absorption of oral medications for glycemic control, comorbidities and diabetic gastroparesis*

Erratic absorption may lead to:

- Too much drug - multi-dose dumping (collecting pills in stomach then absorbed at once; includes metoclopramide and other drugs)
- Too little drug - no absorption due to vomiting (pill ejection) or patient non-compliance due to nausea/vomiting

## Current Treatments

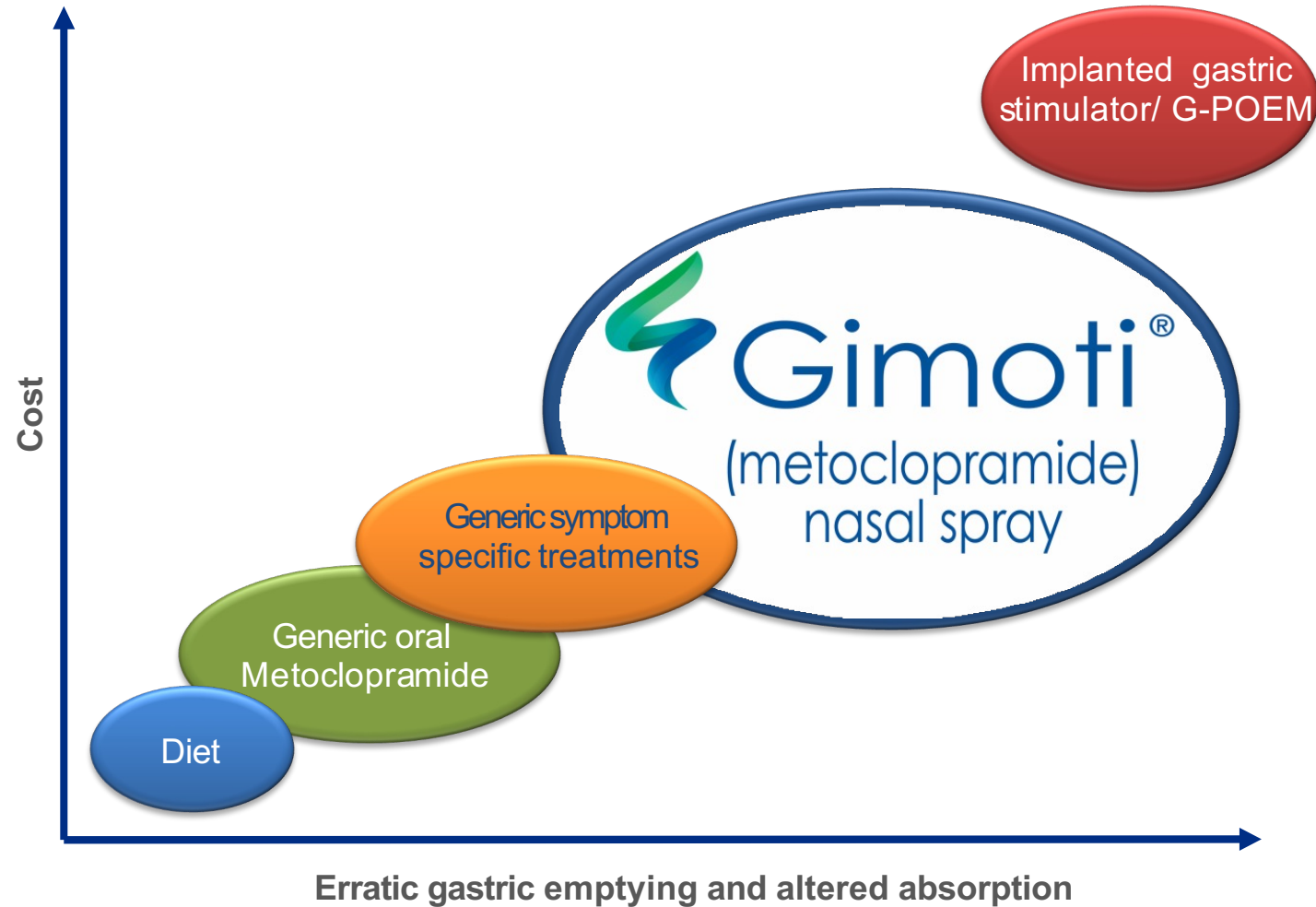
- Motility & Symptoms
  - Oral metoclopramide (AGA recommended)
  - Domperidone (not FDA approved)
- Motility
  - Erythromycin (used off-label)
- Symptoms
  - Ondansetron (nausea/vomiting)
  - PPI's and Narcotics (abdominal pain)



# Gimoti Fills the Treatment Gap for Patients

## Gastroparesis Treatment Journey

- 1<sup>st</sup> line – medication & lifestyle
  - Diet modifications to smaller liquid meals
  - Oral or **nasal (Gimoti)**
- 2<sup>nd</sup> line - medication
  - **For those initially on oral with continued symptoms, move to the non-oral option (Gimoti)**
  - Move to or add other oral treatments to address individual symptoms
- 3<sup>rd</sup> line - surgery
  - Gastric stimulator surgically implanted
    - Not been proven efficacious\*
    - Costly (~\$50 to \$100K)
  - G-POEM (Gastric peroral endoscopic myotomy)
    - Limited efficacy data



\*Humanitarian Device: The Enterra Therapy system for gastric electrical stimulation is authorized by Federal law for use in treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The effectiveness of this device for this use has not been demonstrated."



# FDA Review of Patient Experience Data for Gimoti

## A Need for Effective, Alternative Routes of Administration



- “Together, the results from the interview of the patients who participated in the Gimoti phase 2b trial and the patient discussion forums supports that **patients with gastroparesis may, in general, benefit from alternatives to oral solid dosage forms**, including but not limited to metoclopramide.”<sup>1</sup>
- “Patients with diabetic gastroparesis **may experience further derangement of glucose control** because of unpredictable gastric emptying and altered absorption of orally administered hypoglycemic drugs”<sup>2</sup>



References: 1. Gimoti NDA Multidisciplinary Review FDA 6/18/2020 2. Gastroparesis: Clinical Evaluation of Drugs for Treatment Draft FDA Guidance for Industry. Aug. 2019.

# Gastroparesis: The Market Opportunity

~12-16 million in the US with symptoms of gastroparesis

- Under-diagnosed in part due to lack of awareness
- Diabetes is the number one known cause
- Increasing reports of GLP-1 agonist related gastroparesis

~2-3 million patients currently receive treatment

- Prevalence increasing due to growing diabetes population
- 80% are women

Estimated \$3-4 billion prescription market (and new upside)

- Hospitalizations extended and costly
  - \$3.5 billion in additional hospitalizations costs in a single year
  - ~\$35,000 in mean costs per hospitalization per patient
- GLP-1 treatment driving up gastroparesis diagnosis

Only one product commercially marketed - Gimoti

- Wang, Parkman. "Gastroparesis Related Hospitalizations in the United States: Trends, Characteristics and Outcomes 1995-2004" *AM J Gastroenterol* 2008; 103:313-322
- 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 NI, Koch KL. *Current Gastro Reports*
- Soykan I, Sivi 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
- World Journal Of Gastroenterology, vol 23, no. 24, 2017, p. 4428.





