UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): May 6, 2023

Commission file number 001-39531

PROCESSA PHARMACEUTICALS, INC.
(Exact name of Registrant as Specified in its Charter)

Delaware	**45-1539785**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076
(Address of Principal Executive Offices, Including Zip Code)

(443) 776-3133
(Registrant's Telephone Number, Including Area Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock: Par value $.0001	PCSA	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation Disclosure.

Processa Pharmaceuticals, Inc. ("***Processa***") will be presenting on May 6th at Digestive Disease Week 2023 Annual Meeting. The study, titled "PCS12852, A Novel 5-HT4 Agonist Improves GCSI Symptom Scores and Gastric Emptying in Gastroparesis Patients," will be presented during the Research Forum Session, *AGA Gastroparesis and Small Intestinal Dysmotility* held from 2-3:30 PM CT. Sian Bigora, Pharm.D., Processa Pharmaceuticals' Chief Development and Regulatory Officer, will present the Phase 2a results on the improvement in symptom scores and gastric emptying rate in gastroparesis patients treated with PCS12852.

During these meetings, Processa's presentation will be uploaded into a portal, which is furnished as Exhibit 99.1 and is incorporated herein by reference. The presentation will also be made available in the "Investors" section on Processa's website, located at https://www.processapharmaceuticals.com.

Processa undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time through the filing of other reports or documents with the Securities Exchange Commission, through press releases, or through other public disclosure, including in the "Investors" section of Processa's website. Processa routinely uses its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD.

The information in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Exhibit Description
99.1	Processa Pharmaceuticals Presentation dated May 6, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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, on May 6, 2023.

PROCESSA PHARMACEUTICALS, INC.
Registrant

By: */s/ David Young*
David Young
Chief Executive Officer

PCS12852, A NOVEL 5-HT4 AGONIST, IMPROVES GCSI SYMPTOM SCORES AND GASTRIC EMPTYING IN GASTROPARESIS PATIENTS

Das, Maya; Smythe-Peterkin, Shanique; McCallum, Richard W.; Parks, Kayla; Franks, Peter; Young, David; Bigora, Sian

Author and Disclosures

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  - Study PI
- Kayla Parks
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- Peter Franks
  - Processa Pharmaceuticals (employee)
- David Young, PharmD, PhD
  - Processa Pharmaceuticals (employee)
- Sian Bigora, PharmD
  - Processa Pharmaceuticals (employee)

Abstract

- **INTRODUCTION:** Gastroparesis is a chronic disorder characterized by delayed gastric emptying of solid food in the absence of a mechanical obstruction and is a condition with unmet needs due to the limited available treatment options for patients. This study investigated the effects of PCS12852 (a potent and selective 5-HT_4 receptor agonist) on gastric emptying and core gastroparesis symptoms in patients with idiopathic or diabetic gastroparesis.
- **BACKGROUND & AIMS**: We performed a double-blind placebo-controlled trial of patients with delayed gastric emptying and moderate to severe symptoms of idiopathic or diabetic gastroparesis. Patients were randomized 1:1:1 to PCS12852 0.1 mg, PCS12852 0.5 mg, or placebo given once daily for 28 days. The change in gastric emptying rate from baseline was determined by the gastric emptying rate half time (t_{50}) and the area under the curve (AUC) as assessed by the Gastric Emptying Breath Test (GEBT). Other endpoints included change from baseline in the American Neurogastroenterology and Motility Society Gastroparesis Cardinal Symptom Index Daily Diary (ANMS GCSI-DD), a patient-reported outcome measurement that assesses symptoms (i.e., nausea, vomiting, early satiety, postprandial fullness, and upper abdominal pain) associated with gastroparesis.
- **RESULTS:** Twenty-five (25) patients were enrolled (64% white; 88% female; 24% idiopathic, 76% diabetic) at 8 clinical sites. Although patients were only treated for 28 days, the gastric emptying rate improved as compared to baseline for PCS12852 0.5 mg while no significant improvement was seen with placebo. The mean (±SD) t_{50} declined by -31.90 ± 50.53 minutes in the PCS12852 0.5 mg group vs -9.36 ± 42.43 minutes in the placebo group from baseline to day 28. The PCS12852 0.5 mg group demonstrated a clinically meaningful reduction in the total ANMS GCSI-DD score (>0.5) on day 28 as compared to baseline. Similarly, the PCS12852 0.5 mg group showed a positive improvement in all of the ANMS GSCI-DD subscales over the treatment period. There was no significant improvement in the 0.1 mg group as compared to placebo in gastric emptying or symptom scales. PCS12852 was generally well-tolerated. Adverse events were mild to moderate and resolved without sequalae. There were no serious adverse events, and specifically no cardiac adverse events reported during the study.
- **CONCLUSIONS:** PCS12852 0.5 mg, a potent and selective 5-HT_4 agonist given once daily for 28 days, improved gastric emptying in patients with gastroparesis as compared to placebo. A clinically meaningful reduction in the total ANMS GSCI-DD score and improvements in individual symptom scores were observed in the PCS12852 0.5 mg group. No significant adverse events were noted. This data supports further investigation of PCS12852 as a treatment for gastroparesis.

