

## 4Q/FY 2023 Earnings Call

March 14, 2024

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## "

At doctor's office, and there is a 30-year-old male patient who suffers from Type I diabetes and severe gastroparesis. He came in for a follow up and told the office that GIMOTI has changed his life – he hasn't been to the hospital since he started it."

(Patient had been going to the hospital about every 6 weeks.)

### -Nurse Practitioner, Abingdon, VA



# GIMOTI has advantages over oral therapies that specifically apply to patients with gastroparesis

### **Rapid Absorption**

- GIMOTI bypasses the GI tract, thereby eliminating issues with delayed emptying
- GIMOTI enters the blood stream as early as 15 min
- 9.5X blood levels at 15 min compared to oral metoclopramide

### **Demonstrated Efficacy**

- In Phase 2 trial, GIMOTI 10 or 20 mg was significantly better than 10 mg oral metoclopramide
- In Phase 3 trial, moderate to severe patients had symptom relief as early as week 1 (first time point measured)

### **Better Outcomes**

- In a real-world trial, compared to oral metoclopramide, GIMOTI
  - Reduced office visits by 36%
  - Reduced ER visits by 60%
  - Reduced hospitalizations by 68%
- Nearly 2/3 of patients taking GIMOTI had previously taken oral metoclopramide



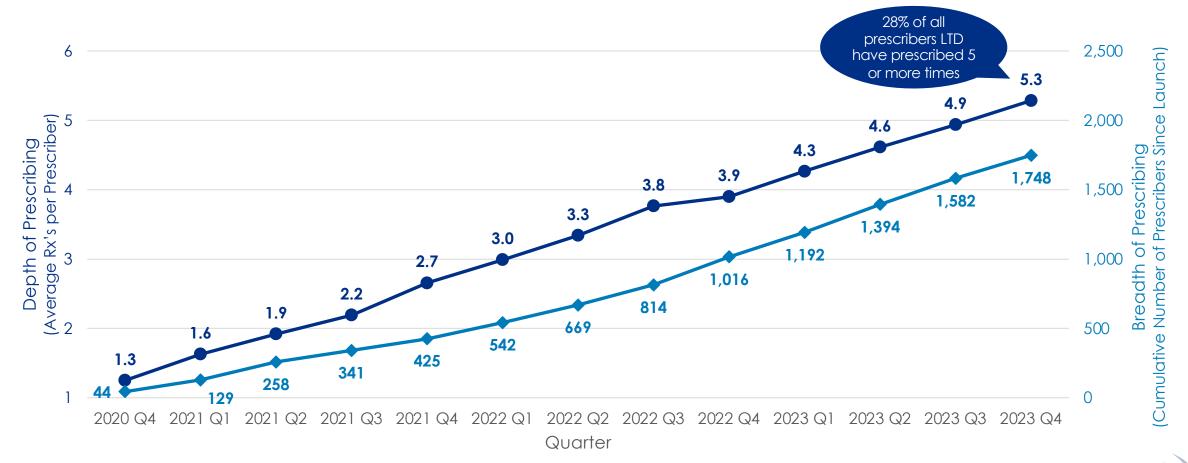
## GIMOTI doubled net revenue in 2023 over 2022, primarily through improved execution and building evidence in support of the brand

- Grew New Rx's by 88% and Total Rx's by 100% YoY
- Grew base of prescribers by 72% while improving depth of prescribing by 36%
- Improved our targeting and reach of HCPs who treat gastroparesis
- Launched HRU data demonstrating reduction in ER visits and hospitalizations at a lower cost compared to oral metoclopramide through plenary presentations at DDW and ACG
- Successfully transitioned to an upgraded pharmacy partner
- Increased the number of patients on therapy by more than double



## The depth and breadth of prescribing continue to steady grow simultaneously

Longitudinal Average Depth of Prescribing by Quarter





We will improve performance through disciplined execution of these 2024 Strategic Imperatives for GIMOTI







Establish the belief in GIMOTI outcomes due to its nasal ROA Improve fill rate of GIMOTI Uncover TD concerns and clarify risks of GIMOTI



## Key tactics are being implemented to support growth



### As acceptance and trial grew, we improved our distribution and increased access to GIMOTI

### Evolution of our pharmacy network



- Implemented quickly
- Manual processes
- Enrollment form
- Longer time to fill

- Integrated with MD workflow
- Ability to e-prescribe
- Automated refill
- Improved speed to fill

#### In addition to prior upgrades

- Real-time patient
   communication
- End-to-end automation
- Transparency of Rx status
   through portals
- Ability to grow pharmacy network