# GLP-1's May Expand the Diabetic Gastroparesis Market

*Diabetes and Delayed Gastric Emptying is the key patient type*

health Life, But Better Fitness Food Sleep Mindfulness Relationships

## They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed

By Brenda Goodman, CNN  
Updated 3:27 PM EDT, Tue July 25, 2023

Glucagon-like peptide (GLP-1) based therapies affect glucose control through several mechanisms

- Enhancement of glucose-dependent insulin secretion
- Reduction of postprandial glucagon and food intake
- Slowed gastric emptying

<https://jamanetwork.com/journals/jama/article-abstract/2810542>  
<https://www.upToDate.com/contents/glucagon-like-peptide-1-based-therapies-for-the-treatment-of-type-2-diabetes-mellitus>  
<https://www.healio.com/news/primary-care/20230227/most-adults-with-diabetes-eligible-for-glp1-ras-salt2-inhibitors-but-few-receive-them>  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5278808/>  
<https://www.cnbc.com/2023/10/23/wall-street-hikes-forecasts-for-anti-obesity-drug-sales-to-100-billion.html>

The market for GLP-1 agonists is growing with disease expansion

- Diabetes
  - 54.9 million US population with diabetes by 2030
  - 80% of adults with type-2 in the US meet the criteria for GLP-1 receptor agonists or SGLT2 inhibitors
  - Only about one in 10 used either medication from 2017 to 2020
- Obesity
  - Estimate ~13% US penetration (15 million adults) by 2030
  - Excludes diabetes usage

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## Researchers link popular weight loss drugs to serious digestive problems for 'hundreds of thousands' worldwide

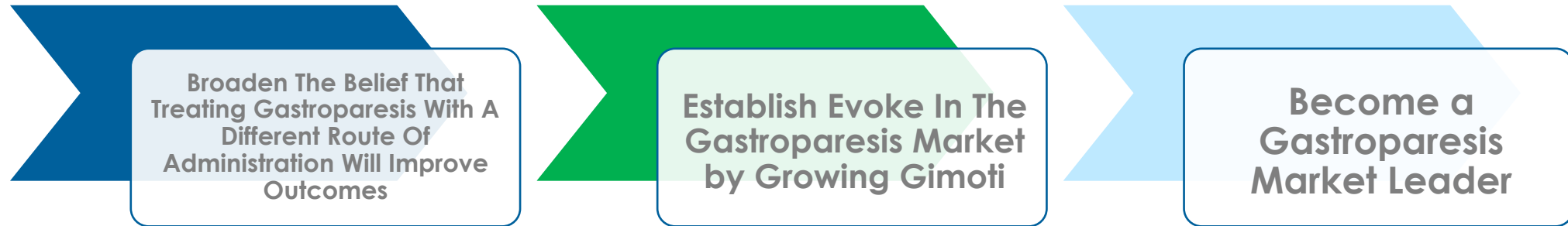
By Brenda Goodman, CNN  
Updated 1:32 PM EDT, Thu October 5, 2023

# Gimoti Performance Update



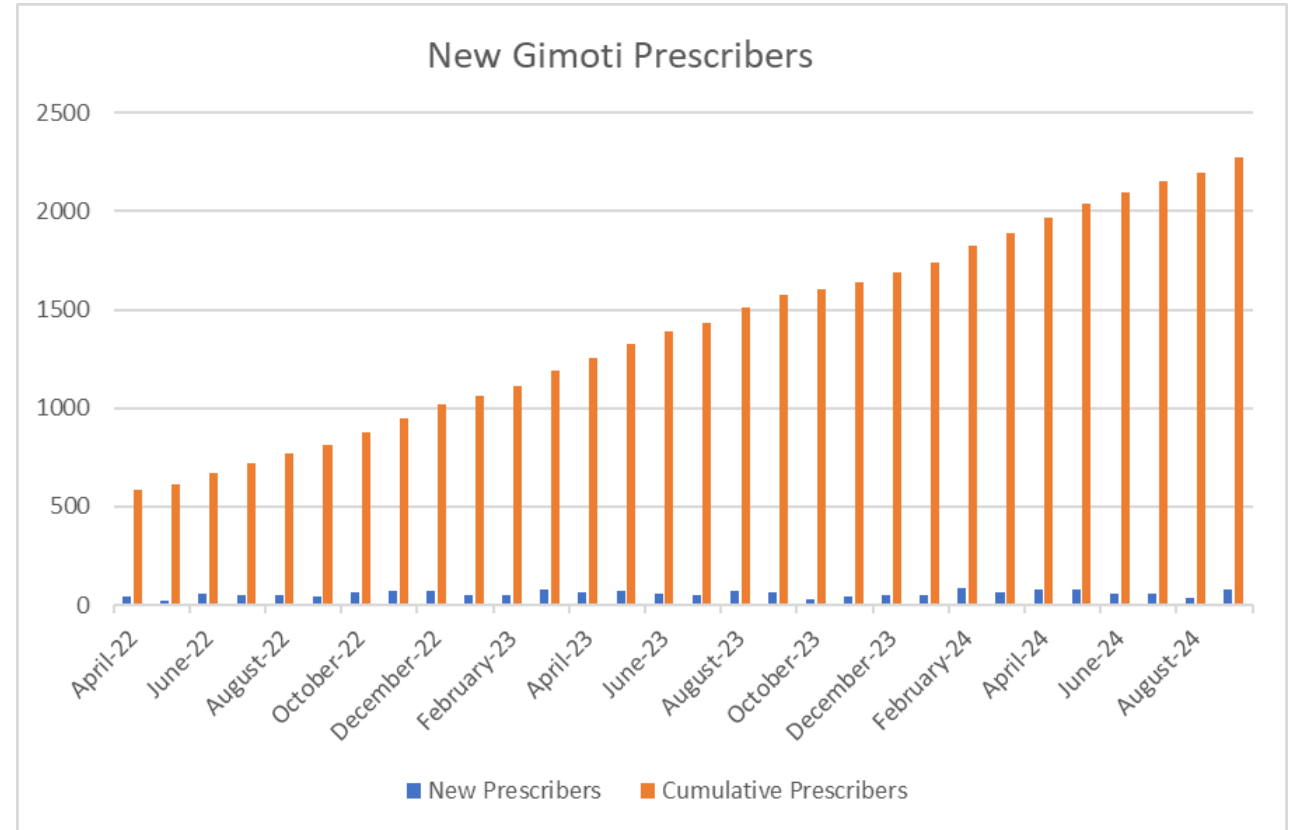
# Current Focus

## Grow Gimoti and Generate Positive Cash Flow



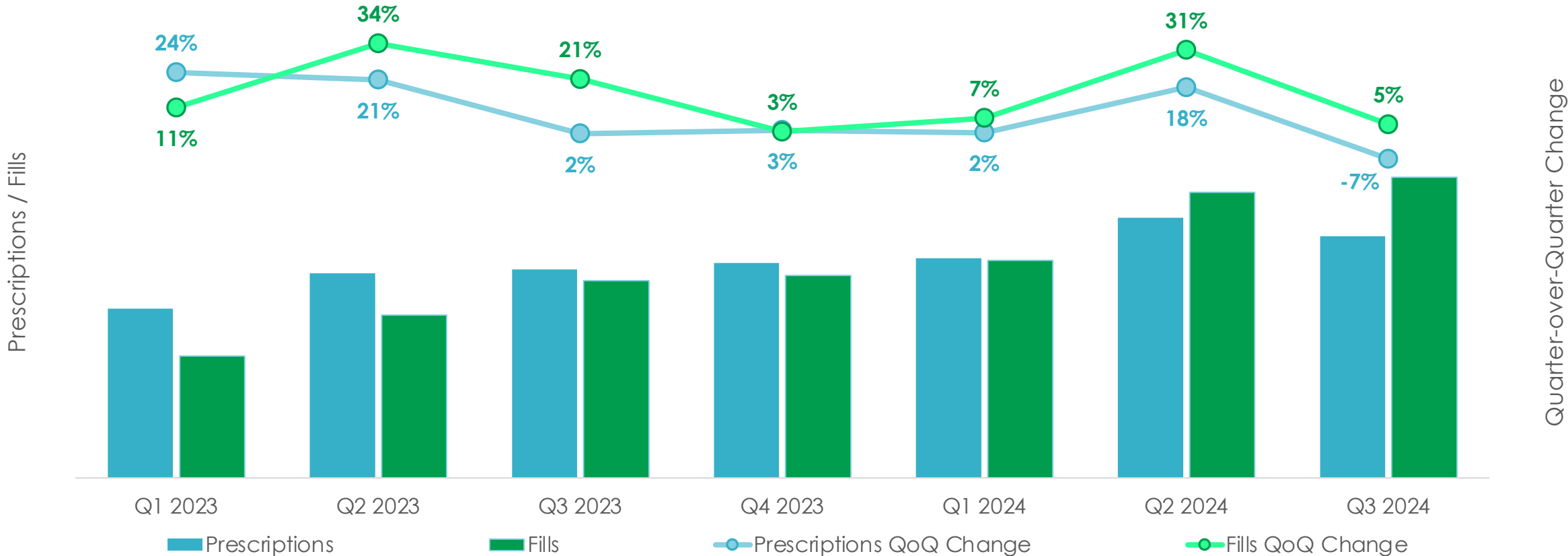
# New Prescribers Continue to Trial Gimoti

