

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): September 25, 2026

Vistagen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of
incorporation)

000-54014
(Commission File Number)

20-5093315
(IRS Employer
Identification Number)

**343 Allerton Ave.
South San Francisco, California 94080**
(Address of principal executive offices)

(650) 577-3600
(Registrant's telephone number, including area code)

Not Applicable
(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 \$0.001 per share	VTGN	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 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2)

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 FD Disclosure.

On September 25, 2026, Vistagen Therapeutics, Inc. (the “Company”) began utilizing a new corporate presentation, a copy of which is attached to this Current Report on Form 8-K as Exhibit 99.1.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits Index

Exhibit No.	Description
99.1	Vistagen Therapeutics, Inc. Corporate Presentation, dated September 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Vistagen Therapeutics, Inc.

Date: September 25, 2026

By: /s/ Shawn K. Singh
Shawn K. Singh
President and Chief Executive Officer

Vistagen

Nasdaq: VTGN

Corporate Presentation

*Harnessing the therapeutic power and potential
of brain regulation with nose-to-brain neurocircuitry*

September 2026



Forward-looking Statements

This presentation contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are within the meaning of federal securities laws. These forward-looking statements involve known and unknown risks that are difficult to predict and include all matters that are not historical facts. In some cases, you can identify forward-looking statements by the use of words such as “may,” “could,” “expect,” “project,” “outlook,” “strategy,” “intend,” “plan,” “seek,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “strive,” “goal,” “continue,” “likely,” “will,” “would” and variations of these terms and similar expressions, or the negative of these terms or similar expressions.

Such forward-looking statements are necessarily based upon estimates and assumptions that, while considered reasonable by Vistagen Therapeutics, Inc. (Vistagen or the Company) and its management, are inherently uncertain. As with all pharmaceutical products, development and commercialization involve substantial risks and uncertainties, and actual results or developments may differ materially from those projected or implied in these forward-looking statements. There can be no guarantee that any of Vistagen’s product candidates, including fasedienol, will successfully complete future clinical trials within estimated timelines or at all, receive regulatory approval or be commercially successful. Because the Repeat Dose Study was not powered to demonstrate statistical significance, there can be no assurance that the numerical trends and nominally significant findings described in this presentation will be replicated in future, adequately powered clinical trials, or that the U.S. Food and Drug Administration (FDA) will view such findings as supportive of a registrational pathway for fasedienol. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to conducting future clinical trials as currently expected or at all; Vistagen’s ability to replicate numerical trends and nominally significant findings from studies in the PALISADE Program or that the FDA will view such findings as supportive of a registrational pathway for fasedienol; Vistagen’s ability to successfully employ cash preservation measures and/or secure adequate financing for its operations, including financing or collaborative support for continued clinical development of its product candidates; Vistagen’s dependence on third-party collaborators for the development, regulatory approval, and/or commercialization of its product candidates and other aspects of its business, which are outside of Vistagen’s full control; the scope and enforceability of Vistagen’s patents, including patents related to Vistagen’s pteridine product candidates; fluctuating costs of materials and other resources and services required to conduct Vistagen’s ongoing and/or planned clinical and non-clinical trials; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; and other technical and unexpected hurdles in the development, manufacture and commercialization of Vistagen’s product candidates. These risks are more fully discussed in the section entitled “Risk Factors” in Vistagen’s Annual Report on Form 10-K for the fiscal year ended March 31, 2026, and Quarterly Report on Form 10-Q for the period ended June 30, 2026, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the U.S. Securities and Exchange Commission (SEC). The Company’s SEC filings are available on the SEC’s website at www.sec.gov.

Given these uncertainties, you should not place undue reliance on these forward-looking statements, which apply only as of the date of this presentation and should not be relied upon as representing the Company’s views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements other than as may be required by law. If the Company does update one or more forward-looking statements, no inference should be made that we will make additional updates with respect to those or other forward-looking statements. Be aware that our development and commercialization plans may change at any time, without public notice, based on the kinds of risk factors described above.

This presentation discusses certain product candidates that have not yet received marketing authorization or clearance by the FDA. No representation is made as to the safety, effectiveness or likelihood of marketing authorization or clearance of these product candidates.

Certain clinical data for fasedienol in this presentation are based on separate studies and include pooled data between such studies. Differences exist between clinical trial design and patient populations, and caution should be exercised when pooling and/or comparing data across trials as pooled data and cross-study comparisons are inherently limited and such data may not be directly comparable.

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. These data involve numerous assumptions and limitations, and you are cautioned not to give undue weight to such estimates and data. Neither we nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this presentation.

Company Highlights

Advancing a Robust and Diverse Neuroscience Pipeline



Phase 3 product candidate in social anxiety disorder

Four product candidates with Phase 2a PoC

Differentiated rapid onset, non-systemic putative MOAs

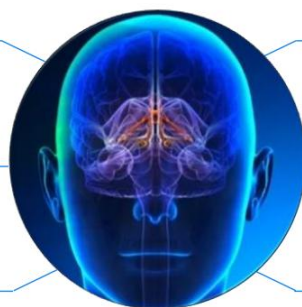
Targeting multiple large markets with inadequate standards of care

Experienced CNS drug development team and clinical advisors

Novel Class of Rapid-Onset, Non-Systemic Neurocircuitry-modulators with the Potential to Address Multiple Conditions¹

Proposed Mechanism of Action

- Rapid-onset neuromodulatory mechanisms of action targeting distinct regions of the brain
- Bind to and rapidly activate receptors in nasal chemosensory neurons, regulating emotion, stress, autonomic function, and metabolism
- Localized action without detectable systemic absorption or brain exposure



Design Attributes

- Favorable safety and tolerability reported in all clinical trials to date
- Successfully administered intranasally by subjects in certain studies, including extended self-administration
- MOA relevant across diverse therapeutic areas including neuropsychiatry, cognitive function, women's health, and cancer supportive care

Pherines rapidly activate nasal chemosensory neurons that modulate neurocircuits from the olfactory bulb to the amygdala ("threat detector"),² hypothalamus ("control center"),³ and other brain regions

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¹Vistagen Internal Data on File