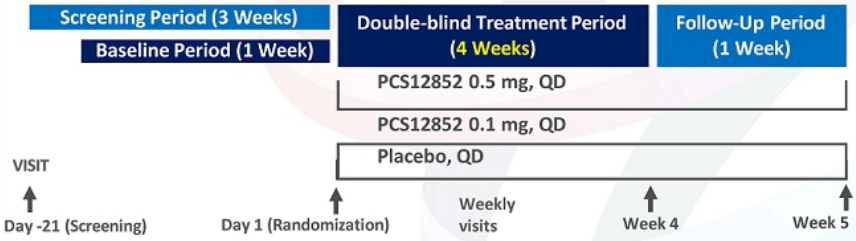
Background

- PCS12852, a new 5-HT4 receptor agonist
  - Superior potency and efficacy in animals and humans
  - High selectivity for 5-HT4 receptors with no evidence of cardiac toxicity
  - Excellent safety and tolerability profile in nonclinical and Phase 1 studies
  - Currently being investigated for the treatment of gastroparesis

Phase 2A: Proof of Concept Study Design

A Phase 2A, Placebo-controlled, Randomized, Dose Response Study of the Safety, Pharmacokinetics and Efficacy of PCS12852 on Gastric Emptying Rate Assessed by ^{13}C Spirulina GEBT in Patients with Moderate to Severe Gastroparesis

Eligibility criteria	• Moderate to severe IG or DG according to ANMS GCSI-DD • Male or female 18 to 80 years of age • Moderate to severe delay in gastric emptying measured by GEBT
Primary endpoints	• Change in gastric emptying rate from baseline assessed by GEBT (AUC and t_{50}) • Pharmacokinetics
Secondary endpoints	• Change from baseline in ANMS GCSI-DD and Day 7, 14, 21 and 28
Sample size	• 24 • Randomized 1:1:1



Patient and Disease Characteristics

Characteristic	PCS12852 0.1 mg (N=9)	PCS12852 0.5 mg (N=8)	Placebo (N=8)	Total (N=25)
Age (Yrs :Mean±SD)	58.6±7.3	58.0±6.4	60.5±5.8	59.0±6.4
Sex (M:F)	2:7	0:8	1:7	3:22
Height (cm: Mean±SD)	163.0±6.8	161.6±7.2	163.3±7.8	162.6±7.0
Weight(kg: Mean±SD)	80.7±14.1	78.6±17.8	80.71±13.9	80.0±14.7
BMI (kg/m^2:Mean±SD)	30.5±5.8	30.0±6.1	30.1±3.4	30.2±5.1
Time Since Diagnosis (Yrs :Mean±SD)	5.0±2.8	4.4±2.6	6.2±7.0	5.2±4.4
Type of Gastroparesis (IG:DG)	2:7	2:6	3:5	7:18