- Growth of total prescribers 20+% in 2024
- Adding and average of 60+ new prescribers per month in 2024
- New prescribers averaging 15-30% of all writers per month in 2024
- Individual markets remain mostly untapped with significant upside as awareness begins to take hold



# Gimoti Demand Momentum: Business Plan Performance

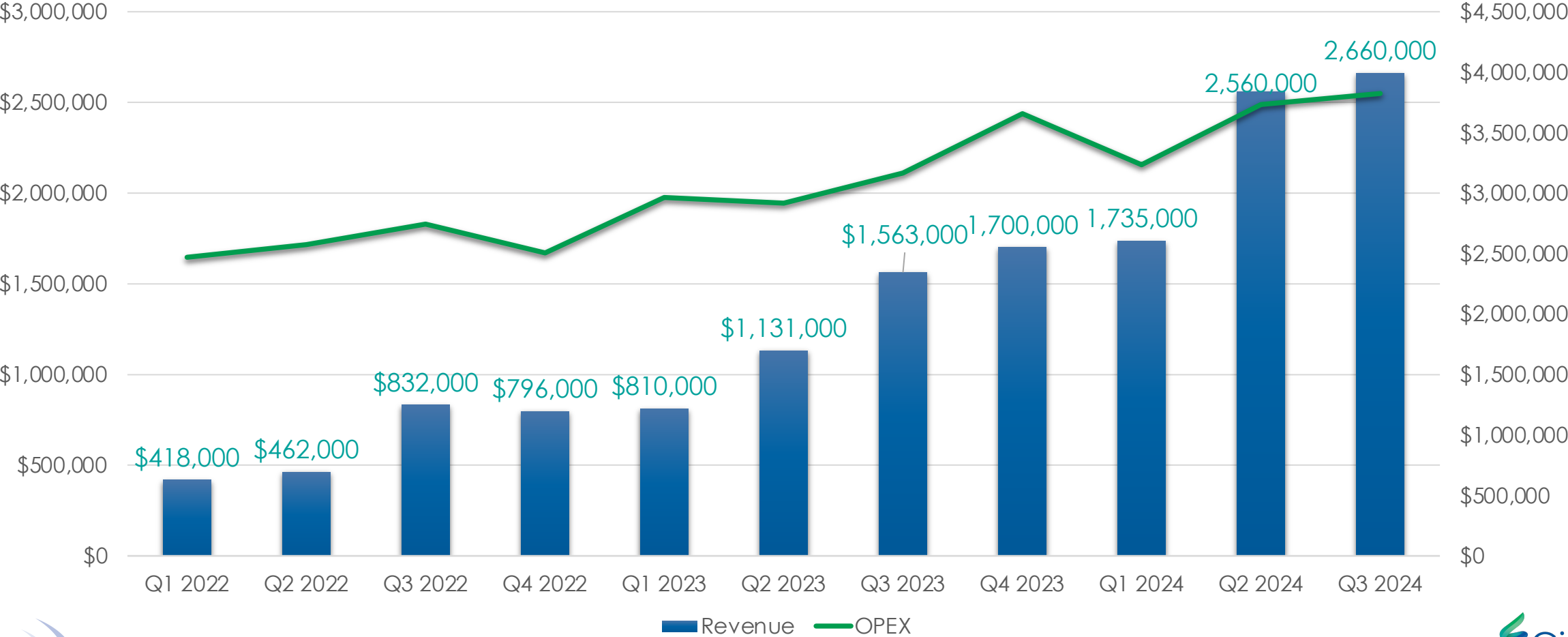
## Prescriptions and Fills by Quarter with Quarter-over-Quarter Change