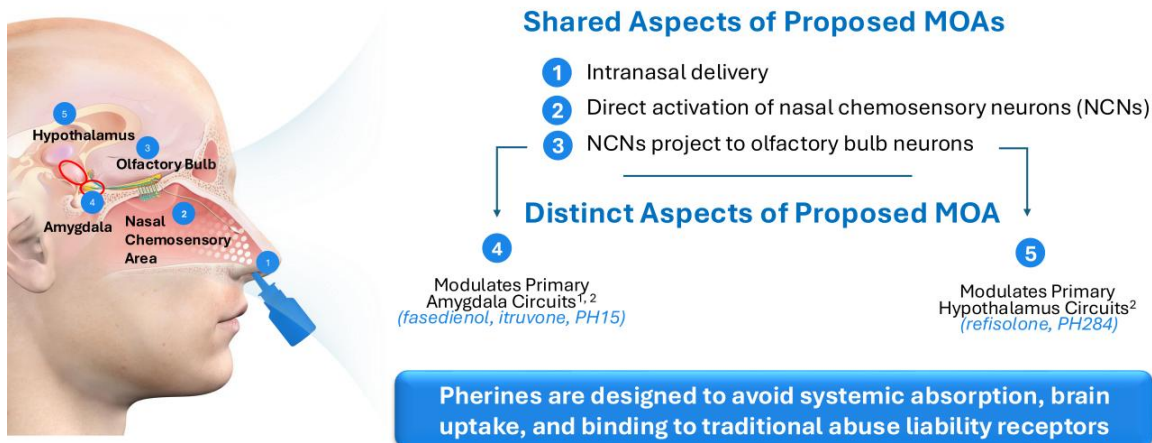
²Daniel J. Siegel & Tina Payne Bryson, *The Whole-Brain Child* (2011)

³"Brain Basics: Understanding Sleep," National Institute of Neurological Disorders and Stroke; Monti Land Liebowitz M. CNS Spectrums (2020)

Image Credit: decade3d - anatomy online/Shutterstock.com

Differentiated Rapid-Onset, Non-Systemic Putative MOAs

Each pherine is designed to modulate distinct neurocircuits in the brain



Lead Clinical-Stage Product Candidates

Advancing programs in neuropsychiatry and women's health

Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Fasedienol	Acute Treatment of Social Anxiety Disorder				
Itruvone	Major Depressive Disorder				
Refisolone	Moderate to Severe VMS (hot flashes) due to Menopause				

Additional Clinical-Stage Candidates with Phase 2a PoC:

Refisolone Premenstrual Dysphoric Disorder	PH15¹ Psychomotor/cognitive impairment	PH284¹ Cancer Cachexia
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Lead Product Candidates Target Highly-Prevalent Unmet Need

Fasedienol Social Anxiety Disorder	Itruvone Major Depressive Disorder	Refisolone Menopausal Hot Flashes
<i>~30 million people in the U.S. with social anxiety disorder ¹</i>	<i>~21 million people in the U.S. with major depressive disorder ²</i>	<i>~27 million women in the U.S. experience hot flashes due to menopause³</i>
• Potential to be the first FDA-approved rapid-onset, non-systemic, as-needed treatment for adults with SAD. • Efficacy signals across multiple clinical trials • Extensive clinical experience has shown favorable short- and long-term safety and tolerability data in studies completed to date • Proposed single Phase 3 study would evaluate acute, as-needed use over six weeks with LSAS as the primary endpoint • Current proposed regulatory strategy is designed to leverage the totality of efficacy and safety evidence	• Potential novel non-systemic treatment for MDD designed to avoid weight gain and other side effects and safety concerns of current depression therapies • Positive exploratory Phase 2a study demonstrated improvement in depressive symptoms as early as one week post-administration • Favorable safety and tolerability data in clinical studies to date • Open U.S. IND supports potential further Phase 2 clinical development	• Potential rapid-onset, non-hormonal, non-systemic treatment for moderate-to-severe VMS (hot flashes) due to menopause • Positive exploratory Phase 2a study demonstrated statistically significant reductions in both hot flash frequency and severity • Favorable safety and tolerability data in clinical studies to date • Open U.S. IND supports further potential Phase 2 clinical development

The background of the slide is a dark blue field filled with a complex, glowing network of lines and nodes, resembling a neural network or a molecular structure. The lines are thin and blue, with some nodes appearing as small, bright blue spheres. A few larger, more prominent nodes are visible, with lines radiating from them. The overall effect is a sense of dynamic, interconnectedness.

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Fasedienol

Acute Treatment of Social Anxiety Disorder

Social Anxiety Disorder: A serious and debilitating mental health condition characterized by intense fear of being judged and embarrassed¹



Emotional Symptoms

- Overwhelming fear
- Surges of anxiety
- Extreme self-consciousness
- Isolation leading to depression



Physical Symptoms

- Blushing / Sweating
- Trembling
- Nausea
- Fast heartbeat / Chest discomfort
- Shortness of breath / Dizziness

Real-Life Impact on Patients²

- ⊖ Missing out on life moments with family and friends
- ⊖ Constant worry in social, school and work situations
- ⊖ Anxiety and difficulty contributing in team settings
- ⊖ Missed career advancement opportunities



I do not like to tell others I'm avoiding them because of anxiety. I feel it may seem silly to others who do not struggle with it.



Feeling anxiety about going to work tomorrow. My brain is running away with all these ridiculous scenarios that "could" happen.

Social anxiety disorder is typically characterized by a combination of symptoms stemming from fear, avoidance, and worry

There is No U.S. FDA-Approved Acute Treatment for Social Anxiety Disorder

Available Rx therapies **fall short of addressing the acute, in-the-moment needs** of SAD patients in anxiety-provoking social and performance situations in everyday life.

FDA-Approved SSRIs, SNRIs (*Zoloft®*, *Paxil®*, *Effexor®*)

- Not FDA-approved for acute treatment of SAD
- Long-onset MOAs are not conducive to producing acute, as-needed therapeutic benefit in anxiety-provoking social and performance situations
- Well-documented unwanted side effects²
- Require daily systemic maintenance dosing
- Potential tolerability and serious safety concerns¹

Benzodiazepines, Beta-blockers (*Xanax®*, *propranolol*)

- Not FDA-approved for treatment of SAD
- Require systemic uptake, with potential neuropsychiatric and other safety risks related to systemic MOAs
- Benzodiazepine risks: sedation, cognitive impairment, addiction, dependency, and withdrawal syndrome³
- Beta blocker safety risks: bradycardia, exacerbation of cardiac and/or pulmonary conditions, sleep disorder

Available Rx therapies have systemic MOAs and considerable safety concerns, especially from repeated same-day off-label use of benzodiazepines and beta blockers

There is a High Unmet Need for a Novel Acute Treatment for Social Anxiety Disorder



U.S. Social Anxiety Disorder Prevalence* = **~30 million** adults

<50% of social anxiety disorder patients
are diagnosed by a healthcare
provider¹

<23% of social anxiety disorder patients are
being treated by available Rx
therapies¹

Diagnosed U.S. Patients = **~15 million**, Treated U.S. Patients = **~7 million**

Onset of social anxiety disorder can occur at any age but most commonly manifests during adolescence²

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*Prevalence estimates include adult patients suffering from social anxiety disorder, but are unaware or not yet motivated to seek help

¹ Baker R, Prince J, Hwang S, Sternbach N. Prevalence trends and demographic profiles of social anxiety disorder NEI (2024)

² Rosellini, A. J., Rutter, L. A., Bourgeois, M. L., Emmert-Aronson, B. O., & Brown, T. A. (2013). The relevance of age of onset to the psychopathology of social phobia. *Journal of Psychopathology and Behavioral Assessment*, 35(3), 356-366. <https://doi.org/10.1007/s10862-013-9338-5>

Fasedienol May Bring New Optimism for Patients with Social Anxiety Disorder^{1,2}

Fasedienol is designed to **trigger neural signals** in the olfactory bulb, which travel to the **“fear centers”** of the limbic amygdala and other brain regions involved in **emotion and behavior**.