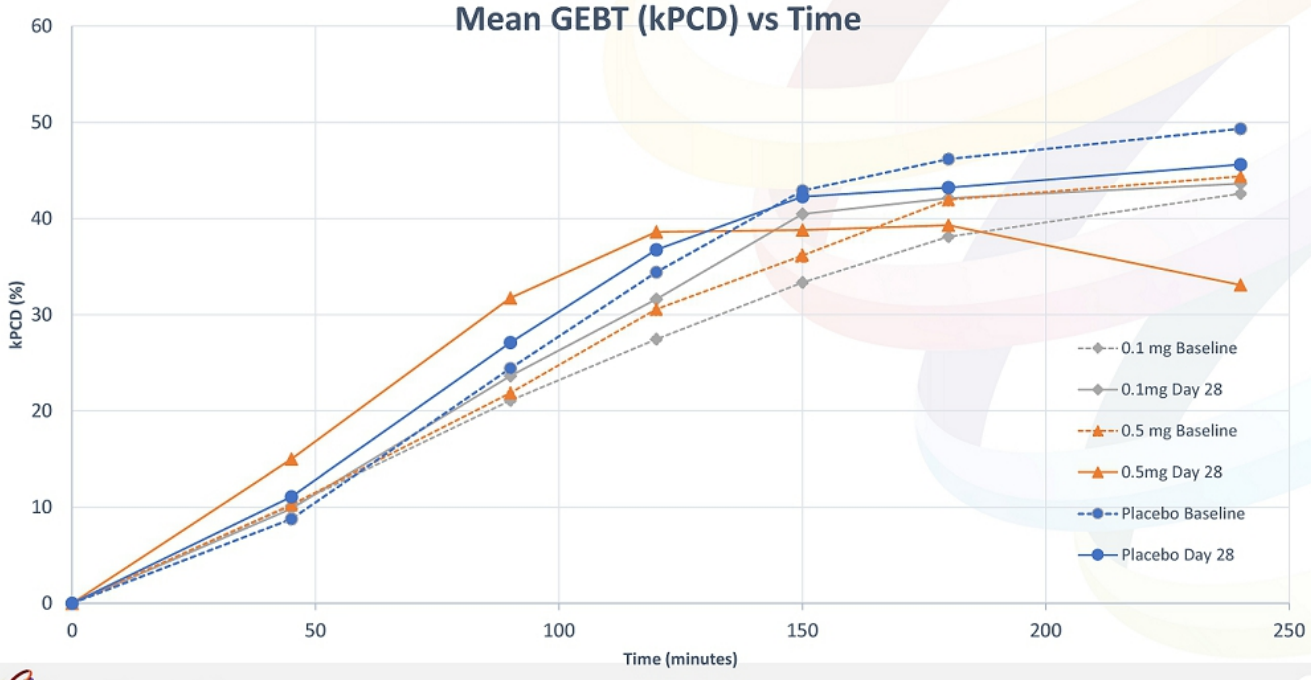
Phase 2A Study: GEBT Results

^{13}C-Spirulina GEBT Data: Changes from Baseline to Day 28

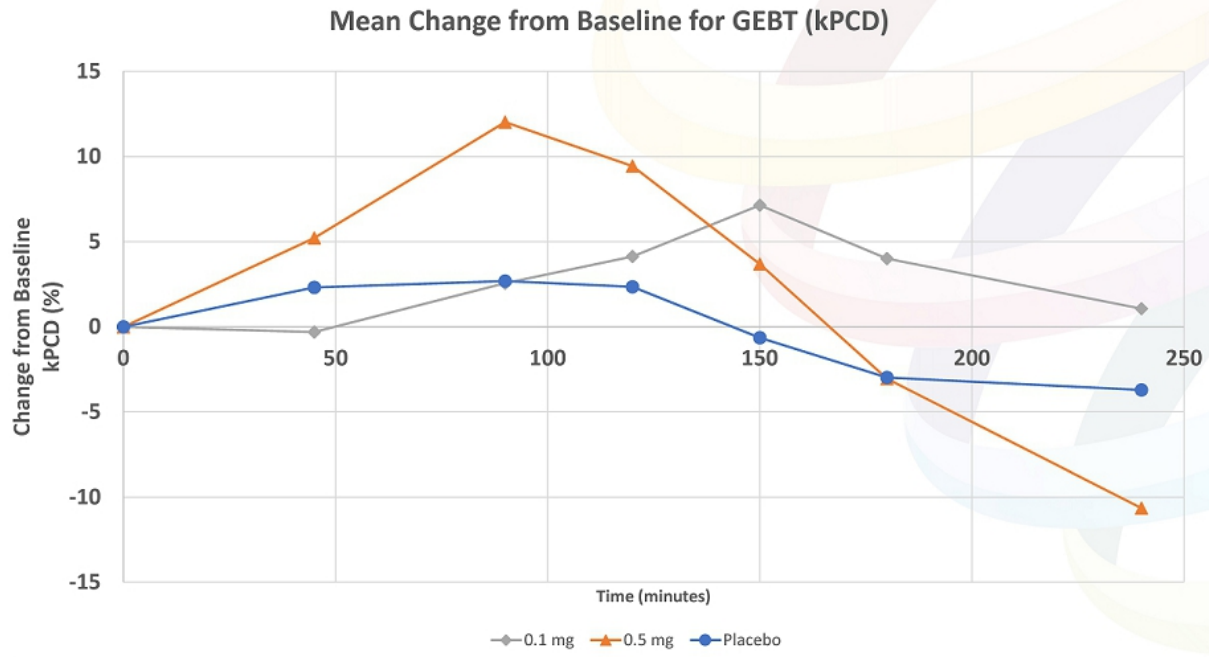
Mean GEBT Parameter** (SD)	PCS12852-GP-01 Study		
	PCS12852 0.1 mg (n=9)	PCS12852 0.5 mg (n=6)	Placebo (n=8)
t_{50} (minutes)	-7.4±20.2	-31.9.±50.5†	-9.4±42.4
AUC	632.7±1881.5	597.1±2635.8	37.4±2022.8
t_{10} (minutes)	2.4±4.7	-9.7±13.7*	-7.8±7.2*

* P value<0.05 vs baseline (ANCOVA analysis)
† p value<0.1 vs baseline (ANCOVA analysis)
** t_{50} and AUC were primary endpoints; t_{10} was an exploratory endpoint