# Net Revenue Growing Faster Than OPEX

Net Revenue

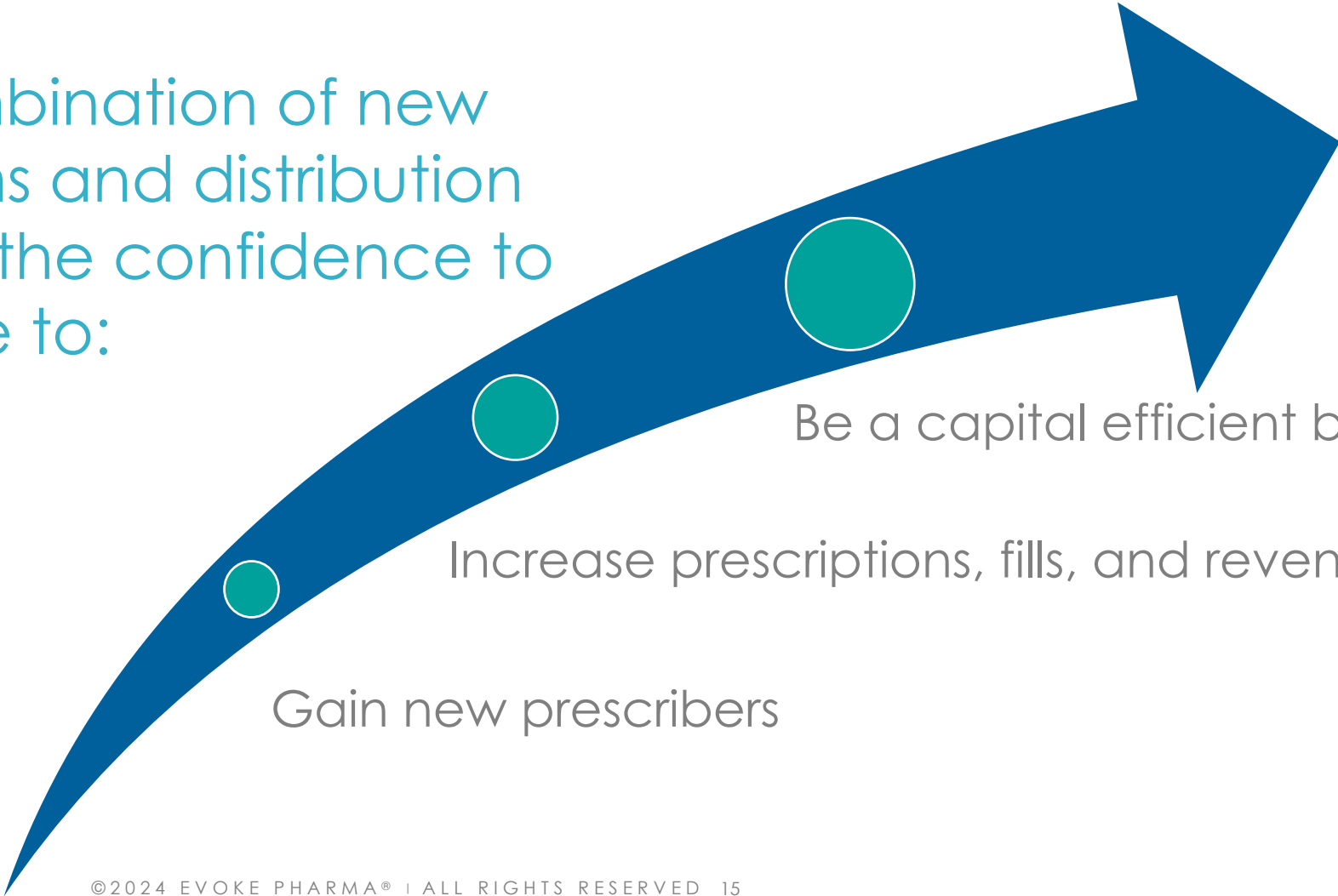
OPEX





# Performance Goals

The combination of new programs and distribution gives us the confidence to continue to:



Achieve Profitability

Gain new prescribers

Increase prescriptions, fills, and revenue

Be a capital efficient business

# Historical P&L and Balance Sheet/Capitalization

USD in thousands	2023 / 2024								
	2022	Q1	Q2	Q3	Q4	YTD	Q1'24	Q2'24	Q3'24
<b>Revenue</b>	<b>2,509</b>	<b>810</b>	<b>1,131</b>	<b>1,563</b>	<b>1,700</b>	<b>3,504</b>	<b>1,735</b>	<b>2,551</b>	<b>2,654</b>
Cost of goods	370	51	57	35	58	201	93	41	104
<b>Gross Profit</b>	<b>2,139</b>	<b>759</b>	<b>1,074</b>	<b>1,528</b>	<b>1,642</b>	<b>5,003</b>	<b>1,642</b>	<b>2,510</b>	<b>2,550</b>
Research & development	301	67	92	-		159	4		12
Selling, general & administrative	9,624	2,848	2,766	3,131	3,500	12,227	3,139	3,733	3,824
<b>Total operating expenses</b>	<b>9,925</b>	<b>2,915</b>	<b>2,858</b>	<b>3,131</b>	<b>3,600</b>	<b>12,600</b>	<b>3,143</b>	<b>3,733</b>	<b>3,836</b>
<b>Operating income (loss) ("EBIT")</b>	<b>(7,786)</b>	<b>(2,156)</b>	<b>(1,784)</b>	<b>(1,603)</b>	<b>(3,600)</b>	<b>(7,430)</b>	<b>(1,501)</b>	<b>(1,223)</b>	<b>(1,286)</b>
Other income (expense)	(438)	(88)	(83)	(90)	(100)	(361)	(79)	(44)	(26)
<b>Net loss</b>	<b>(8,224)</b>	<b>(2,244)</b>	<b>(1,867)</b>	<b>(1,693)</b>	<b>(1,988)</b>	<b>(5,804)</b>	<b>(1,580)</b>	<b>(1,267)</b>	<b>(1,312)</b>

**Cash & Cash Equiv.**  
(as of 9/30/2024) **\$11.3 million**

**Debt**  
(as of 9/30/2024) **\$7.0 million**

**Common Stock O/S**  
(as of 9/30/2024) **894K**

**Dilutive Securities**  
(as of 9/30/2024) **3.3 million shares**

Eversana Credit Agreement (Notes)

- Agreement provides for a \$5m facility secured by all assets
- Interest: 10.0% paid at maturity
- Maturity: 12/31/2026

Cash runway into Q4, 2025 or longer depending upon revenue ramp

# Gimoti Business Plan

Potential For Further Upside



# The Most Impactful Issues Facing GIMOTI

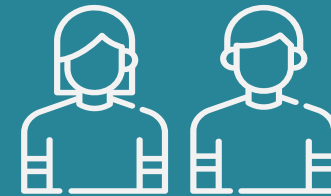
Each issue is actively being met with strategic initiatives