Fasedienol Design Traits



Rapid-onset effect on both emotional and physical symptoms of peak anxiety, as needed, without sedation or dizziness (associated with benzos or beta blockers)



No detectable absorption, no observed drug/drug interactions, or binding to neurons in the brain



No observed binding to abuse liability receptors in the brain (“not a benzo”)



Patient-tailored administration, as needed up to several times a day



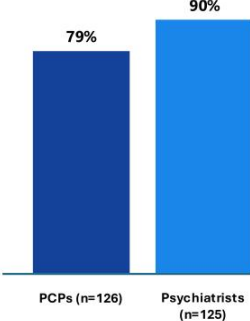
Low incidence of adverse events, favorable safety and tolerability profile

Potential to be first FDA-approved acute treatment for adults with social anxiety disorder

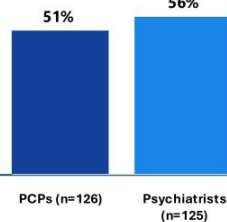
Physician Adoption: Fasedienol's Target Product Profile (TPP) elicited a high intent-to-prescribe among Health Care Providers (HCPs)

Evaluation by Psychiatrists and Primary Care Physicians (PCPs)¹

Likely to prescribe Product X
(top 2-box of 5 pt scale)



% of your social anxiety disorder patients who would be appropriate candidates for Product X



HCP Reaction²

- When given fasedienol's TPP anonymously as "Product X", prescribing HCPs believe it may be appropriate for more than half of their patients with social anxiety disorder
- Most compelling attributes include unique MOA, efficacy, and low risk of addiction
- HCPs also liked rapid onset, minimal side effects, and better safety (i.e., versus benzos) as highly positive attributes for adoption
- HCPs noted specific use of "Product X" when patients feel they will be going into a "socially risky" environment or situation



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Fasedienol

Clinical Development Program

Fasedienol PALISADE Phase 3 Program Clinical Trials



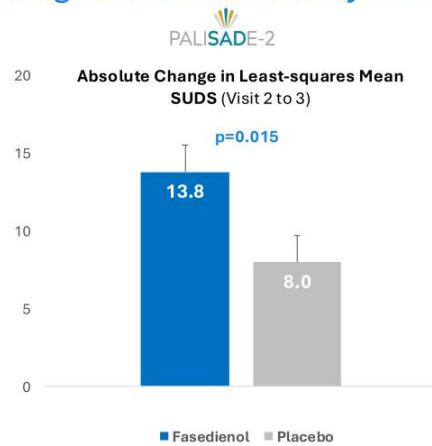
PALISADE Phase 3 Program data contribute to the deep clinical dataset informing understanding of fasedienol’s potential clinical utility to help patients experience less fear, anxiety, and avoidance in social and performance situations over time in everyday life



Notes: * The PALISADE-2 Phase 3 fasedienol study for the acute treatment of social anxiety disorder met its primary endpoint of change on the Subjective Units of Distress Scale (SUDS). PALISADE-2 was ended early following an independent analysis of 140 subjects in the efficacy population. The decision was made not to restart the study due to business reasons. Across the four PALISADE Phase 3 studies completed to date, changes in SUDS were generally similar across the fasedienol treatment groups; however, placebo responses were variable. PALISADE-1, PALISADE-3 and PALISADE-4 did not demonstrate statistically significant improvements on their respective primary endpoints, which assessed reduction in anxiety as measured by SUDS scores compared to placebo.

PALISADE-2 Phase 3 Trial Positive Primary Efficacy:

Statistically significant relief of acute anxiety in single-dose public speaking challenge trial as measured by the Subjective Units of Distress Scale (SUDS)



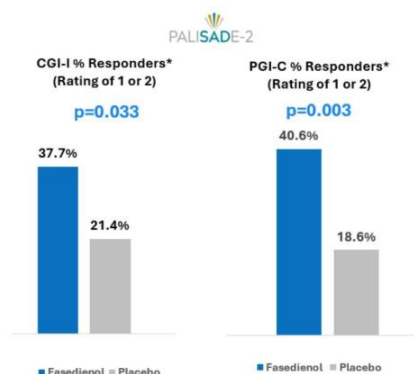
Primary Efficacy Endpoint

- The LS¹ mean SUDS change from baseline vs. placebo (SUDS change from Baseline Speech #1 to Randomized Speech #2) was statistically significant v. placebo
 - ✓ The PALISADE-2 Phase 3 study (n=140) met its primary endpoint with a change from baseline of **5.8 points better than placebo**
 - ✓ Results were statistically significant (**p=0.015**)^{*}

¹ LS=Least Squares, LS Mean Change is the model-adjusted change from baseline

^{*} The PALISADE-2 Phase 3 fasedienol study for the acute treatment of social anxiety disorder met its primary endpoint of change on the Subjective Units of Distress Scale (SUDS). PALISADE-2 was ended early following an independent analysis of 140 subjects in the efficacy population. The decision was made not to restart the study due to business reasons. Across the three PALISADE Phase 3 studies completed to date, changes in SUDS were generally similar across the fasedienol treatment groups; however, placebo responses were variable. PALISADE-1, PALISADE-3 and PALISADE-4 did not demonstrate statistically significant improvements on their respective primary endpoints, which assessed reduction in anxiety as measured by SUDS scores compared to placebo.

PALISADE-2 Positive Secondary & Exploratory Endpoints: Statistically significant and supportive of primary efficacy



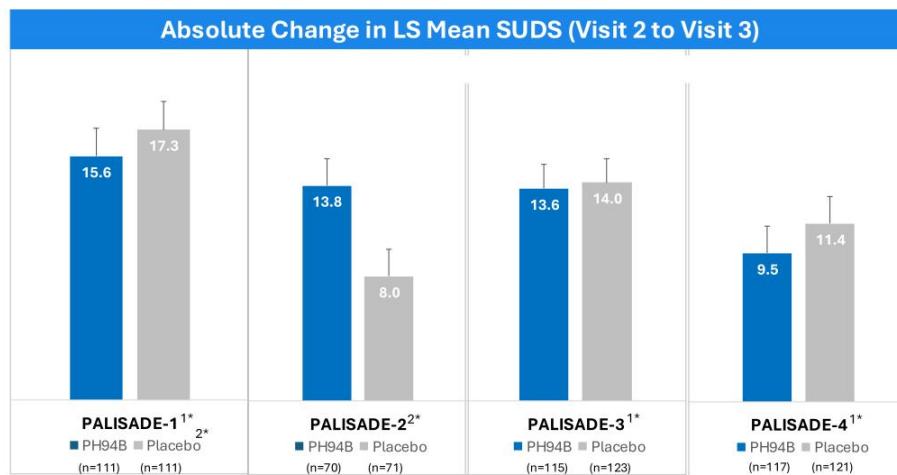
Secondary & Exploratory Endpoints

- On CGI-I proportion of responders vs placebo, rating of 1 (very much less anxious) or rating of 2 (much less anxious) from Baseline Speech #1 to Randomized Speech #2
 - ✓ Fasedienol responders were **1.8 times greater** than placebo
- On PGI-C proportion of responders vs placebo, rating of 1 (very much less anxious) or rating of 2 (much less anxious) from Baseline Speech #1 to Randomized Speech #2
 - ✓ Fasedienol responders were **2.2 times greater** than placebo

