



# 2024 CORPORATE PRESENTATION

June 2024

# Forward-Looking Statements



Various statements in this presentation, including, but not limited to statements regarding Vanda's commercial products, plans and opportunities, as well as statements about Vanda's products in development and the related clinical development and regulatory timelines and commercial potential for such products, are "forward-looking statements" under the securities laws. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward-looking statements are based upon current expectations and assumptions that involve risks, changes in circumstances and uncertainties. If the risks, changes in circumstances or uncertainties materialize or the assumptions prove incorrect, Vanda's results may differ materially from those expressed or implied by such forward-looking statements. Therefore, no assurance can be given that the results or developments anticipated by Vanda will be realized or, even if substantially realized, that they will have the expected consequences to, or effect on, Vanda. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements include, among others: Vanda's ability to continue to commercialize HETLIOZ® for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the U.S., in light of existing and potential generic competition, and Europe and for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in the U.S.; Vanda's ability to increase market awareness of Non-24 and SMS and market acceptance of HETLIOZ®; Vanda's ability to obtain regulatory approval in Europe for HETLIOZ® in SMS; Vanda's ability to overcome the increased reimbursement challenges it faces as a result of declining third-party payor coverage; Vanda's ability to continue to generate U.S. sales of Fanapt® for the treatment of schizophrenia; Vanda's ability to generate U.S. sales of Fanapt® for the acute treatment of bipolar I disorder in adults; Vanda's ability to generate U.S. and Canadian sales of PONVORY® for the treatment of relapsing forms of multiple sclerosis; Vanda's ability to complete the clinical development of and obtain regulatory approval of tradipitant in the treatment of gastroparesis, motion sickness and atopic dermatitis, HETLIOZ® in the treatment of jet lag disorder, insomnia, delayed sleep phase disorder and pediatric Non-24, the Fanapt® long acting injectable, milsaperidone in the treatment of adults with schizophrenia and bipolar I disorder, VTR-297 in the treatment of hematologic malignancies, VSJ-110 for the treatment of dry eye, VPO-227 for the treatment of secretory diarrhea disorders, including cholera, VQW-765 for the treatment of social/performance anxiety, VHX-896 for the treatment of psychiatric disorders and PONVORY® in the treatment of psoriasis and ulcerative colitis; Vanda's ability to progress VCA-894A in Charcot-Marie-Tooth Disease, Type 2S; Vanda's dependence on third-party manufacturers to manufacture HETLIOZ®, Fanapt® and PONVORY® in sufficient quantities and quality; Vanda's ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights; Vanda's ability to maintain rights to develop and commercialize Vanda's products under its license agreements; Vanda's ability to obtain and maintain regulatory approval of Vanda's products, and the labeling for any approved products; Vanda's level of success in commercializing HETLIOZ® and Fanapt® in new markets; Vanda's expectations regarding the timing and success of preclinical studies and clinical trials; the safety and efficacy of Vanda's products; regulatory developments in the U.S., Europe and other jurisdictions; limitations on Vanda's ability to utilize some or all of its prior net operating losses and orphan drug and research development credits; the size and growth of the potential markets for Vanda's products and the ability to serve those markets; Vanda's expectations regarding trends with respect to its revenues, costs, expenses, liabilities and cash, cash equivalents and marketable securities; Vanda's ability to identify or obtain rights to new products; Vanda's ability to attract and retain key scientific or management personnel; the costs and effects of litigation; Vanda's ability to obtain the capital necessary to fund its research and development or commercial activities; the costs and effects of litigation; potential losses incurred from product liability claims made against Vanda; the use of existing cash, cash equivalents and marketable securities and other factors that are described in the "Cautionary Note Regarding Forward-Looking Statements", "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's most recent annual report on Form 10-K, as updated by Vanda's subsequent quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC, which are available on the SEC's website at [www.sec.gov](http://www.sec.gov).

Vanda cautions investors not to rely too heavily on the forward-looking statements contained in this presentation. The information in this presentation is provided only as of the date of this presentation, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.



Vanda is a leading global biopharmaceutical company dedicated to innovating in the service of people's pursuit of happiness

## Commercialized Products

Fanapt®

HETLIOZ®  
HETLIOZ LQ®

PONVORY®

## Robust pipeline

Recent and upcoming regulatory submissions

Multiple products across wide range of therapeutic areas

## Strong Financial Position

Approx. \$390 million cash as of Q1 2024 with no debt

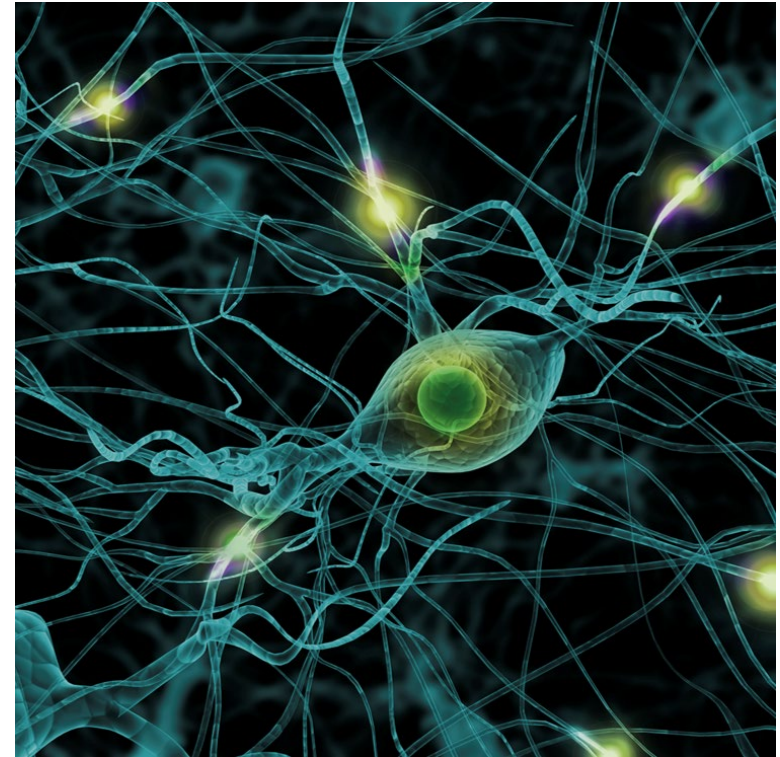
# Acquisition of PONVORY® from Johnson & Johnson Company



In December 2023, Vanda acquired U.S. and Canadian rights to PONVORY® (ponesimod) from Actelion Pharmaceuticals Ltd., a Johnson & Johnson Company, for \$100 million. PONVORY® is approved by the U.S. Food and Drug Administration (FDA) and Health Canada to treat adults with relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. In May 2024, Vanda announced the completion of the transfer of the FDA marketing authorization for PONVORY® which fully allows Vanda to commercialize PONVORY® in the U.S.