*Low Payer Coverage/ Prior Authorization Challenges*



*Out of Network Prescriptions*



*Patient Non-Response / Abandonment*



*GIMOTI Retail Leakage*



*No Perceived Difference Between Oral and Nasal*

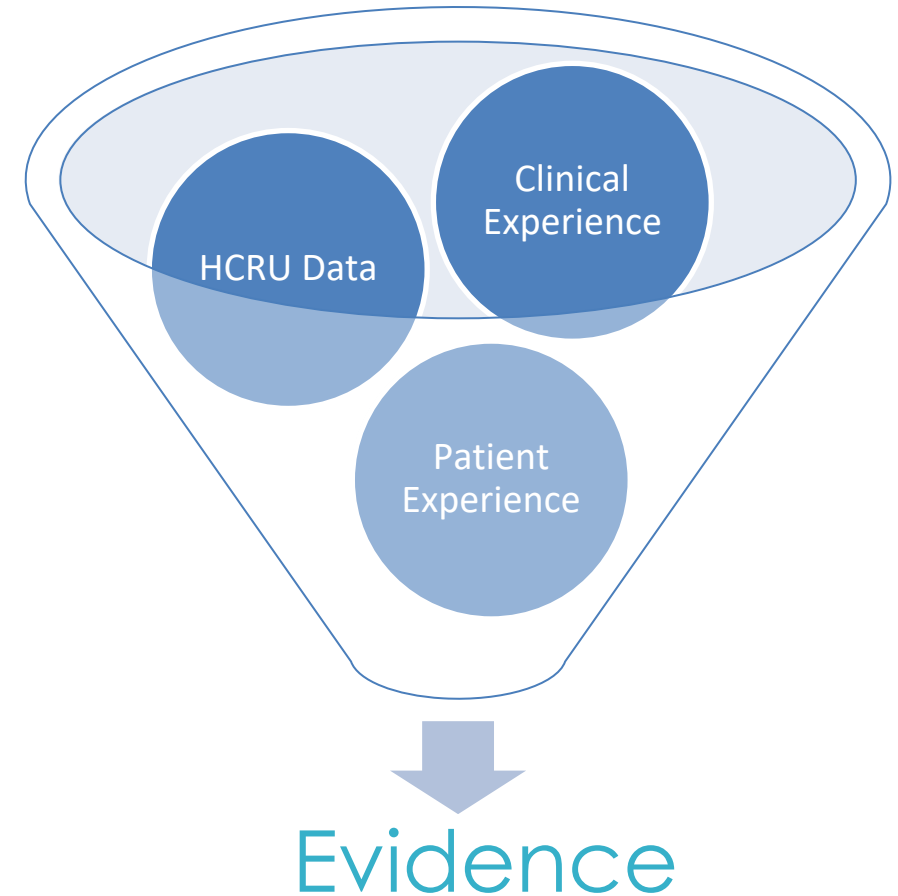


*Concerns About Potential TD Risk*

# Building Evidence to Support Further Access to Gimoti

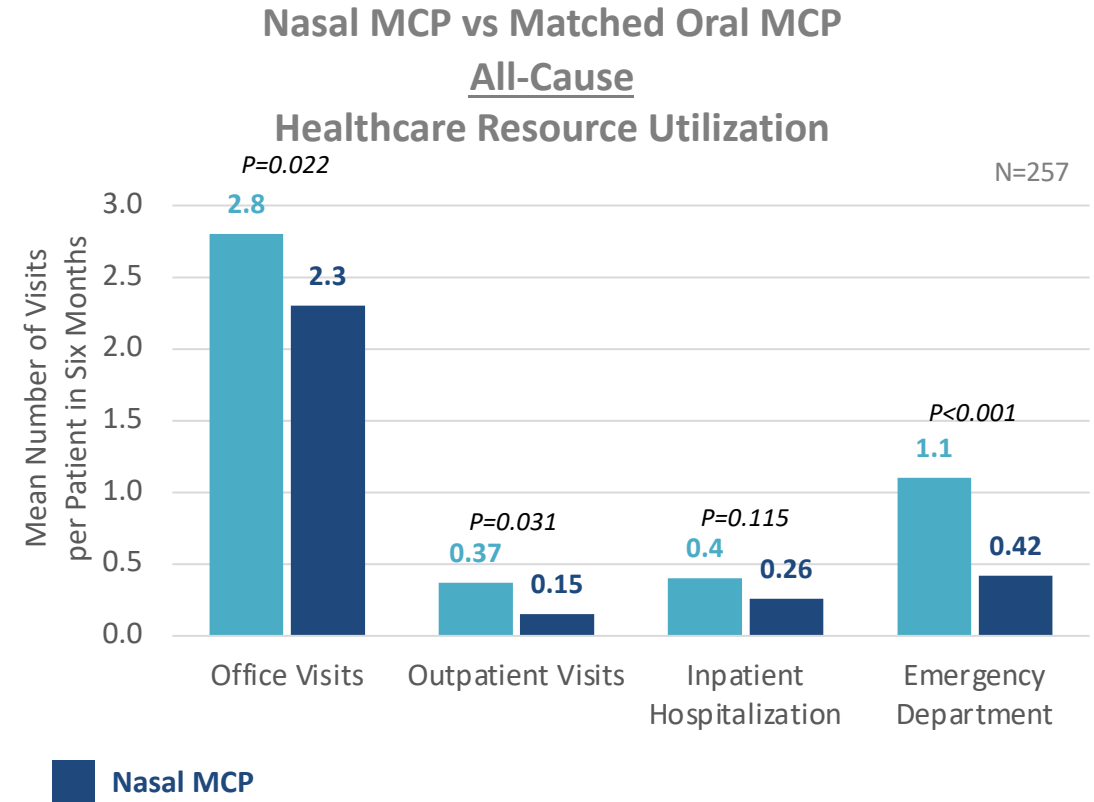
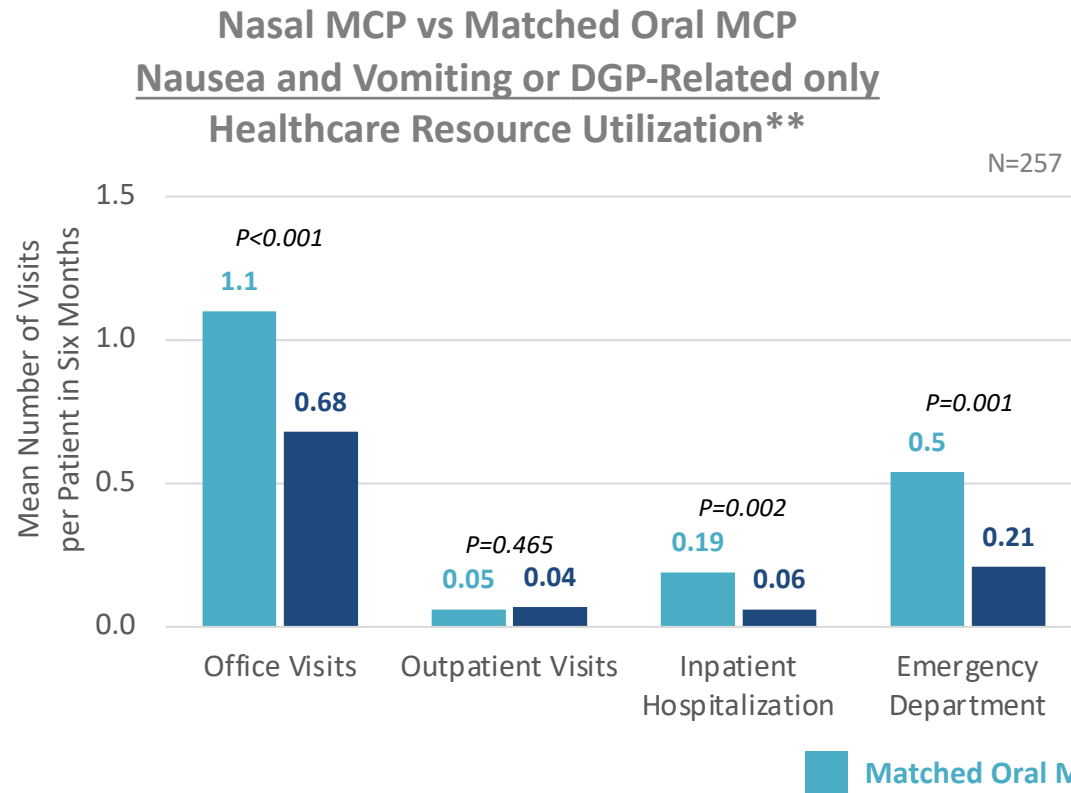
## Retrospective Claims Analysis

- Patients prescribed Gimoti to evaluate Health Care Resource Utilization
- Costs analysis of HCRU for nasal (Gimoti) vs. oral
- Tardive dyskinesia incidence in gastroparesis patients based on DDW “Poster of Distinction”



# Nasal MCP showed a significant reduction in the rate of HCRU compared to a matched control\* of oral metoclopramide patients

36% reduction in inpatient hospitalizations and 61% reduction in emergency department visits in the 6 months following initiation of treatment



In 257 patients, there were a total of 167 fewer emergency department visits in the nasal MCP cohort compared to the matched oral MCP cohort over the six-month period.

DGP = Diabetic Gastroparesis; MCP = metoclopramide

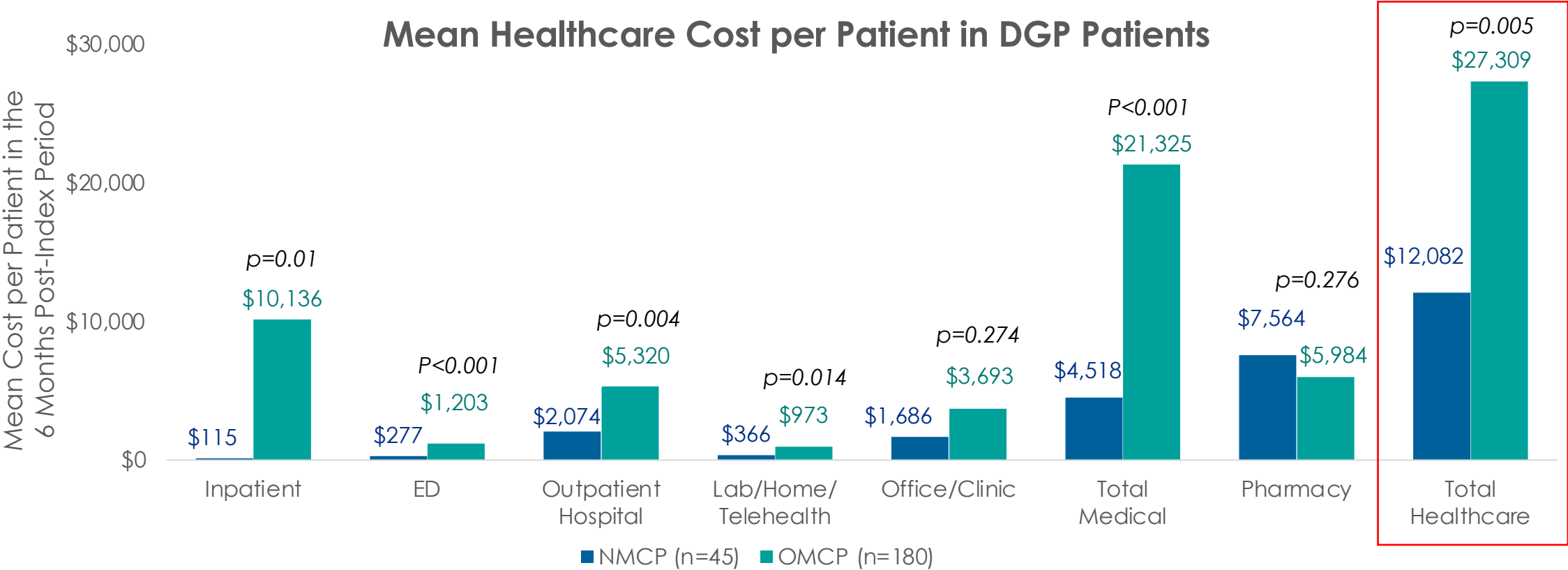
\* 257 patients in the nasal MCP cohort were matched to 257 patients on oral MCP based on demographics