ASPN = Asembia Specialty Pharmacy Network

## ASPN is a critical lever to improving our fill rate

### Improved conversion rate of a NRx to a fill

↑ **2%** Improvement in conversion rate

↑ **22%** Improvement if excluding ASPN's in-process Rxs Less reliance on patient affordability programs to

fill scripts

Pharmacy Transition Metrics

Lower rates of patient abandonment

 $\uparrow$  6% of fills that are reimbursed with ASPN

 $\downarrow$  **12%** of patient led abandonment

### **Improvement Areas**

Communication



ASPN = Asembia Specialty Pharmacy Network

Process



Network





Communicating with Prescribers, Pharmacists, and Patients to Help Curb Retail Leakage at Key Leverage Points

Remind HCPs to Write to ASPN Pharmacies at the Point of Prescription

> Covering nearly **50% of all EHRs** with messaging

Intercept Scripts Sent to Retail

Helping to redirect 1,500+ scripts to ASPN





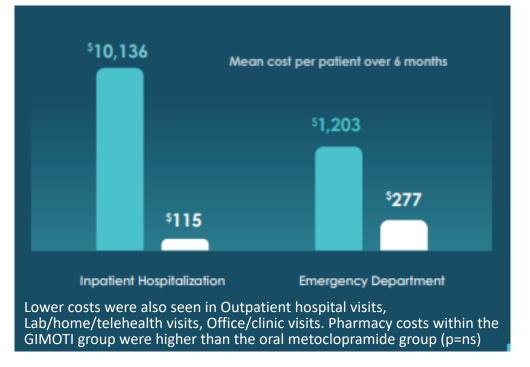


## Patients treated with GIMOTI had significantly lower rates of healthcare resource utilization compared to oral metoclopramide<sup>1</sup>

## Nearly two-thirds of patients in GIMOTI arm previously took oral metoclopramide



#### Total Healthcare Cost\* in GIMOTI arm were \$15,227 lower<sup>2</sup>



\*Total Healthcare cost = Total Medical Costs - Pharmacy Costs; please see McCallum poster for complete information

1. Kunkel D. Reducing real-world healthcare resource utilization for patients with diabetic gastroparesis (DGP) treated with metoclopramide nasal spray versus oral metoclopramide. Plenary lecture presentation at: Digestive Disease Week; May 6-9, 2022; Chicago, IL.

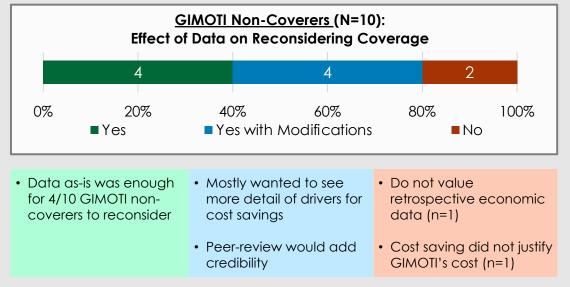
2. McCallum R, Cline M, Shokoohi M, Marium S, Kish J, Kunkel DC. Superiority of nasal spray compared to orally administered metoclopramide in reducing healthcare costs for treating diabetic gastroparesis patients. Abstract presented at: American College of Gastroenterology Annual Scientific Meeting; October 20-25, 2023; Vancouver, BC.



# Initial feedback from payers demonstrates that our HRU data may have potential to impact coverage decisions

#### Preliminary Payer market research feedback (N=20)

**Objective:** test receptivity of HRU and cost data and potential impact on coverage for GIMOTI



#### <u>GIMOTI Coverers (N=10)</u>: Effect of Data on Reconsidering Coverage

• 5 payers would ease process/documentation for obtaining coverage

## Additional evidence generation\* under consideration to further strengthen the value story



Hospitalization length of stay and readmit rates



Reduction in Prescription Burden



Avoidance of Medical Procedures



**Burden of Illness** 



Safety



\*Sample endpoints listed. A full list will be assembled as part of the RWD/E Feasibility Assessment and/or study protocols/synopses.