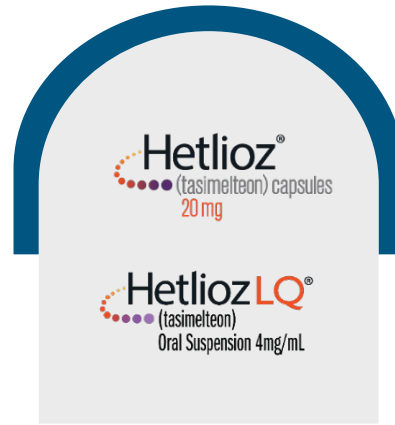
The mechanism of action of PONVORY® makes it also a potential therapeutic candidate for the treatment of a diverse group of inflammatory/autoimmune disorders including but not limited to ulcerative colitis, psoriasis, Crohn's disease, atopic dermatitis, eosinophilic esophagitis and alopecia areata. In a randomized placebo controlled clinical study, PONVORY® has been shown to reduce the symptoms and signs of psoriasis.<sup>1</sup>

The PONVORY® Orange Book listed patent with the latest expiry date is set to expire in December 2042.



1. Vaclavkova, A., Chimentì, S., Arenberger, P., Holló, P., Sator, P. G., Burcklen, M., Stefani, M., & D'Ambrosio, D. (2014). Oral ponesimod in patients with chronic plaque psoriasis: a randomised, double-blind, placebo-controlled phase 2 trial. *Lancet* (London, England), 384(9959), 2036–2045. [https://doi.org/10.1016/S0140-6736\(14\)60803-5](https://doi.org/10.1016/S0140-6736(14)60803-5)

# Commercialized Products



- Fanapt® is approved in the U.S. for the acute treatment of bipolar I disorder in adults and for the treatment of adults with schizophrenia.
- Pursuing FDA approval for milsaperidone for the treatment of adults with acute bipolar I disorder and schizophrenia. NDA expected to be submitted in early-2025.
- Phase III program for Fanapt Long Acting Injectible (LAI) expected to be initiated by end of 2024.
- HETLIOZ® oral capsules are approved in the U.S. and Europe for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).
- HETLIOZ® oral capsules and HETLIOZ LQ® liquid formulation are approved in the U.S. for the treatment of nighttime sleep disturbances in adults and children, respectively, with Smith-Magenis Syndrome (SMS).
- Pursuing FDA approvals for HETLIOZ® in the indications of insomnia and jet lag disorder.
- PONVORY® is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- Phase III studies of PONVORY® in the treatment of psoriasis and in the treatment of ulcerative colitis expected to be initiated by the end of 2024.

# Clinical Development Pipeline: Key Milestones



Recent and upcoming clinical and regulatory developments include:

Product	Recent Action
Fanapt®	FDA approval of Bipolar in April 2024
Milsaperidone	NDA expected to be submitted in early-2025
Tradipitant	Gastroparesis: PDUFA Date: 9/18/2024
Tradipitant	Motion Sickness: 2 Positive Phase III studies; NDA expected to be submitted by end of 2024
VCA-894A	Charcot-Marie-Tooth Disease, Type 2S: expect to enroll patient in mid-2024
VSJ-110	Dry Eye: Phase II study >50% enrolled

# Strategic Focus



## Increase revenue

Organically through existing products

Business development opportunities

## Advance pipeline

Late / early-stage programs

Emerging ASO platform

## Consumer focus

Increase access and affordability for patients

Engage directly with consumer

# Commercial Priorities & Milestones



- Commercial launch of Fanapt in acute bipolar I disorder.
- Continued focus on market for schizophrenia.
- Pursue FDA approval for milsaperidone for the treatment of adults with acute bipolar I disorder and schizophrenia.
- Advance Long Acting Injectable (LAI) with phase III program expected to be initiated by end of 2024.

- Retain market share despite generic competition through focus on patient loyalty.
- Continue growth of HETLIOZ® in SMS in U.S. market.
- Pursue approval of HETLIOZ® in SMS in the E.U. market.
- Pursue FDA approvals for HETLIOZ® in the indications of insomnia and jet lag disorder.

- Commercial launch in existing multiple sclerosis (MS) market.
- Phase III studies of PONVORY® in the treatment of psoriasis and in the treatment of ulcerative colitis expected to be initiated by the end of 2024.

- Pursue FDA approval for tradipitant in patients with gastroparesis.
- Pursue FDA approval for tradipitant in patients with motion sickness.





# Research and Development

# Late-Stage Clinical Development Pipeline



Product	Indication	Preclinical	Phase I	Phase II	Phase III	Regulatory
	Long Acting Injectable (LAI)	Progress bar from Preclinical to Phase III				
	Bipolar I Disorder	Progress bar from Preclinical to Phase III				
	Schizophrenia	Progress bar from Preclinical to Phase III				
	Jet Lag Disorder	Progress bar from Preclinical to Regulatory				
	Insomnia	Progress bar from Preclinical to Regulatory				
	Delayed Sleep Phase Disorder (DSPD)	Progress bar from Preclinical to Phase III				
	Non-24 Pediatric	Progress bar from Preclinical to Phase III				
	Psoriasis	Progress bar from Preclinical to Phase III				
	Ulcerative Colitis	Progress bar from Preclinical to Phase III				
	Gastroparesis	Progress bar from Preclinical to Regulatory				
	Motion Sickness	Progress bar from Preclinical to Phase III				
	Atopic Dermatitis	Progress bar from Preclinical to Phase III				



# HETLIOZ<sup>®</sup> Lifecycle Management

# HETLIOZ<sup>®</sup> Lifecycle Management Programs



Hetlioz<sup>®</sup>  
(tasimelteon) capsules  
20 mg

Hetlioz LQ<sup>®</sup>  
(tasimelteon)  
Oral Suspension 4mg/mL

1

## Jet Lag Disorder

- Clinical program completed

2

## Insomnia

- Clinical program completed

3

## Delayed Sleep Phase Disorder

- Phase III program initiated

4

## Non-24 Pediatric

- Phase III clinical program in preparation



# Fanapt<sup>®</sup> Lifecycle Management

# Fanapt® Lifecycle Management Programs



Fanapt®  
(iloperidone) tablets  
1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg

1

## Bipolar I Disorder

- Phase III program complete; positive results announced in December 2022
- FDA approved Fanapt® in bipolar I disorder in adults in April 2024

2

## Long Acting Injectable

- Expect to initiate a Phase III program for the long acting injectable (LAI) formulation of Fanapt® by the end of 2024. Fanapt® LAI could reach the U.S. market after 2026 and there are pending patent applications that, if issued, could extend exclusivity into the 2040s

3

## Milsaperidone

- Expect to submit a New Drug Application (NDA) for milsaperidone (also known as VHX-896 and P-88), the active metabolite of Fanapt®, in schizophrenia and acute bipolar I disorder to the FDA in early-2025. If approved, there are pending patent applications that, if issued, could extend exclusivity into the 2040s



# Bipolar I Disorder

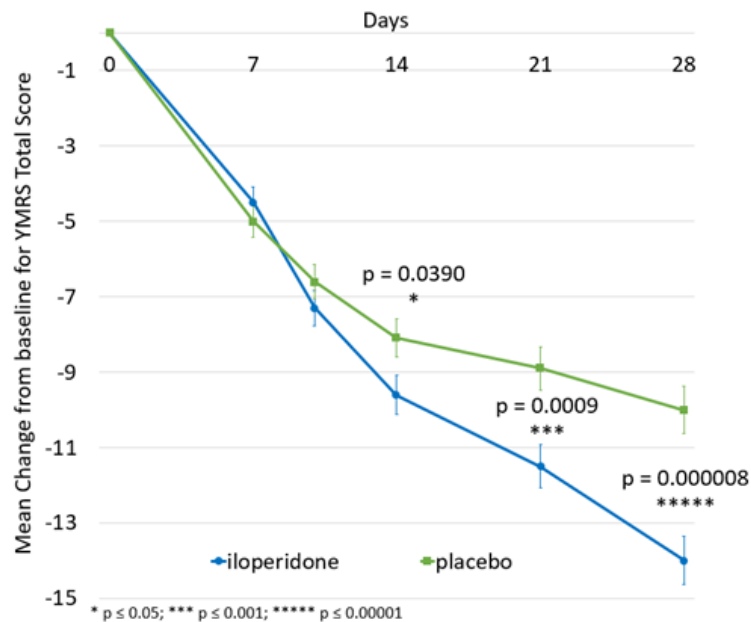
# Fanapt® for Bipolar I Disorder



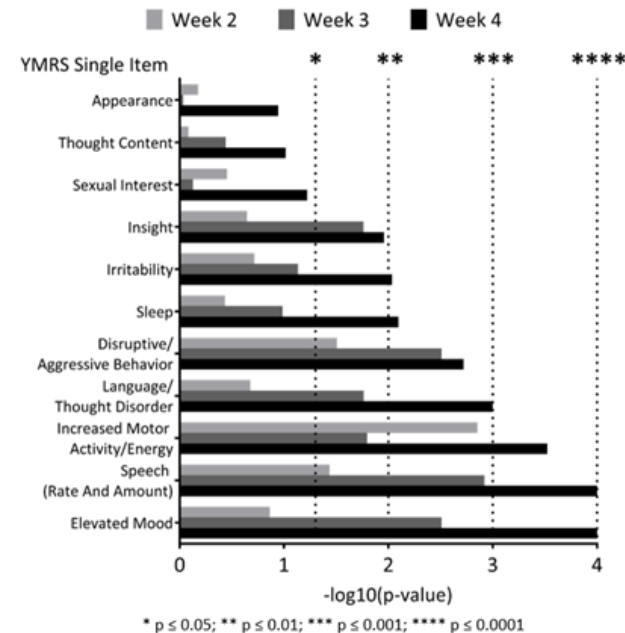
## Results reported in December 2022

- The Phase III study enrolled approximately 400 volunteers with a history of bipolar I disorder suffering from a current episode of mania.
- The primary endpoint was assessed by the Young Mania Rating Scale (YMRS), a rating scale of clinical severity in the core symptoms of mania.
- Looking at the YMRS change from baseline at week 4, Fanapt® was significantly superior to placebo ( $p=0.000008$ ).

Young Mania Rating Scale (YMRS) Change From Baseline Total Score



Significance of YMRS Change From Baseline Single Items





# Fanapt® for Bipolar I Disorder



## Results reported in December 2022

- The secondary endpoints, Clinician Global Impression of Severity (CGI-S) and Clinician Global Impression of Change (CGI-C), also achieved statistical significance ( $p=0.0005$  and  $p=0.0002$ , respectively) at week 4.
- Bipolar disorder is highly prevalent in the United States, estimated to affect 2.8%<sup>1</sup>, of the U.S. adult population, a number approximately up to ten times higher than the estimated prevalence of schizophrenia<sup>2,3</sup>.
- This pivotal study data of Fanapt® for the treatment of acute manic and mixed episodes associated with bipolar I disorder in adults included in supplemental New Drug Application (sNDA). Pursuing FDA approval for Fanapt® in the indication of bipolar I disorder in adults; sNDA accepted for filing with PDUFA target action date of 4/2/2024.

1. Harvard Medical School, 2007. National Comorbidity Survey (NSC). (2017, August 21). Retrieved from <https://www.hcp.med.harvard.edu/ncs/index.php>.

2. Kessler, R.C., Birnbaum, H., Demler, O., Falloon, I.R., Gagnon, E., Guyer, M., Howes, M.J., Kendler, K.S., Shi, L., Walters, E., Wu, E.Q. (2005). The prevalence and correlates of nonaffective psychosis in the National Comorbidity Survey Replication (NCS-R). *Biological Psychiatry*, 58(8), 668-76. doi: 10.1016/j.biopsych.2005.04.034

3. Wu, E.Q., Shi, L., Birnbaum, H., Hudson, T., Kessler, R. (2006). Annual prevalence of diagnosed schizophrenia in the USA: a claims data analysis approach. *Psychological Medicine*, 36(11), 1535-40. doi: 10.1017/S0033291706008191



# Tradipitant Programs

# Tradipitant Programs



1

## Gastroparesis

- Pursuing FDA approval for tradipitant in patients with gastroparesis; NDA accepted for filing with PDUFA target action date of 9/18/2024
- Phase III study results reported in February 2022; 12-week study of ~200 patients with idiopathic or diabetic gastroparesis
- Phase II positive study with results reported in December 2018 and published in Gastroenterology in January 2021

2

## Motion Sickness

- Second Phase III positive study results reported in May 2024
- First Phase III positive study results reported in May 2023
- Phase II positive study results reported in July 2019

3

## Atopic Dermatitis

- EPIONE 2 Phase III study on hold
- EPIONE Phase III study results reported in February 2020



# Gastroparesis

# Tradipitant for Gastroparesis



- Completed two clinical studies of tradipitant in gastroparesis. NDA accepted for filing with PDUFA target action date of 9/18/2024.
- Gastroparesis is a significant unmet medical need.
- Last treatment approved more than 40 years ago<sup>1</sup>.