The clinical relevance of the primary endpoint is further supported by a near 2-fold greater response rate for fasedienol on the CGI-I & the PGI-C response

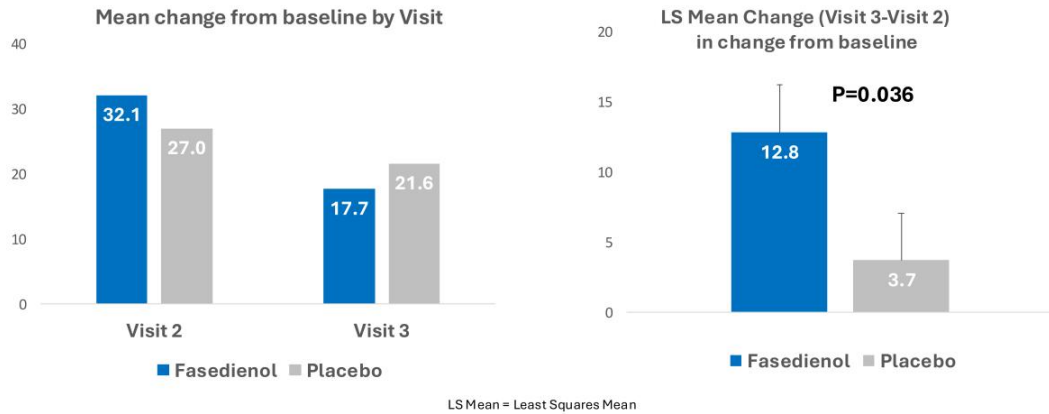
Notes: * re-specified statistical analysis plan, missing CGI-I values for one subject on placebo and one subject on fasedienol were not imputed for the ITT CGI-I responder analysis. The missing values resulted from site error and are considered missing at random. The PALISADE-2 Phase 3 fasedienol study for the acute treatment of social anxiety disorder met its primary endpoint of change on the Subjective Units of Distress Scale (SUDS). PALISADE-2 was ended early following an independent analysis of 140 subjects in the efficacy population. The decision was made not to restart the study due to business reasons. Across the four PALISADE Phase 3 studies completed to date, changes in SUDS were generally similar across the fasedienol treatment groups; however, placebo responses were variable. PALISADE-1, PALISADE-3 and PALISADE-4 did not demonstrate statistically significant improvements on their respective primary endpoints, which assessed reduction in anxiety as measured by SUDS scores compared to placebo.

Fasedienol Across Phase 3 Public Speaking Challenge Trials

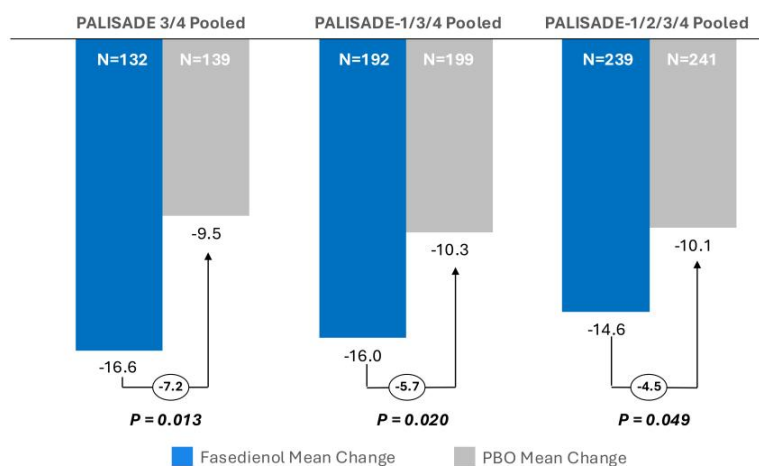


PALISADE-4 Post-Hoc Analysis: Very Severe (LSAS ≥ 95) Subjects Statistically Significant LS Mean SUDS Change vs Placebo (P=0.036)

Excluding: one site for potentially unreliable data, subjects with V1 LSAS <95, and subjects with ceiling SUDS values¹
All P-Values calculated using ANCOVA model per PALISADE-4 SAP



Post-Hoc Stratification Analyses of Very Severe SAD Subjects^{1*}

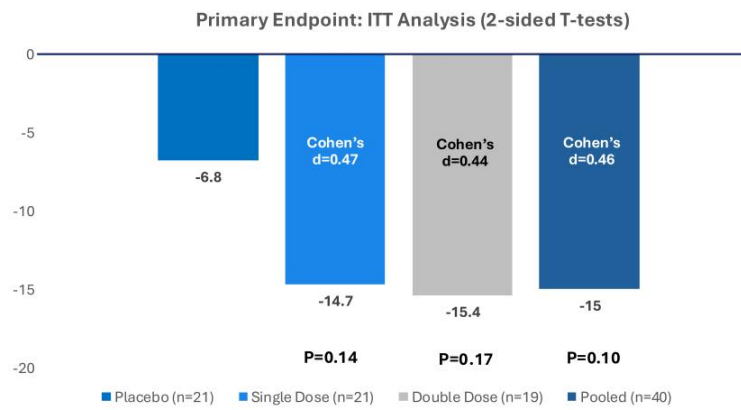


¹ Based on p-values calculated from unstructured model T-tests. The post-hoc analysis for the very severe social anxiety disorder subpopulation (defined by LSAS ≥95) excludes data from one site (n=15) for irregularities documented and communicated before database lock that led to site disqualification from the trial. The post-hoc analysis also excluded data to account for Public Speaking Challenge (PSC) ceiling and placebo effects: 1) subjects who had SUDS scores > 90 at visit 2 or visit 3 at baseline could not be provoked effectively by the PSC to have higher SUDS scores for the experiment to work effectively (SUDS scale is from 0-100 with above 90 being extreme anxiety) (n=5); and 2) subjects who had SUDS score improvement higher than 20 from baseline at Visit 2 (the placebo run-in) either were placebo responders or could not be provoked effectively by the PSC (n=1).

*Differences exist between clinical trial design and patient populations, and caution should be exercised when pooling data across trials; pooled data is inherently limited and such data may not be directly comparable.