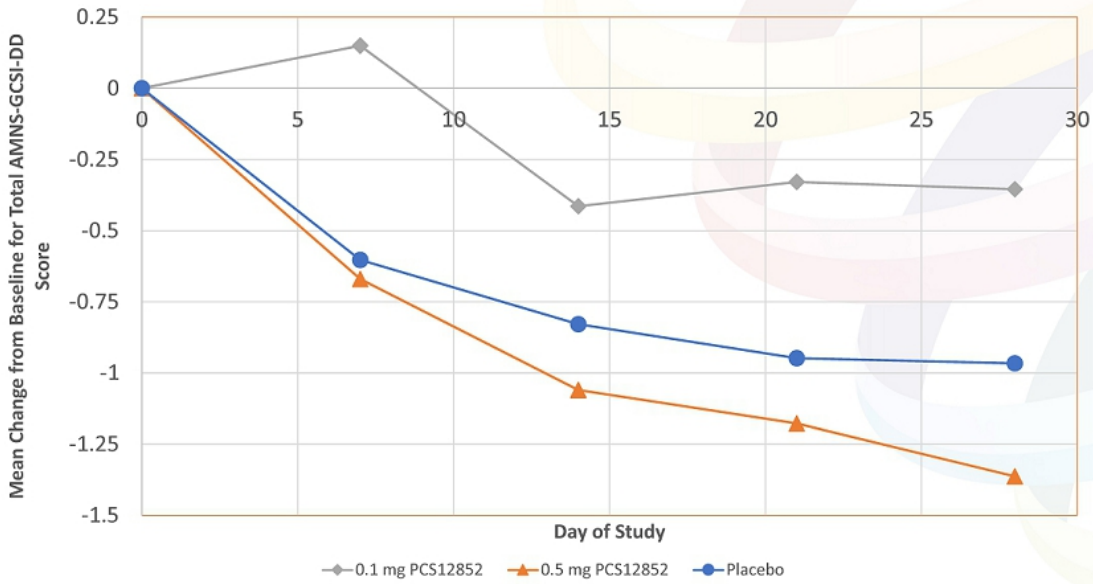
Phase 2a Study: GEBT Results



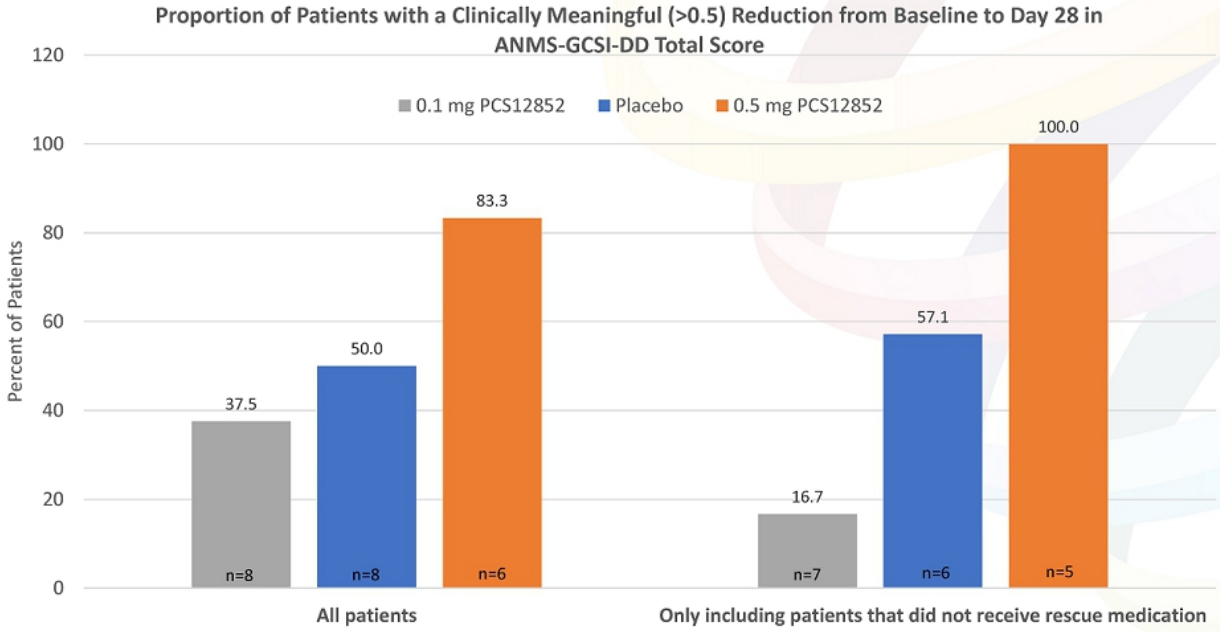
Phase 2a Study: GEBT Results



Phase 2a Study: Efficacy Results – Change from Baseline for Total GCSI Score at Day 28