**600,000  
diagnosed**

600,000 people  
estimated to be  
diagnosed in the  
U.S.<sup>2</sup>



**300,000  
prescriptions**

Appx. 300,000  
metoclopramide  
prescriptions per  
month.<sup>3</sup>



**6 million  
people**

Estimated U.S.  
prevalence of 1.8%  
of the population.<sup>2</sup>

1. Reglan (metoclopramide) initial FDA approval 1979.

2. Rey et al J Neurogastroenterol Motil, Jan 2012.

3. IQVIA Prescription Data

# Gastroparesis – Symptoms & Clinical Expression<sup>1</sup>



## Diabetic or Idiopathic Gastroparesis

### Chronic Nausea



Patients with gastroparesis suffer from chronic, severe and debilitating nausea.

### Delayed Gastric Emptying



Many patients with gastroparesis have a mechanical defect of delayed gastric emptying, which may be the cause of some of their symptoms.



### Vomiting

Gastroparesis can cause vomiting, which can lead to weight loss and hospitalization due to nutritional deficiencies.



### Additional GI Symptoms

Patients with gastroparesis may also experience postprandial fullness, early satiety and abdominal pain.



# Tradipitant Gastroparesis Clinical Program



1

## Phase II Study (VP-VLY-686-2301)

- 4-week study of approximately 150 adult patients with diabetic or idiopathic gastroparesis
- Tradipitant was shown to be effective in improving nausea and overall symptoms in patients with gastroparesis
- Efficacy established by tradipitant in the 4-week double-blind phase was persistent in the open-label phase

2

## Phase III Study (VP-VLY-686-3301)

- 12-week study of approximately 200 adult patients with diabetic or idiopathic gastroparesis
- The study did not meet its primary endpoint; however, when accounting for confounders, strong evidence of drug effect across a number of symptoms was observed
- Open-label phase remains open with over 300 patients already enrolled

3

## Expanded Access Program

- Vanda initiated an expanded access program for patients requesting access to tradipitant outside of the clinical studies
- Vanda continues to receive requests from patients reaching out to gain access to tradipitant through the Expanded Access program, which has multiple patients continuing to take tradipitant for more than a year

# Gastroparesis – Phase II Study



Results reported in December 2018, published in *Gastroenterology* January 2021<sup>1</sup>

## Study Design



- 4 weeks of double-blind treatment followed by optional 8 weeks of open-label treatment
- 85 mg b.i.d.
- 47 study sites in the U.S.

## Population



- Approximately 150 randomized subjects
- Stratified by idiopathic or diabetic gastroparesis

## Assessments



- Patient Reported Daily Diary: Nausea, Vomiting & Other Symptoms
- Patient Assessment of GI Disorders (PAGI-SYM)
- Patient Global Impression (PGI-C)
- Clinical Global Impression (CGI-S)



# Gastroparesis – Phase III Study



Study is complete and results were reported in February 2022

## Study Design



- 12 weeks of double-blind treatment
- 85 mg b.i.d.
- 40 study sites in the U.S.

## Population



- Approximately 200 randomized subjects
- Stratified by idiopathic or diabetic gastroparesis

## Assessments



- Patient Reported Daily Diary: Nausea, Vomiting & Other Symptoms
- Patient Assessment of GI Disorders (PAGI-SYM)
- Patient Global Impression (PGI-C)
- Clinical Global Impression (CGI-S)

# Gastroparesis – Pooled Study Results



- **Vanda completed a pooled analysis of two clinical studies of tradipitant in gastroparesis.**
  - **Population of 342 patients with relevant clinical endpoints.**
  - **Both studies were large multi-site, randomized, double-blind, placebo-controlled studies**
- **Tradipitant was shown to be superior to placebo in key clinical parameters:**
  - **Daily Diary-Nausea (primary endpoint parameter)**
  - **% Nausea Free Days**
  - **Patient Global Impression scale change (PGI-C)**
  - **Overall Benefit Score and Gastroparesis Cardinal Symptom Index (GCSI) score**
- **Both studies demonstrate the efficacy of tradipitant in relieving symptoms of gastroparesis.**

# Gastroparesis – Pooled Study Results



Figure 1 and Table 1 show the results of such pooled analysis of all patients randomized in the two studies (intent to treat population, ITT) and Figure 2 and Table 2 show the results for the same parameters in the population of patients who were judged as compliant to treatment based on analysis of drug exposure (treatment compliant population).