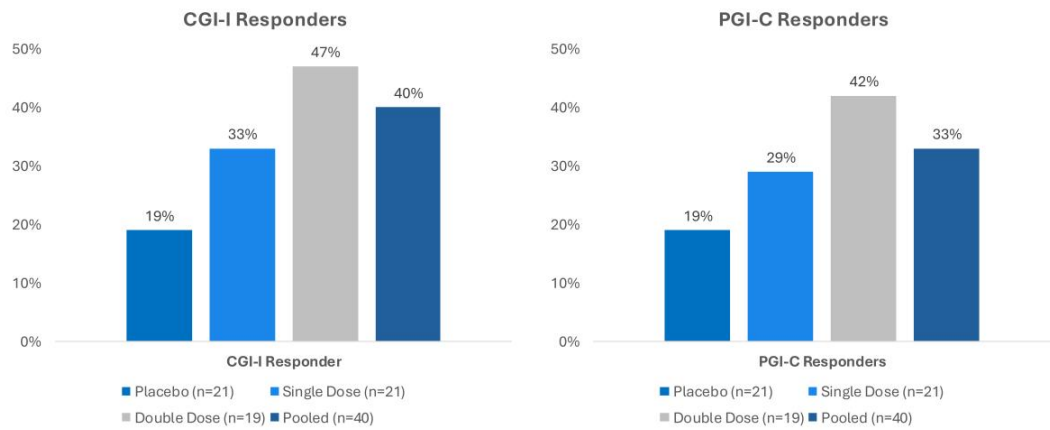
Exploratory Phase 2 Repeat Dose Study Primary Endpoint¹

Change in Average SUDS from Visit 2 to Visit 3



Exploratory Phase 2 Repeat Dose Study Secondary Endpoints

CGI-I and PGI-C % Responders

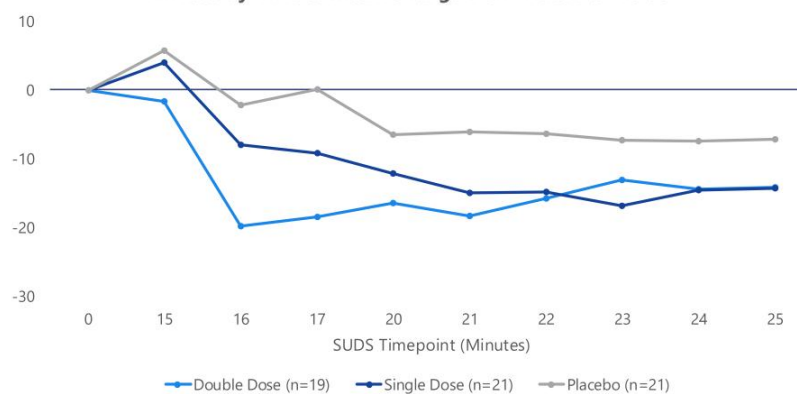


Exploratory Phase 2a Repeat Dose Study

Minute-by-Minute Anxiety

SUDS Mean Changes from Visit 2 to Visit 3

Minute by Minute Mean Change from Visit 2 to Visit 3¹

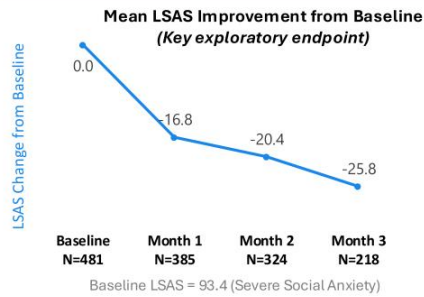


A rapid, pronounced reduction in SUDS was observed following repeat dosing, with both active-treatment groups showing sustained numerical improvement versus placebo

PALISADE-1/PALISADE-2 Long Term Safety Study Exploratory LSAS Efficacy Results from As-needed Use in Everyday Life

Clinically relevant improvements in social anxiety observed over time

Mean LSAS Improvement from Baseline²



Additional Exploratory Findings

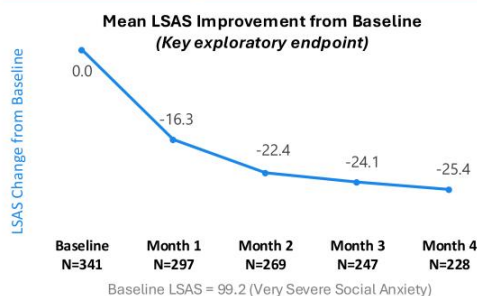
- Subjects enrolled from PALISADE-1, PALISADE-2, or de novo
- For subjects who continued in the study, total LSAS scores continued to decline from baseline; LSAS improvements were observed each month through 9 months
- The Clinician Global Impression of Improvement (CGI-I) indicated 28.6% of the 385 patients assessed after one month were "much" or "very much" improved
- The Patient Global Impression of Change (PGI-C) indicated 26.8% of the 385 patients assessed after one month considered themselves "much" or "very much" improved

Continued LSAS reductions and patient-reported improvements indicate rapid-onset and sustained efficacy and tolerability over time

PALISADE-3 Preliminary Open Label Extension Exploratory LSAS Efficacy Results from As-needed Use in Everyday Life

Clinically relevant improvements in social anxiety observed over time¹

Mean LSAS Improvement from Baseline²



	1st month	2nd month	3rd month	4th month
LSAS reduction	38% ≥20 point LSAS Improv.	49% ≥20 point LSAS Improv.	54% ≥20 point LSAS Improv.	56% ≥20 point LSAS Improv.

Additional Exploratory Findings

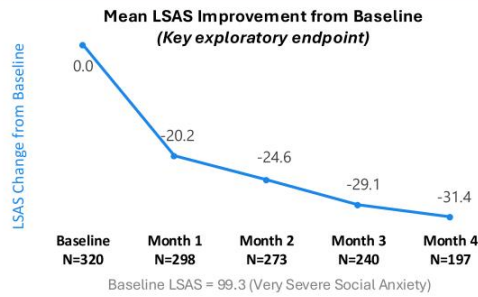
- Improvements observed in both fear and avoidance subscales
- Improvement observed on patient-reported SPIN assessments
- Findings consistent with prior LTSS and Phase 2 real-life study
- Supports the potential clinical meaningfulness of repeated as-needed use in everyday life

Progressive reductions in social anxiety from acute, as-needed use of fasedienol in everyday life situations support the potential benefit over time

PALISADE-4 Preliminary Open Label Extension Exploratory LSAS Efficacy Results from As-needed Use in Everyday Life

Clinically relevant improvements in social anxiety observed over time¹

Mean LSAS Improvement from Baseline²



	1st month	2nd month	3rd month	4th month
LSAS reduction	44% ≥20 point LSAS Improv.	54% ≥20 point LSAS Improv.	60% ≥20 point LSAS Improv.	65% ≥20 point LSAS Improv.