\*\* Nausea, vomiting, and gastroparesis related HCRU were assessed by examining only insurance claims with ICD-10 diagnosis codes specific to each condition

Source: Kunkel et al. DDW 2023 (to be presented in May 2023)



# Patients Treated with Gimoti Had Significantly Lower All-Cause Healthcare Costs Compared to Oral Metoclopramide Patients



Lower healthcare costs in NMCP versus Oral MCP patients are driven by lower costs for Inpatient, ED and Outpatient Hospital visits. NMCP pharmacy cost was higher than generic OMCP, but not statistically significant.

† Includes Laboratory, Ambulatory, Image, Home, Telehealth and Other  
 †† Office is a location, other than a hospital, skilled nursing facility, State/local public health clinic, where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.  
 ‡ Clinic includes walk-in health clinic, independent clinic and public/rural health clinic, that is not part of a hospital and that is organized and operated to provide preventive, diagnostic, therapeutic, rehabilitative, or palliative services to outpatients only.

# Digestive Disease Week Poster of Distinction

## Incidence of Tardive Dyskinesia Approximately 0.1%

**DDW2022**  
Digestive Disease Week®

**MAY 21-24 | SAN DIEGO, CA**

### Revisiting the Risk of Tardive Dyskinesia with Metoclopramide Use: A Real-World Data Driven Epidemiology Study from 2011-2020

Authors, R. McCallum<sup>1</sup>, H. Parkman<sup>2</sup>, D. Kunkel<sup>3</sup>, L. Nguyen<sup>4</sup>, B. Wright<sup>3</sup>, M. Kalas<sup>1</sup>, B. Ramamoorthy<sup>5</sup>, J. Donders<sup>5</sup>, C. Quesenberry<sup>5</sup>, B. Hyde<sup>5</sup>  
1 Texas Tech University Health Sciences Center El Paso, TX, United States; 2, Temple University Hospital, Philadelphia, PA, United States; 3 University of California San Diego, CA, United States; 4 Stanford University, CA, United States; 5 EVERSANA Life Science Services, Chesterfield, MO, United States.

#### INTRODUCTION

The risk of drug-induced tardive dyskinesia (TD) is a critical factor in assessing the utility of dopamine receptor blocking agents (DRBA), including metoclopramide. However, there is limited literature available on the published rates of drug-induced TD. The few studies that have been conducted are largely outdated and report varying frequencies of TD with metoclopramide use (from 1% to 15%)<sup>1-3</sup>, likely due to small sample sizes and different outcome definitions. Given the importance of metoclopramide as the only FDA-approved therapy to treat diabetic gastroparesis, there is a substantial need to elucidate the incidence of TD using more recent data.

#### AIMS

- To update the medical literature on the incidence of TD in the US population including relevant subgroups (metoclopramide-prescribed patients, gastroparesis patients, and gastroparesis patients prescribed metoclopramide).
- To identify risk factors to help clinicians in selecting appropriate patients for use of DRBAs, including metoclopramide.

#### METHOD

This retrospective analysis was conducted with administrative claims data representing 35% of the US population (Truven Health MarketScan® Commercial Database). This robust dataset is comprised of more than 300 unique employers, 25 different health plans, and 240 million covered lives.

- Data from January 1, 2011 through December 31, 2020
- All patients required to have 12 months minimum enrollment.
- Cumulative incidence projected from the database to a national level based on census population counts segmented by age and sex.
- The primary outcome definition of TD used in this study was:
  - 333.85, Subacute dyskinesia due to drugs
  - G24.01, Drug induced subacute dyskinesia
  - G24.09, Other drug-induced dystonia
- Subgroup definitions were based on physician recommended International Classification of Diseases (ICD) 9/10 codes.
- Risk ratios were used to measure the association between TD and renal dysfunction, diagnosis of mental health disorders, DRBA use, and diabetes. 95% CIs were calculated for the risk ratios.

#### RESULTS

The incidence of TD in the general population was 9.4 per 100,000.

In metoclopramide-prescribed patients, gastroparesis patients, and gastroparesis patients prescribed metoclopramide, the incidence of TD was 33.4 per 100,000, 76.6 per 100,000, and 98.8 per 100,000.

The cumulative incidence of TD generally increased with age (Figure 1). Elderly patients (ie, patients aged 65 years and older) had higher incidence of TD compared with younger than 65 years of age in all groups evaluated. Females aged 40 years and older had higher incidence of TD compared with males in the same age group. Overall, elderly females (65 years of age and older) had the greatest incidence of TD.

Among all cohorts, there were positive associations between incidence of TD and renal dysfunction, diagnosis of mental health disorders, DRBA use, and diabetes (Table 1). For gastroparesis patients with metoclopramide use, the risk of TD incidence increased 2.3-fold, 3.0-fold, 3.2-fold, and 1.5-fold with renal dysfunction, diagnosis of mental health disorders, DRBA use, and diabetes, respectively.

The incidence of TD increased with longer durations of metoclopramide use. TD incidence was highest among patients with 24 to 48 months of prescription claims for metoclopramide (Figure 2).

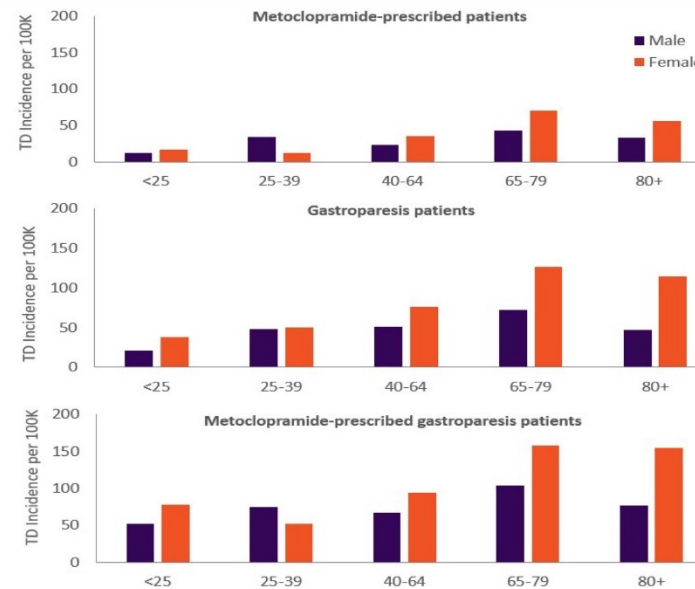


Figure 1. Incidence of TD per 100,000 by age group and sex

Table 1. Risk ratios of TD in the general population, metoclopramide-prescribed patients, gastroparesis patients, and gastroparesis patients treated with metoclopramide according to renal dysfunction, diagnosis of mental health disorder, DRBA use, and diabetes