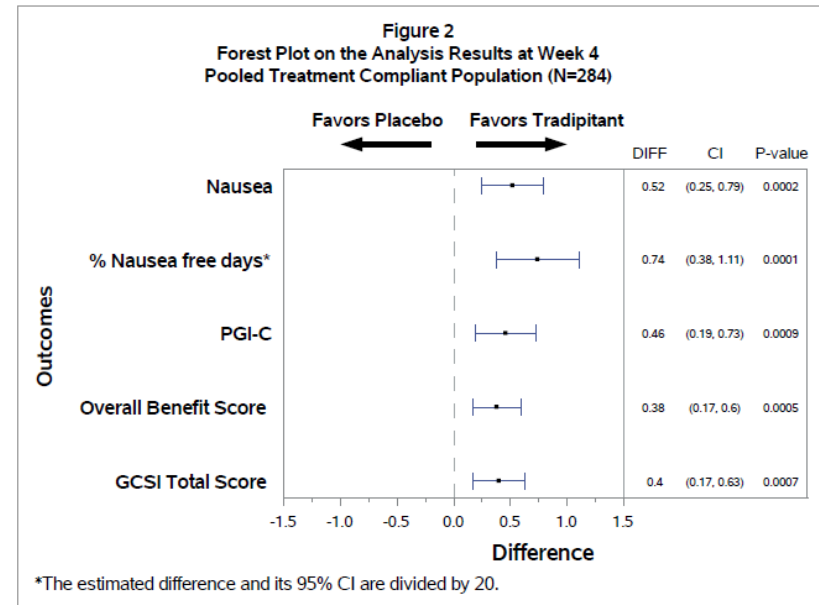
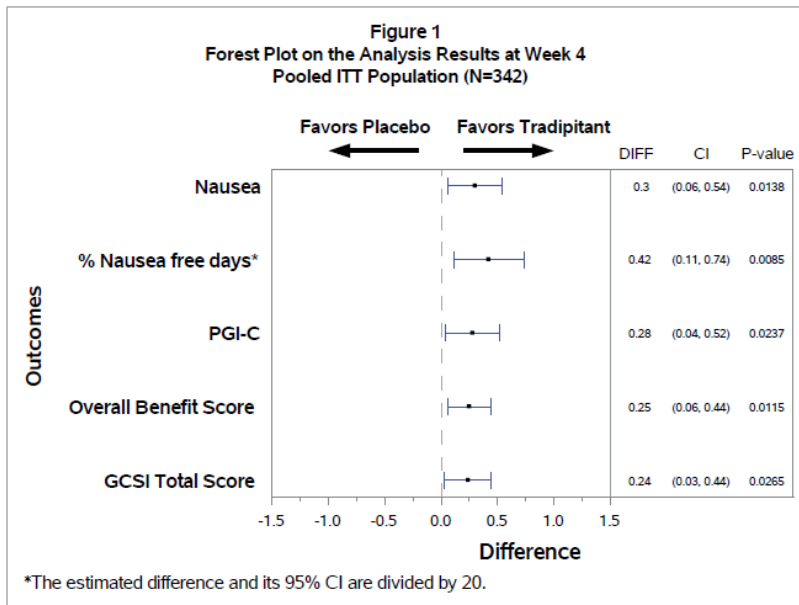


Table 1: Week 4 Pooled Analysis : ITT population for Study 1 and Study 2

	Tradipitant n=175	Placebo n=167	P-value
DD-Nausea	-1.15	-0.85	0.0138
% Nausea Free Days	20.96	12.52	0.0085
PGI-C	2.72	3.00	0.0237
Overall Benefit Score	1.13	0.88	0.0115
GCSI	-0.99	-0.76	0.0265

Table 2: Week 4 Pooled Analysis: Treatment Compliant Population for Study 1 and Study 2

	Tradipitant n=117	Placebo n=167	P-value
DD-Nausea	-1.37	-0.85	0.0002
% Nausea Free Days	27.44	12.58	0.0001
PGI-C	2.53	2.99	0.0009
Overall Benefit Score	1.27	0.88	0.0005
GCSI	-1.15	-0.75	0.0007



# Motion Sickness

# Tradipitant for Motion Sickness



Neurokinin-1 (NK-1) receptor antagonists have the potential to be effective in improving the symptoms of motion sickness, given the involvement of substance P in nauseogenic and emetic pathways and the expression of NK-1 receptors in the gastrointestinal system.<sup>1</sup>



Nausea and vomiting are the core symptoms of motion sickness<sup>2</sup>



The sensory mismatch resulting in motion sickness is due to discordance between actual and expected movement as perceived by the visual, vestibular, and kinesthetic systems<sup>3</sup>



About 2 to 3 million doses of Dramamine are purchased each month in the U.S.<sup>4</sup>



1. Polymeropoulos VM, Czeisler ME, Gibson MM, Anderson AA, Miglo J, Wang J, Xiao C, Polymeropoulos CM, Birznieks G and Polymeropoulos MH (2020) Tradipitant in the Treatment of Motion Sickness: A Randomized, Double-Blind, Placebo-Controlled Study. *Front. Neurol.* 11:563373. doi: 10.3389/fneur.2020.563373

2. Golding JF. Motion sickness. In: Furman JM, Lempert T, editors. *Handbook of Clinical Neurology*. Amsterdam, Boston, Heidelberg, London, New York, Oxford, Paris, San Diego, San Francisco, Singapore, Sydney, Tokyo: Elsevier. (2016). p. 371–90.

3. Graybiel A, Knepton J. Sopor syndrome: a sometimes sole manifestation of motion sickness. *Aviat Space Environ Med.* (1976) 47:873–82.

4. IQVIA data

# Motion Sickness – Phase II Study Results



Results reported in July 2019, published in *Frontiers in Neurology* in September 2020<sup>1</sup>

- Tradipitant was shown to be effective in preventing motion sickness<sup>1</sup>
- An exploratory analysis was performed to evaluate the effects of tradipitant under “calm” and “rough” seas. Under “rough” sea conditions (seas above 1 meter):
  - 72.2% of the placebo treated patients vomited as compared to 15.8% of those treated with tradipitant
  - A significant effect was also seen under “rough” conditions in the MSSS Worst score

Endpoint	Tradipitant	Placebo	Difference	P-Value
ITT	N=63	N=63		
% Vomiting	17.5%	39.7%	22.2%	0.0039
Worst MSSS	3.40	3.75	0.35	0.2936
<b>Calm Sea</b>	N=44	N=45		
% Vomiting	18.2%	26.7%	8.5%	0.3123
Worst MSSS	3.4	3.32	-0.09	0.8271
<b>Rough Sea</b>	N=19	N=18		
% Vomiting	15.8%	72.2%	56.4%	0.0009
Worst MSSS	3.19	4.57	1.38	0.0235

## Motion Sifnos Phase II Study Results<sup>1</sup>

Single day sea travel in the Pacific Ocean

Patients with a history of motion sickness

170mg tradipitant versus placebo

Primary Endpoints:

- % Vomiting
- Worst MSSS - Motion Sickness Severity Scale

ITT = Intent to Treat

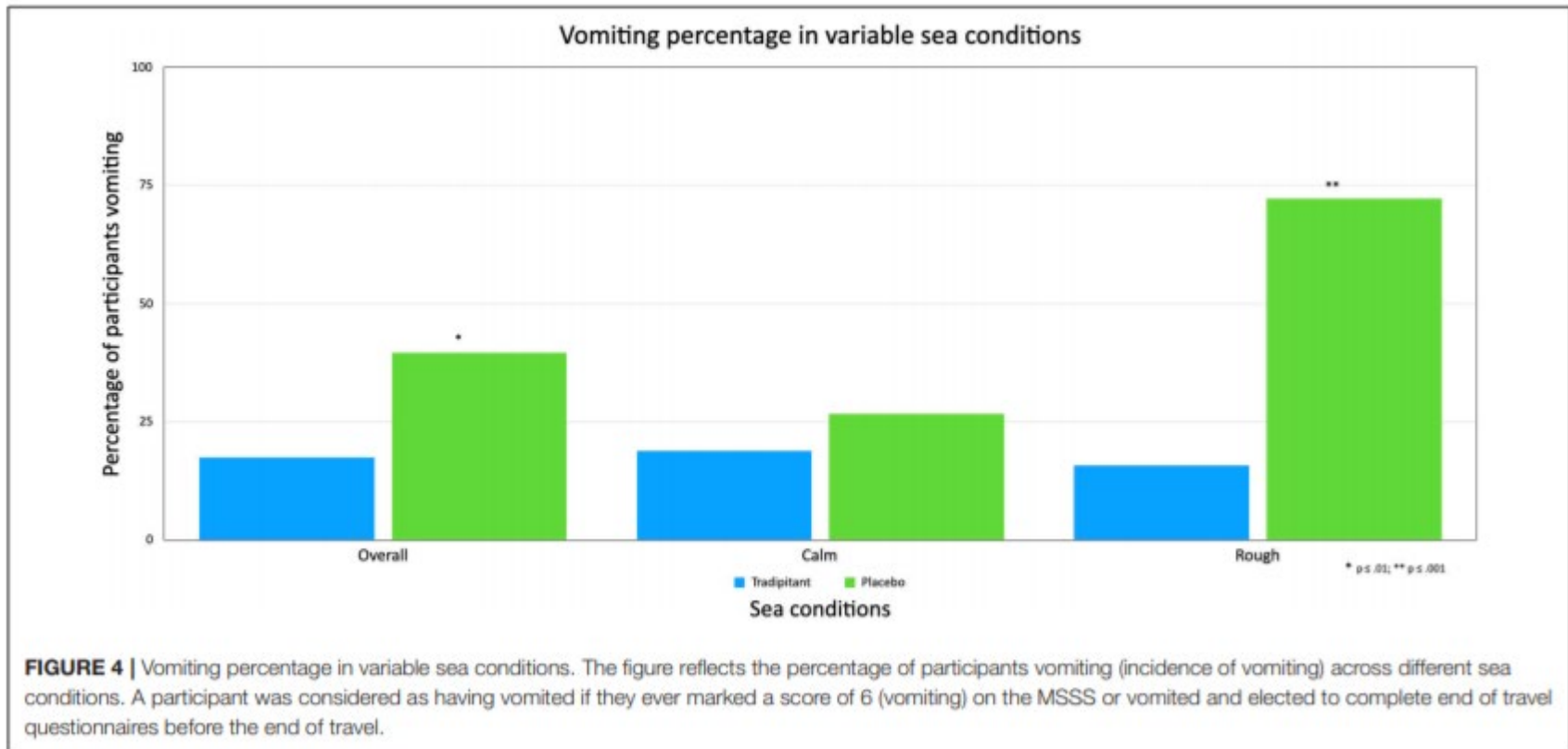
1. Polymeropoulos VM, Czeisler ME, Gibson MM, Anderson AA, Miglo J, Wang J, Xiao C, Polymeropoulos CM, Birznieks G and Polymeropoulos MH (2020) Tradipitant in the Treatment of Motion Sickness: A Randomized, Double-Blind, Placebo-Controlled Study. *Front. Neurol.* 11:563373. doi: 10.3389/fneur.2020.563373

# Motion Sickness – Phase II Study Results



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  - 72.2% of the placebo treated patients vomited as compared to 15.8% of those treated with tradipitant
  - A significant effect was also seen under “rough” conditions in the MSSS Worst score



# Motion Sickness: Phase III Program



- **First Phase III study completed – Positive results in prevention of vomiting**
- **Second Phase III study completed – Positive results in prevention of vomiting**
- **Open label safety study started**

## Enrollment



- **First Phase III Study: 365 randomized**
  - **85 and 170mg tradipitant both met primary endpoint preventing vomiting on the boats**
- **Second Phase III Study: 316 randomized**
  - **170mg met primary endpoint and 85mg met secondary endpoint, both preventing vomiting on the boats**

## Program Timeline



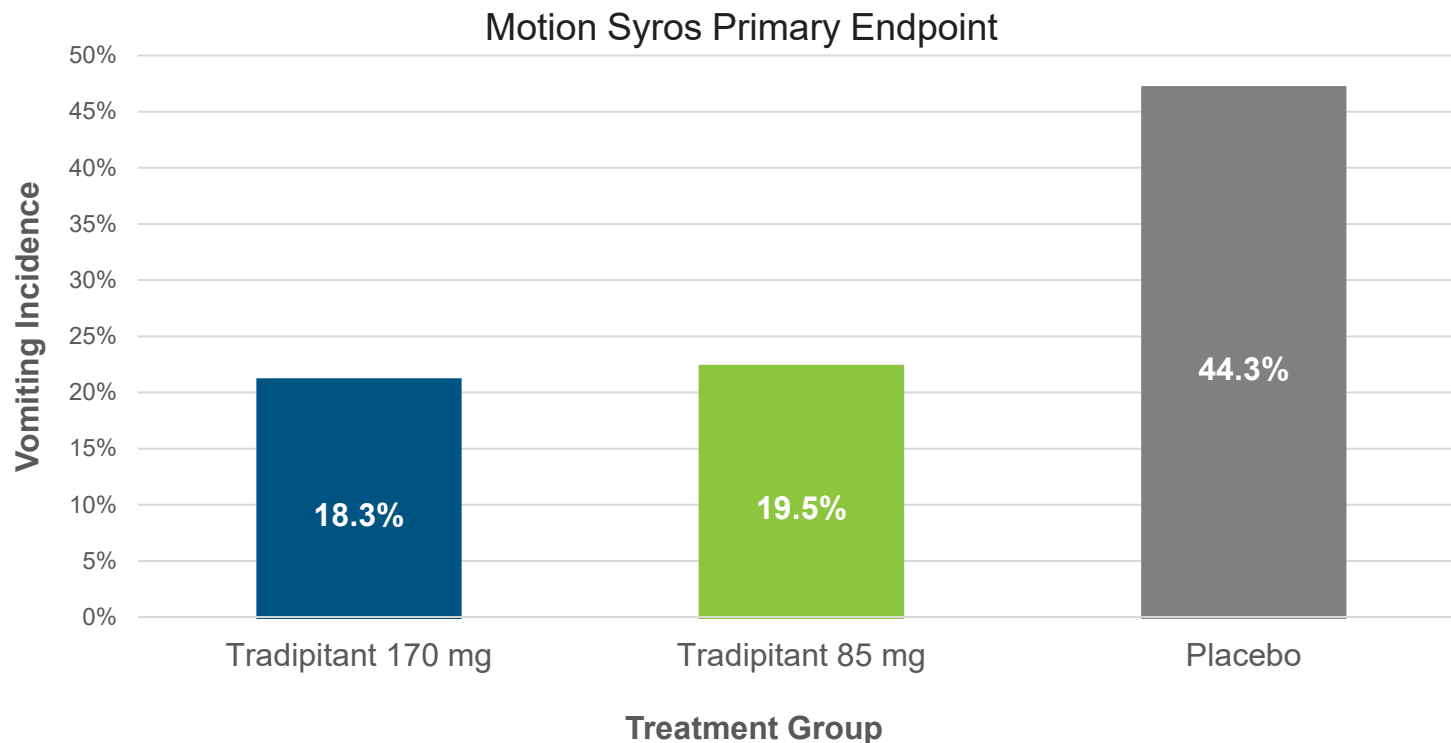
- **First Phase III results reported in May 2023**
- **Second Phase III results reported in May 2024**
- **New Drug Application expected to be submitted in Q4 2024**