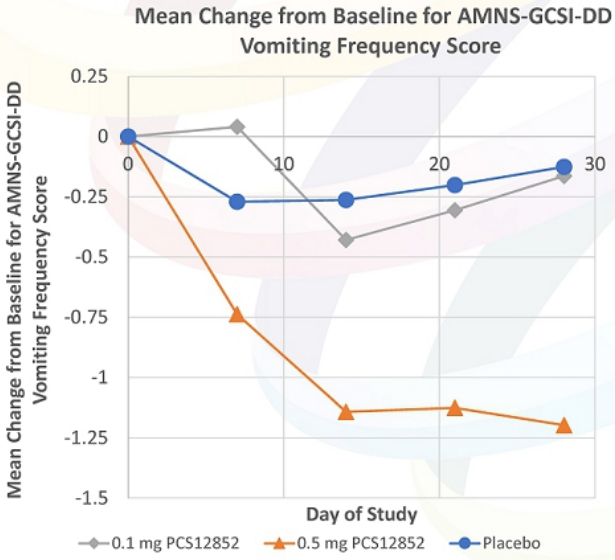


Phase 2a Study: Efficacy Results- Responders Assessment



Phase 2a Study: Efficacy Results – AMNS-GCSI-DD Subscores

- For the 0.5 mg PCS12852 group compared to placebo, greater improvements were noted in 4 of the 5 subscores – vomiting, nausea, abdominal pain and feeling excessively full.
- No differences were noted between the 0.1 mg PCS12852 and placebo groups.
- The changes were mostly noted in the DG patients and not the IG patients



Phase 2a Study: Safety Results

- A total of 12 Treatment Emergent Adverse Events (TEAEs) occurred in 6 subjects, all in the 0.5 mg PCS12852 group
  - All TEAEs were either mild or moderate, with no severe cases, and resolved without sequelae
  - AEs were the following:
    - Diarrhea (5)
    - GERD (1)
    - Dizziness (1)
    - Increased WBC counts (1)
    - Abdominal Pain (1)
    - Nausea (1)
    - Headache (1)
    - Concussion (1)
  - 1 subject experienced mild nausea, dizziness, headache, upper abdominal pain, and GERD, as well as moderate diarrhea, and withdrew from the study
- There were no cardiac events reported during the study
- There were no serious adverse events reported during the study

Phase 2A: Pharmacokinetic Results

Mean (±SD) Pharmacokinetic Parameters	PCS12852 0.1 mg		PCS12852 0.5 mg	
	Day 1	Day 28	Day 1	Day 28
Cmax (ng/ml)	0.12±0.04	0.11±0.69	0.59±0.33	0.48±0.26
Tmax (h)	2.58±0.95	3.32±2.07	2.10±1.44	3.35±2.06
AUC(0-last) (h*ng/mL)	0.63±0.28	1.10±1.23	3.06±1.59	7.42±7.11
t½ (h)	NC	15.91±3.70	NC	27.97±15.76

NC = Not Calculated

Phase 2a: Summary

- GEBT results demonstrated a significant improvement in gastric emptying in patients receiving 0.5 mg of PCS12852
- PCS12852 0.5 mg administered daily over 28 days in gastroparesis patients successfully improved gastroparesis symptoms in a clinically meaningful way as defined by > 0.5 reduction in the total ANMS GCSI-DD score compared to baseline
  - Patients in the 0.5 mg group showed a greater improvement than placebo in 4 out of the 5 ANMS-GCSI-DD subscores
  - The PCS12852 0.1 mg daily dose group showed little to no improvement in gastroparesis symptoms
- Greater improvement in the GEBT results and the symptomology results were observed in the DG group compared to the IG group
- Overall, PCS12852 was well tolerated, showed a very low risk of any off-target cardiovascular effects, and demonstrated a favorable safety profile
- These data suggest that a longer treatment than 28 days, as well as a higher dose of PCS12852, may result in even greater differences in the gastroparesis symptoms when compared to placebo

QUESTIONS?