	General population		Metoclopramide prescribed patients		Gastroparesis patients		Gastroparesis patients prescribed metoclopramide	
	Incidence per 100K	Ratio (95% CI)	Incidence per 100K	Ratio (95% CI)	Incidence per 100K	Ratio (95% CI)	Incidence per 100K	Ratio (95% CI)
<b>Renal dysfunction</b>								
Yes	37.5	6.8	65.2	3.5	113.6	2.8	134.7	2.3
No	5.5	(6.3, 7.4)	18.6	(2.6, 4.7)	40.9	(1.8, 4.3)	57.5	(1.3, 4.3)
<b>Diagnosis of mental health disorder</b>								
Yes	35.9	15.6	60.1	4.4	110.7	3.4	134.0	3.0
No	2.3	(14.1, 17.3)	13.7	(3.2, 6.0)	32.4	(2.2, 5.4)	45.2	(1.5, 5.7)
<b>DRBA use</b>								
Yes	40.4	12.2	61.8	6.2	106.9	2.4	131.2	3.2
No	3.3	(11.2, 13.4)	10.0	(4.2, 9.0)	45.2	(1.5, 3.6)	40.9	(1.5, 6.7)
<b>Diabetes</b>								
Yes	28.9	5.5	64.2	3.5	89.6	1.9	108.4	1.5
No	5.3	(5.0, 5.9)	18.5	(2.6, 4.6)	46.7	(1.2, 3.1)	70.2	(0.8, 2.9)

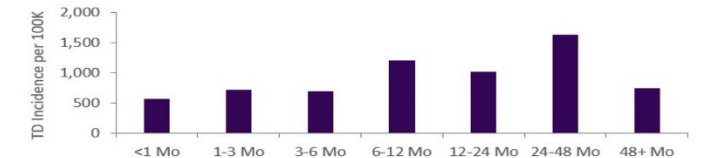


Figure 2. Incidence of TD per 100,000 by duration of metoclopramide use (months)

#### CONCLUSIONS

TD is rare among metoclopramide-treated patients with an incidence of 33.4 per 100,000; critically, this is much lower than previously reported in national guidelines on the treatment of gastroparesis.<sup>2,3</sup> Age and sex appear to be significant risk factors for TD, with the highest TD incidence reported among elderly females. Additional risk factors for TD include renal dysfunction, coadministration of other DRBAs, diagnosis of mental health disorders, and diabetes. The incidence of TD was also found to increase with prolonged metoclopramide use, with the greatest risk of TD observed after 24 to 48 months of chronic metoclopramide use. This large database permits a real-world study emphasizing the rarity of TD with metoclopramide use and identifies risk factors that can further lower this risk.

**Limitations:** Only those individuals with commercial health coverage were included. As a result, the findings may not be generalizable to patients with other forms of insurance or without health insurance coverage. Common to any retrospective claims analysis, coding inaccuracies or lack of coding may have introduced bias.

**Strengths and Future Directions:** The incidence TD is anticipated to rise because of increasing DRBA use. Compared to previous investigations, this study employed robust methods to report on cumulative TD incidence using recent, scalar, real-world data. The findings are intended to support clinicians in selecting appropriate candidates for DRBA use, including metoclopramide. Future studies are warranted to confirm these findings and further explore the impacts of specific risk factors such as metoclopramide dose on risk of TD.

#### DISCLOSURES

This study was funded by EVOKE. C. Quesenberry is an employee of EVOKE. B. Ramamoorthy, J. Donders, and B. Hyde are current or former employees of EVERSANA who were paid consultants.

#### REFERENCES

- Shaffer D, Butterfield M, Pamer C, Mackey AC. Tardive dyskinesia risks and metoclopramide use before and after US market withdrawal of cisapride. *J Am Pharm Assoc* 2004; 44: 661-5.
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- Parkman HP, Hasler WL, Fisher RS. American Gastroenterological Association technical review on the diagnosis and treatment of gastroparesis. *Gastroenterology* 2004;127: 1592-1622.

# ACG 2024 Poster: GIMOTI for DGP in GLP-1 Agonist Users

Won Presidential Poster Award and Outstanding Research in Stomach Category

## Study Details

**Objective:** Assess Nasal Metoclopramide (NMCP) impact on Health Care Resource Utilization (HCRU) in GLP-1 users with DGP

## Methodology

- Real World, retrospective, matched cohort study (n=51 nasal [NMCP] vs n=41 oral [OMCP])
- Pre/post HCRU for all-cause and NV-GP visits

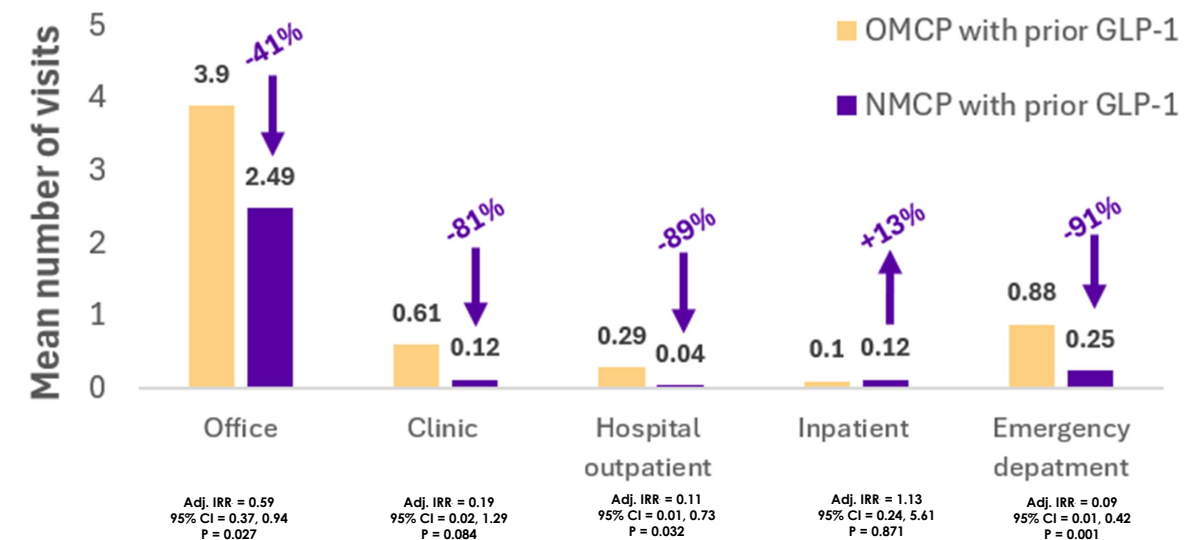
## Study Context

- GLP-1 agonists can exacerbate DGP symptoms, increasing the need for effective treatments

## Results at-a-Glance

- **Significant Reduction in Visits for Patients Using GIMOTI**
- All-Cause ED Visits: -55% (pre- vs. post-index for NMCP patients) (p=0.063)
- All-Cause ED Visits: -91% NMCP vs. OMCP (p=0.001)
- All-Cause and DGP-related office visits: -41% (p=0.027) and -66% (p=0.001) reductions compared to OMCP

Figure: NMCP and OMCP all-cause HCRU



## Conclusions

- GIMOTI offers effective symptom relief and significantly reduces the burden on healthcare resources and associated costs for GLP-1 users with DGP
- Establishes GIMOTI's potential as supportive care for GLP-1 therapy