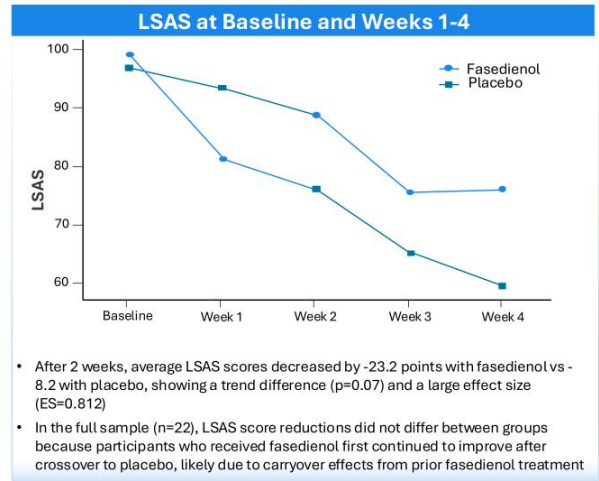
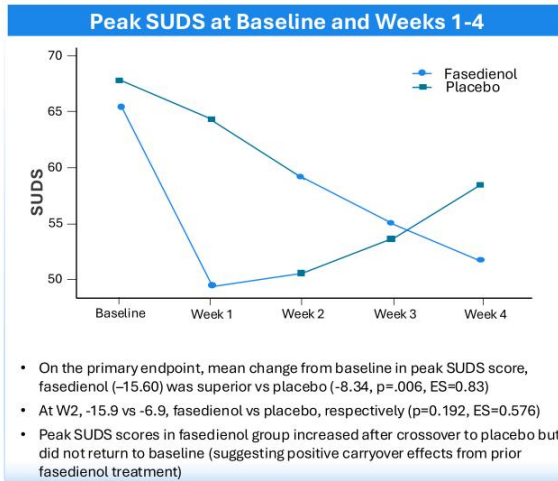
Additional Exploratory Findings

- Improvements observed in both fear and avoidance subscales
- Improvement observed on patient-reported SPIN assessments
- Findings consistent with prior LTSS and Phase 2 real-life study
- Supports the potential clinical meaningfulness of repeated as-needed use in everyday life

Progressive reductions in social anxiety from acute, as-needed use of fasedienol in everyday life situations support the potential benefit over time

Phase 2 Real-Life Crossover Study Results (SUDS & LSAS)

Acute use of fasedienol in anxiety-provoking social and performance situations in everyday life



PALISADE Open Label Long-term Safety Study (LTSS)¹

Across open label safety studies, TEAEs were generally mild or moderate in severity

TEAE by Preferred Term ¹	N=481, n (%)
Headache	82 (17.0)
COVID-19 infection	55 (11.4)
Dizziness	22 (4.6)
Epistaxis	18 (3.7)
Nausea	15 (3.1)
Oropharyngeal pain	15 (3.1)
Nasopharyngitis	13 (2.7)
Urinary tract infection	13 (2.7)
Nasal congestion	12 (2.5)
Upper respiratory tract infection	12 (2.5)

Safety¹

1. Subjects enrolled from PALISADE-1, PALISADE-2, or de novo (N=481)
2. Over 30,000 doses self-administered by social anxiety disorder subjects in daily life
3. Intranasal administration of 3.2 µg of fasedienol as-needed, up to 4x/day
4. Mean study duration of 4 months, with a maximum over 10 months
5. 2.9% of subjects discontinued due to AE's
6. Severe TEAEs reported: 1.9% of participants
7. Drug-related TEAEs: Headache (8.7%); All others (<5%)

Overall, the safety profile of fasedienol was consistent across multiple double-blind, placebo-controlled studies and open-label treatment extensions, with no safety concerns identified..

Totality of Clinical Evidence Inform Proposed Next Step in Registration-directed U.S. Phase 3 Development Program

1

Positive Phase 3 SUDS PSC (PALISADE-2)

PALISADE-2 showed **statistically significant separation of fasedienol from placebo in change from baseline on Subjective Units of Distress Scale (SUDS (p=0.0153))**

2

Phase 3 Post-hoc Analyses SUDS PSC (PALISADE-4)

Post-hoc stratification analysis of patients with **very severe social anxiety** showed fasedienol was **nominally statistically significant as measured by the LS mean change from baseline on the SUDS score compared with placebo (p=0.036)**

3

Repeat Dose Study

Exploratory dosing study, not powered for statistical significance; showed that fasedienol was **well-tolerated**, supporting further evaluation flexible/repeat use with encouraging potential efficacy signals in **patients with very severe social anxiety**; also showed **strong potential signal in anticipatory anxiety** with more than one dose

4

Positive Phase 2 SUDS PSC and SIC

Data from Phase 2 studies demonstrated statistically significant separation of fasedienol from placebo in change from baseline in **SUDS scores in public speaking challenges (p=0.002)** and **social interaction challenges (p=0.009)**

5

Phase 2 + open-label LSAS in everyday life settings

Data from a Phase 2 crossover study and three Phase 3 open-label trials conducted in real-life settings suggest that the PRN treatment with fasedienol has the potential to provide **relief in anxiety-provoking situations in everyday life as measured by the LSAS**

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Proposed Next Step: U.S. Phase 3 LSAS study in everyday life setting



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Fasedienol

Potential Registrational Path Forward

LSAS is Relevant to Measuring Treatment Benefit in Everyday Life

LSAS Aligns with How Fasedienol is Intended to be Used in Everyday Life

- PRN dosing in multiple outpatient anxiety provoking situations rather than a single laboratory challenge
- Measures the full burden of social anxiety disorder, including both fear/anxiety and avoidance behaviors across social and performance settings
- Evaluates the impact of repeated use over time, reflecting anticipated clinical practice

Regulatory & Clinical Precedent

- ✓ LSAS served as primary efficacy endpoint in registrational trials for the other FDA-approved social anxiety disorder therapies
- ✓ Prior FDA feedback has supported LSAS as a primary efficacy endpoint¹
- ✓ Phase 2 placebo-controlled data and PALISADE open-label findings have shown consistent improvements on LSAS

As-needed use data from Multiple Real-life Anxiety-provoking Situations Suggest Potential for Meaningful Improvement in Social Anxiety Disorder

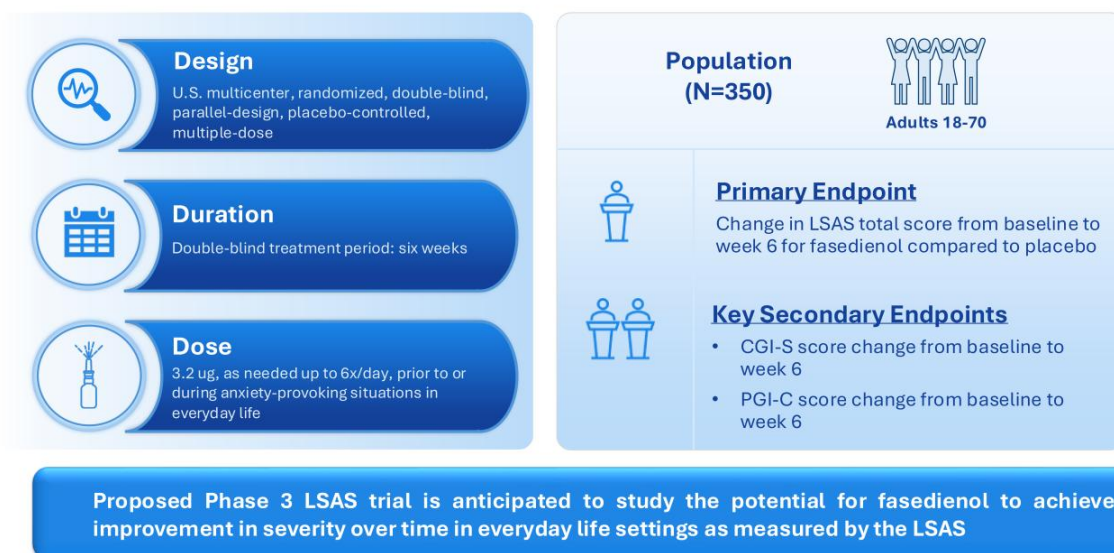
Phase 2 and Open Label Studies Support Use of LSAS as the Primary Efficacy Endpoint for Potential Phase 3 Path Forward