# Tardive Dyskinesia is likely preventing some providers from prescribing GIMOTI for <u>appropriate</u> patients

Tardive Dyskinesia is a serious movement disorder that causes involuntary movements of the face or body

### Educate on Incidence

The 2022 ACG Guideline<sup>+</sup> states that the estimated risk of TD from metoclopramide is likely <1%<sup>1</sup>



### Inform on who's at risk

- >65 years of age
- Use of dopaminereceptor blocking agents
- Mental health disorders
- Moderate to severe Liver or Renal impairment
- Risk increases with longer duration of use

### **Encourage Monitoring**

#### No Tardive Dyskinesia (TD) Has Been Reported With GIMOTI

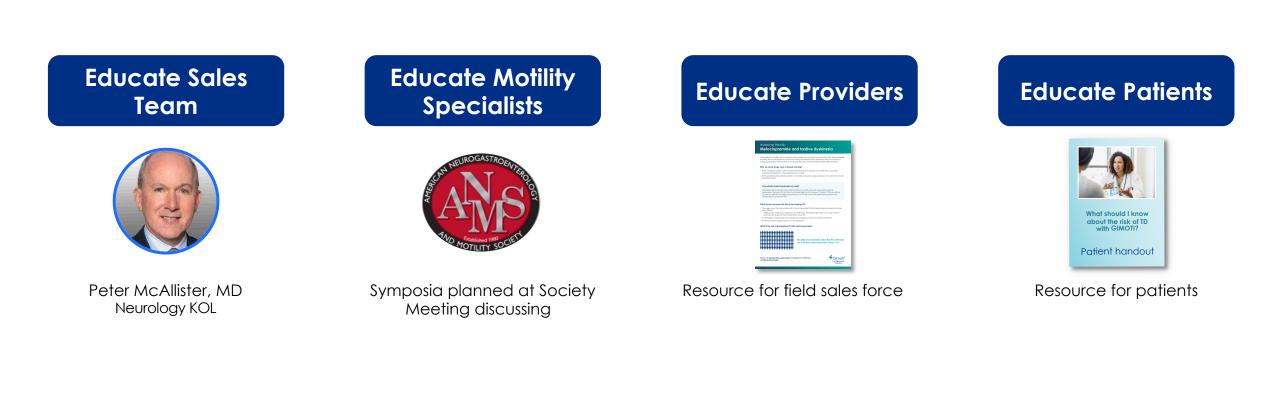
- During the clinical development program<sup>2</sup>
- To EVOKE PHARMA® since the launch of GIMOTI in October 2020<sup>2\*</sup>

Monitor patients closely and discontinue GIMOTI if they develop signs or symptoms of TD<sup>3</sup>

† 2013 ACG Guideline indicated risk at 1-10% \*As of January 2024.



Focused effort to educate providers on tardive dyskinesia will support appropriate benefit : risk assessment





## Historical P&L and Balance Sheet/Capitalization

|                                     |         | 2023    |         |         |         |         |
|-------------------------------------|---------|---------|---------|---------|---------|---------|
| USD in thousands                    | 2022    | Q1      | Q2      | Q3      | Q4      | YTD     |
| Revenue                             | 2,509   | 810     | 1,131   | 1,563   | 1,677   | 5,181   |
| Cost of goods                       | 370     | 51      | 57      | 35      | 59      | 202     |
| Gross Profit                        | 2,139   | 759     | 1,074   | 1,528   | 1,618   | 4,979   |
| Research & development              | 301     | 67      | 92      | -       | 23      | 182     |
| Selling, general & administration   | 9,624   | 2,848   | 2,766   | 3,131   | 3,483   | 12,228  |
| Total operating expenses            | 9,925   | 2,915   | 2,858   | 3,131   | 3,506   | 12,410  |
| Operating income (loss)<br>("EBIT") | (7,786) | (2,156) | (1,784) | (1,603) | (1,888) | (7,431) |
| Other income (expense)              | (438)   | (88)    | (83)    | (90)    | (100)   | (361)   |
| Net loss                            | (8,224) | (2,244) | (1,867) | (1,693) | (1,988) | (7,792) |

| <b>Cash &amp; Cash Equiv.</b><br>(as of 12/31/2023) | \$4.7 million |
|---|---------------|
| <b>Debt</b><br>(as of 12/31/2023)                   | \$6.6 million |

Eversana Credit Agreement (Note)

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

Additional cash infusion Feb 2024



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

Diabetes and Delayed Gastric Emptying is the key patient type

### $\equiv \frac{1}{1000}$ 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/alucagon-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-sglt2-inhibitors-but-few-receive-ther
https://www.ncbi.nlm.nih.gov/pmc/tricles/PMC52788087

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

E M health Life, But Better Fitness Food Sleep Mindfulness Relationships

### 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



### **Executive Summary**

- 2023 was a positive year of growth from which we can build momentum in 2024
- Projecting 2024 Net Revenue of \$14.0M
- Established a focused strategy and investment to strengthen belief in GIMOTI
- Further improved execution to improve breadth and depth of prescribing
- Continued investment in **developing evidence** to support the brand



THANK YOU



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