# We are generating evidence to strengthen the value proposition of GIMOTI

## Phase 3 Study

Metoclopramide Nasal Spray in Women with Symptomatic Diabetic Gastroparesis:

A Randomized, Double-blind, Placebo-controlled Phase 3 Study

**Short Title:** Metoclopramide nasal spray in women with diabetic gastroparesis

Richard W. McCallum<sup>1</sup>, Henry P. Parkman<sup>2</sup>, Ronnie Fass<sup>3</sup>, Bal R. Bhandari<sup>4</sup>, Marilyn R. Carlson<sup>5</sup>, Raymond D. Buck<sup>6</sup>

<sup>1</sup>Texas Tech University Health Sciences Center, El Paso, Texas, United States; <sup>2</sup>Temple University, Philadelphia, Pennsylvania, United States; <sup>3</sup>Case Western Reserve University, Cleveland, Ohio, United States; <sup>4</sup>Delta Research Partners, Monroe, Louisiana, United States; <sup>5</sup>Evoke Pharma, Inc., Solana Beach, California, United States; <sup>6</sup>Consultant, Oak Island, North Carolina, United States

Clinical Gastroenterology and Hepatology 

Potentially in print by year end

## Healthcare Cost Reduction

**SUPERIORITY OF NASAL SPRAY COMPARED TO ORALLY ADMINISTERED METOCLOPRAMIDE IN REDUCING HEALTHCARE COSTS FOR TREATING DIABETIC GASTROPARESIS PATIENTS**

October 2023

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<sup>4</sup>University of California San Diego, La Jolla, CA, United States;



Manuscript in draft

## Tardive Dyskinesia Study

Revisiting the Incidence of Tardive Dyskinesia with Oral Metoclopramide

Use: a US Real-World Epidemiology Study from 2011-2020

Richard W. McCallum, MD<sup>1</sup>; Henry P. Parkman, MD<sup>2</sup>; Linda A. Nguyen, MD<sup>3</sup>; Brenton A. Wright, MD<sup>4</sup>; Ammar M. Kalas, MD<sup>1</sup>; Chris Quesenberry, BSc<sup>5</sup>; David Kauffman, BSc<sup>5</sup>; Jordan Donders, MSc<sup>5</sup>; David C. Kunkel, MD<sup>4</sup>

<sup>1</sup>Texas Tech University Health Sciences Center El Paso, El Paso, Texas, United States <sup>2</sup>Temple University Hospital, Philadelphia, Pennsylvania, United States

<sup>3</sup>Stanford University, Stanford, California, United States

<sup>4</sup>University of California San Diego, La Jolla, California, United States

<sup>5</sup>EVERSANA Life Science Services, Chicago, Illinois, United States

Working on Submission

A retrospective medical chart review will potentially add additional clinical support (e.g., A1c control, weight, symptoms, concomitant medications, dosing)

# We partnered with ASPN Pharmacies November 2023 to accelerate a collection of distribution initiatives




## HUB Patient Services + Connected Care

 **5,500,000**  
Specialty & Specialty  
Lite Prescriptions  
Supported Annually

 **215,000**  
Prescribers

**Non-Dispensing  
Pharmacy**

 **60+**  
HUB Programs

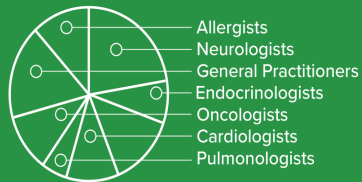
 **58%**  
Portal Rx Utilization  
(Programs with  
PA Service)

**Technology**

 **25+**  
Manufacturers

 **96% eRx**

**ASPN  
Pharmacy  
Network**



**Direct Payer  
Connections**

- A specialty pharmacy network with **strong payer connections**
- **Increased automation** from receipt of Rx to patient communication to processing prior authorizations electronically
- Ability to **route Rx to pharmacy with coverage** and then fill (e.g. out of network prescriptions)

ASPN provides us a key opportunity to convert current business and grow into the future.

# Commercial Collaboration with EVERSANA



## Intellectual Property

- Continuing to build portfolio

## Regulatory filings

- Maintain appropriate reporting requirements

## Manufacturing

- Maintain supplies and CDMO relationship



EVERSANA™

## Distribution & Trade

- 3PL shipping to pharmacy network
- Pharmacy HUB

## Commercial

- Strategic marketing plans
- Sales hiring, training, fleet, infrastructure

## Financing

- Cash delivery to Evoke to record revenue
- Investing time & materials with payment terms via net product profit only





# Complete Commercialization Partnership

*A First of its kind that EVERSANA has continued to utilize*

## Financials

- Evoke
  - Receives all revenue from product sales and reports each quarter
  - Received \$5M loan from Eversana
- Eversana
  - Provides agreed upon yearly commercial budget
    - Personnel and other internal infrastructure
    - External commercial costs
  - Receives from Evoke portion of monthly net product profit

## Term

- Both parties have right to terminate ongoing partnership under certain terms
  - If Evoke terminates, it owes some/all of previously incurred commercial costs by EVERSANA
  - If EVERSANA terminates for reasons other than breach, prior commercial unreimbursed fees are forfeited
  - Evoke maintains rights to hire certain personnel from EVERSANA dedicated to GIMOTI
  - Partnership agreement expires December 31, 2026

# Limited Current Competitive Landscape

Product	Class	Route	Company	Development Status
Tradipitant	NK-1 antagonist	Oral	Vanda	<b>Complete Response Letter (CRL)</b> Prior failed phase 3 October 2024 FDA issued CRL for gastroparesis NDA; requested additional studies
CIN-102	D2/D3 antagonist	Oral	CinRx	<b>Phase 2a (n=60) Completed; Phase 2b recently started</b> No results reported
PCS12852	5-HT4 receptor agonist	Oral	Processa	<b>Phase 2a (n=25) Completed</b> Not powered to show a statistically significant difference from the placebo

Few products in development and years away from commercialization

# Long-Term IP Protection

Gimoti is protected by robust, granted, Orange Book listed patents that provide protection of:

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

Additional granted gender specific patents in the European Union, Japan, and Mexico that expire in 2032

## U.S. Granted Patents

Patent #	Title	Expires
8,334,281	Nasal formulations of metoclopramide	2030
11,020,361	Nasal formulations of metoclopramide	2029
11,628,150	Nasal formulations of metoclopramide	2029
11,813,231	Nasal formulations of metoclopramide	2029
11,517,545	Treatment of moderate and severe gastroparesis	2037

## U.S. Pending Applications

Application #	Title	Expires
17/366,839	Nasal formulations of metoclopramide	Recently allowed
17/366,818	Nasal formulations of metoclopramide	Recently allowed
16/016,246	Treatment of symptoms associated with female gastroparesis	2029
16/646,527	Methods of intranasal metoclopramide dosing	2030

# Gimoti® (metoclopramide) nasal spray



Gimoti® (metoclopramide) nasal spray is indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

#### Limitations of Use:

GIMOTI is not recommended for use in pediatric patients, in patients with moderate or severe hepatic impairment, in patients with moderate or severe renal impairment, or in patients concurrently using strong CYP2D6 inhibitors.

#### **BOXED WARNING: TARDIVE DYSKINESIA**

- Metoclopramide can cause tardive dyskinesia (TD), a serious movement disorder that is often irreversible. The risk of developing TD increases with duration of treatment and total cumulative dosage.
- Discontinue GIMOTI in patients who develop signs or symptoms of TD. In some patients, symptoms may lessen or resolve after metoclopramide is stopped.
- Avoid treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks because of the increased risk of developing TD with longer-term use.

Please see Important Safety Information, including Boxed Warning. For complete prescribing information, go to [www.gimotirx.com](http://www.gimotirx.com).