Further evaluation of fasedienol for repeated, as-needed use is supported by continued reductions in LSAS scores observed in prior studies from as early as 2 weeks of treatment

Study	Setting	Treatment	LSAS Evidence
PH94B-CL028 (Phase 2)	Phase 2, Placebo-controlled, multiple-use, real-life events	PRN up to 4x/day	~23-point reduction at 2 weeks vs ~8 placebo
PH94B-CL030¹ (PALISADE-1/2 LTSS)	Long term open label, Multiple-use, real-life events	PRN up to 4x/day	Improvement beginning Month 1 and sustained
PALISADE-3¹ (Open Label Extension)	Long term OLE, Multiple-use, real-life events	PRN up to 6x/day	Improvement beginning Month 1 and sustained
PALISADE-4¹ (Open Label Extension)	Long term OLE, Multiple-use, real-life events	PRN up to 6x/day	Improvement beginning Month 1 and sustained

Evidence from placebo-controlled and open label studies suggests that repeated, as-needed administration of fasedienol may be best evaluated using the LSAS, an endpoint that captures clinically meaningful improvements in patients' everyday lives over time.

Proposed Path Forward: LSAS-Based Phase 3 Study¹



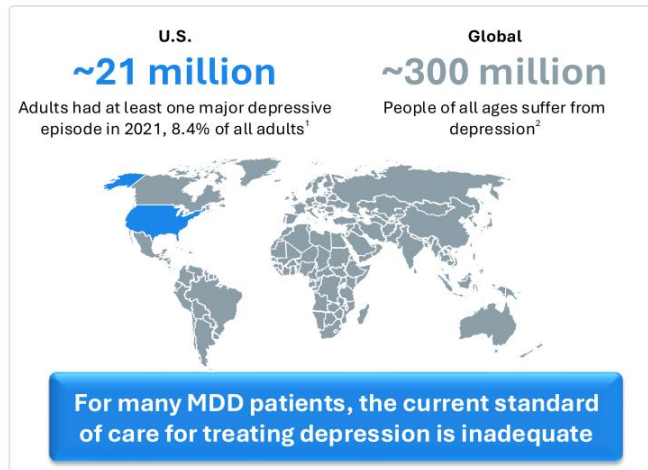
The background of the slide is a dark blue field filled with a complex, glowing network of lines and nodes, resembling a neural network or a web of connections. The lines are a lighter blue, and the nodes are small, bright blue dots. The overall effect is a sense of interconnectedness and complexity.

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Itruvone

Major Depressive Disorder

Major Depressive Disorder Market is Large and Underserved



Oral Antidepressants³

(Drug classes: SSRIs, SNRIs, NDRI, 5-HT1A, TCAs, MAOIs)

- Often do not work or are slow to work
- STAR*D showed ADT[#] effective in 1 of 3 patients³
- Significant and persistent side effects reported
 - Anxiety, weight gain, sexual dysfunction, insomnia, sedation, dizziness, vomiting, headache, sweating
- Serious side effects reported & safety concerns
 - Increased suicidal ideation, hypertension, QT prolongation, liver damage, serotonin syndrome

Oral Atypical Antipsychotics³

(Approved: Abilify®, Rexulti®, Seroquel®, Vraylar®, and Caplyta®)

- Variable effectiveness
- Significant side effects
 - Weight gain, tardive dyskinesia, stomach pain, tiredness, dizziness, headache, nervousness, cognitive impairment
- Serious safety concerns
 - Metabolic syndrome, Neuroleptic malignant syndrome, seizures, agranulocytosis, GI hypomotility

Itruvone: A novel, non-systemic product candidate with transformative potential for MDD patients

Itruvone

Itruvone is designed to **modulate olfactory-amygdala circuits** and activate local **GABAergic inhibitory pathways**, which help improve anhedonia and restore **balanced autonomic response**.¹



Itruvone Design Traits



Rapid-onset antidepressant effects have been observed



No observed evidence of systemic absorption or binding to neurons in the brain



Non-sedating, non-addictive, without dissociative side effects



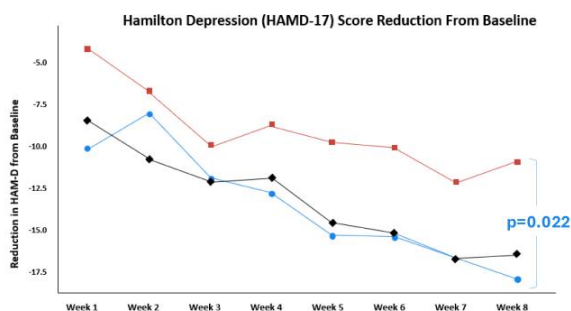
No observed binding to GABA_A receptors (low potential for abuse or withdrawal)



Favorable safety data without burdensome side effects (weight gain, sexual dysfunction, sedation, or brain fog/cognitive impairment)

Itruvone Exploratory Positive Phase 2a Study

Major Depressive Disorder



Phase2a Study Results

- ✓ 6.4 µg dose significantly reduced depressive symptoms as early as Week 1 and sustained through Week 8 compared to placebo (p=0.022)
- ✓ Rapid onset numerical improvements observed for 3.2 µg and 6.4 µg vs placebo at Week 1
- ✓ Itruvone was well-tolerated, with no drug-related serious adverse events observed, no dissociative side effects, no reports of weight gain or sexual side effects¹

Itruvone Dose	HAM-D Score	p (Itruvone vs placebo)	Cohen's D (Effect Size)
◆ 3.2 µg (Low Dose)	-16.3	0.101	0.74
● 6.4 µg (High Dose)	-17.8	0.022	0.95
■ Placebo	-10.9	--	--

Itruvone 6.4 µg delivered rapid, significant, and sustained antidepressant effects