# Motion Sickness: First Phase III Study



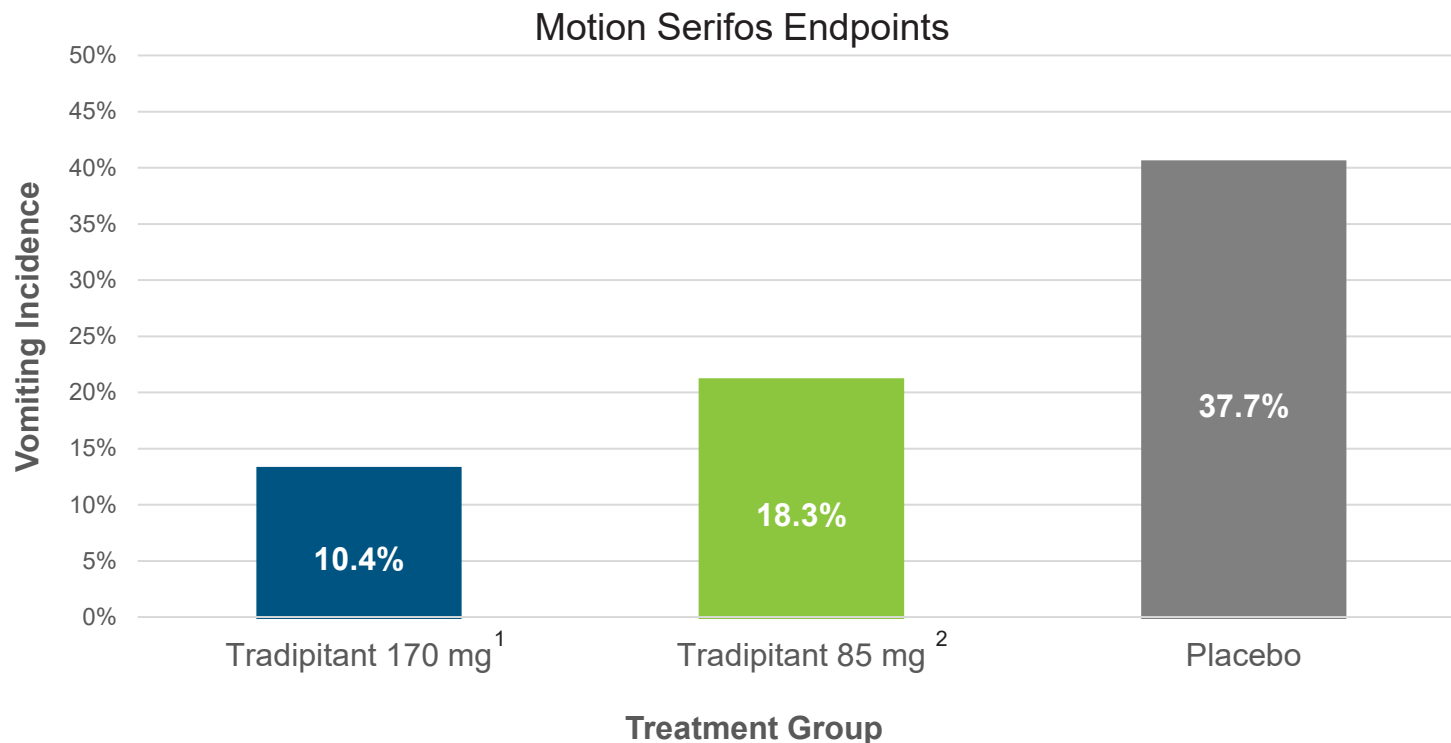
- 365 participant study across 34 boat trips in coastal waters of U.S. from November 2021 to April 2023
- Participants randomized 1:1:1 tradipitant 170mg v tradipitant 85mg v placebo 1 hour prior to departure
- Approximately 4-hour trips with questionnaires of vomiting and nausea every 30 minutes
- Incidence of vomiting was significantly lower in tradipitant 170mg (18.3%) and tradipitant 85mg (19.5%) as compared to placebo (44.3%)



# Motion Sickness: Second Phase III Study



- 316 participant study across 20 boat trips in coastal waters of U.S. from September 2023 and April 2024
- Participants randomized 1:1:1 tradipitant 170mg v tradipitant 85mg v placebo 1 hour prior to departure
- Approximately 4-hour trips with questionnaires of vomiting and nausea every 30 minutes
- Incidence of vomiting was significantly lower in tradipitant 170mg (10.4%) and tradipitant 85mg (18.3%) as compared to placebo (37.7%)



1. Primary Endpoint: Tradipitant 170mg vs Placebo  
2. Secondary Endpoint: Tradipitant 85mg vs Placebo



# Early-Stage Programs



## Cystic Fibrosis Transmembrane Conductance Regulators (CFTR)

- **VSJ-110** – CFTR Activator: VSJ-110 has shown efficacy in a dry eye model<sup>1</sup> and exhibited anti-inflammatory properties in both in vitro and in vivo assays
- Phase II study of VSJ-110 for the treatment of dry eye is ongoing and more than 50% enrolled
- **VPO-227** – CFTR Inhibitor: CFTR inhibitors decrease water secretion across epithelia, such as where aberrant CFTR activation occurs; they may be useful in the treatment of cholera, traveler's diarrhea, polycystic kidney disease, and other conditions of water hyper-secretion
- Cholera Disease: VPO-227 was granted Orphan Drug Designation by FDA for the treatment of cholera



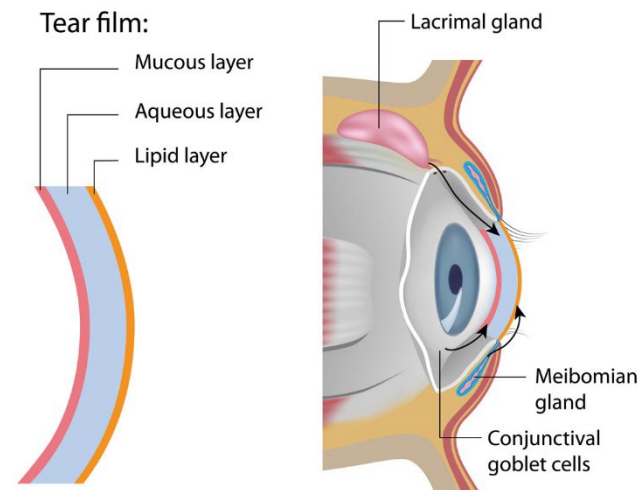
## Hematologic Malignancies

- VTR-297 is a histone deacetylase (HDAC) inhibitor
- Ongoing Phase II study of VTR-297 in Hematologic Malignancies at sites in the U.S. and Europe
- Phase I study of VTR-297 for the treatment of onychomycosis, a fungal infection of the nail, was initiated in April 2024



## Social/Performance Anxiety

- VQW-765 is an Alpha-7 nicotinic acetylcholine receptor partial agonist
- Phase II study of a single-dose treatment to alleviate social/performance anxiety complete; results announced in December 2022



1. Lee, S., P.W. Phuan, C.M. Felix, J.A. Tan, M.H. Levin and A.S. Verkman (2017). Nanomolar-potency aminophenyl-1,3,5-triazine activators of the cystic fibrosis transmembrane conductance regulator (CFTR) chloride channel for prosecretory therapy of dry eye diseases. *J. Med. Chem.* 60:1210-1218.

# Early-Stage Programs

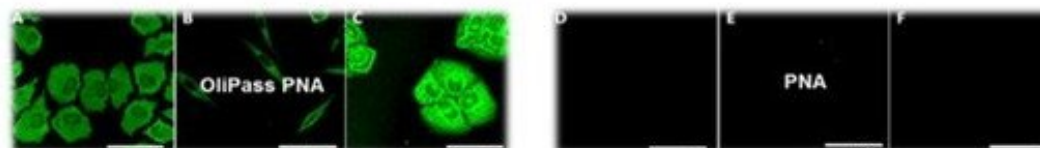
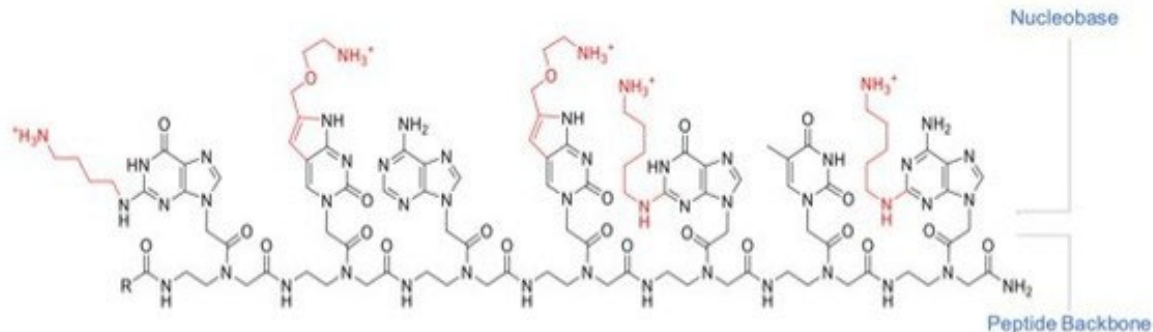


## Antisense Oligonucleotide (ASO)

- VCA-894A was granted Orphan Drug Designation for the treatment of Charcot-Marie-Tooth disease, axonal, type 2S (CMT2S), caused by cryptic splice site variants within IGHMBP2. Phase I study expects to enroll patient in mid-2024.
- In September 2022, Vanda and OliPass Corporation (OliPass) announced a research and development agreement to jointly develop a set of antisense oligonucleotide (ASO) molecules based on OliPass' proprietary modified peptide nucleic acids.
- This evolving discovery and development platform is intended to support Vanda's development of ASO-based precision medicine therapeutics.



## OliPass Peptide Nucleic Acids (OPNA) – Chemically modified PNA



Improvement of cell permeability by OPNA modification in 3 different cell types .



# Financial Results



## Q1 2024 Financial Highlights

**\$47.5 million**

Total net product sales from Fanapt<sup>®</sup>, HETLIOZ<sup>®</sup> and PONVORY<sup>®</sup> were \$47.5 million in the first quarter of 2024

**Fanapt<sup>®</sup>**  
(iloperidone) tablets  
1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg

Fanapt<sup>®</sup> net product sales were \$20.6 million in the first quarter of 2024

**Hetlioz<sup>®</sup>**  
(tasimelteon) capsules  
20mg

HETLIOZ<sup>®</sup> net product sales were \$20.1 million in the first quarter of 2024

**Ponvory<sup>®</sup>**  
(ponesimod) once-daily tablets

PONVORY<sup>®</sup> net product sales were \$6.8 million in the first quarter of 2024

# Financials – Results Through March 31, 2024



## Results Through March 31, 2024

Fanapt® Net Product Sales	\$20.6M
HETLIOZ® Net Product Sales	\$20.1M
PONVORY® Net Product Sales	\$6.8M
Total Revenues	<u>\$47.5M</u>
Cost of Goods Sold	\$3.4M
Research & Development	\$21.2M
Selling, General & Administrative	\$30.1M
Intangible Asset Amortization	\$2.0M
Operating Expenses	<u>\$56.7M</u>
Net Income (Loss)	(\$4.1M)
Cash <sup>1</sup>	\$394.1M





For more information on HETLIOZ®, please visit [www.HETLIOZ.com](http://www.HETLIOZ.com)

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For more information on Fanapt®, please visit [www.FANAPT.com](http://www.FANAPT.com)

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For more information on PONVORY®, please visit [www.PONVORYUS.com](http://www.PONVORYUS.com)