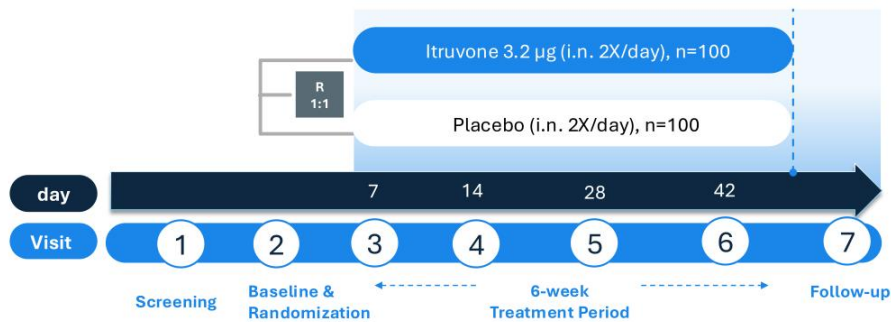
Itruvone 6-Week Double-blind Phase 2b Study Plan

Key Inclusions

- Male or female, 18-65 years of age
- Major Depressive Disorder, as defined by DSM-5
- HAMD-17 $\geq$ 21 at screening & randomization
- MacLean screen for BPD < 6

Key Exclusions

- No history of other significant psychiatric disorders
- No other psychotropic drugs w/in 14 days of screening
- Current diagnosis of substance use disorder
- Epilepsy, benzodiazepine use, THC use



Efficacy Endpoints¹ & Safety

Primary Endpoint:

Change from baseline to Day 42 on HAMD-17 rating scale

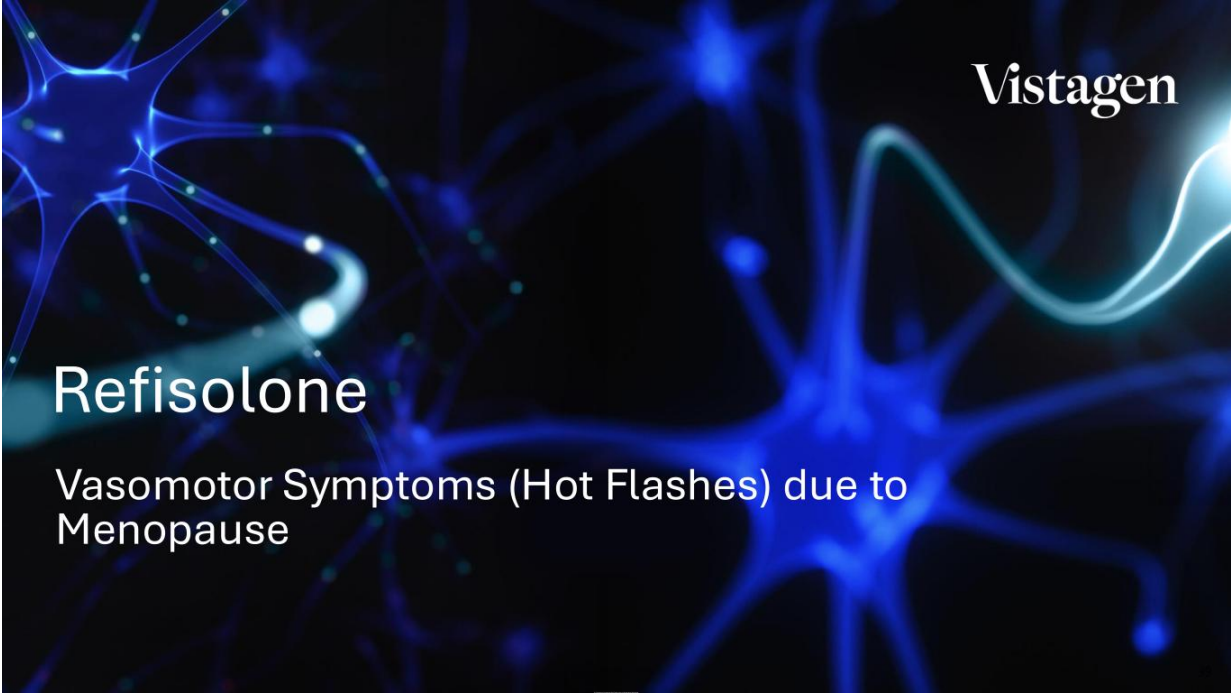
Secondary & Exploratory Endpoints:

- Change from baseline to Day 7, Day 14, and Day 28 on HAMD-17 rating scale
- SHAPS, SDS, HAM-A, BDI, CGI-I, CGI-S, CPFQ

Safety

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¹ L. Snaith-Hamilton Pleasure Scale (SHAPS; Snaith et al., 1995), Sheen Disability Scale (SDS), Hamilton Anxiety Rating Scale (HAM-A), Beck Depression Inventory (BDI), Clinical Global Impression Improvement and Severity Scales (CGI-I, CGI-S), Cognitive and Physical Functioning Questionnaire (CPFQ; Fava et al., 2006)



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Refisolone

Vasomotor Symptoms (Hot Flashes) due to
Menopause

A Significant Portion of Menopausal Women Experience Vasomotor Symptoms (Hot Flashes)

Approximately 75% of all women in the US experience hot flashes during the menopausal transition^{1,2,3}

~27M

women
in the U.S.^{1,2,3}

~9M

suffering
with severe
form of hot
flashes^{1,2,3,4}



Hot flashes are the **most common symptoms** of menopause for which women seek treatment⁵



Symptoms persist for a **median of 7.4 years**⁶

Refisolone: A novel, on-demand, non-hormonal, non-systemic product candidate designed for the treatment of Menopausal Hot Flashes

Refisolone

Designed as a potential **on-demand, fast-acting, non-hormonal, non-systemic treatment** for menopausal hot flashes, without the potential of serious adverse events or safety concerns of current approved Rx therapies.



Refisolone Design Traits



Novel and differentiated proposed MOA from all currently FDA-approved treatments for hot flash symptoms due to menopause



Designed to be **taken on-demand, with rapid onset**, to provide relief in the moment to reduce the number and severity of hot flashes



Non-hormonal, non-systemic, and no observed *in vitro* binding on neuronal or steroidal receptors¹

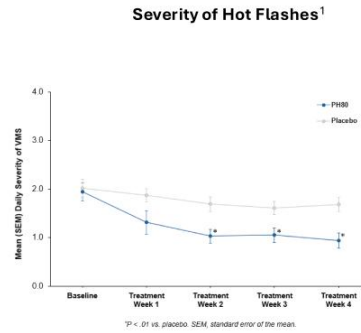
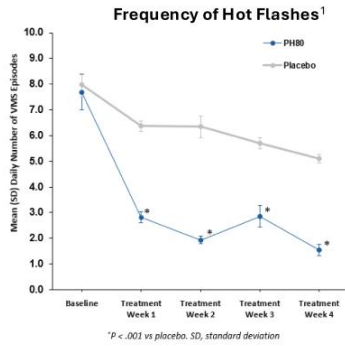


Potential for **differentiated safety and tolerability** advantages over currently approved hormonal and systemic oral NK3 therapies

Positive Phase 2a study (n=36) completed with open U.S. IND to facilitate further Phase 2 development

Refisolone Positive Exploratory Phase 2a Study

Menopausal Hot Flashes

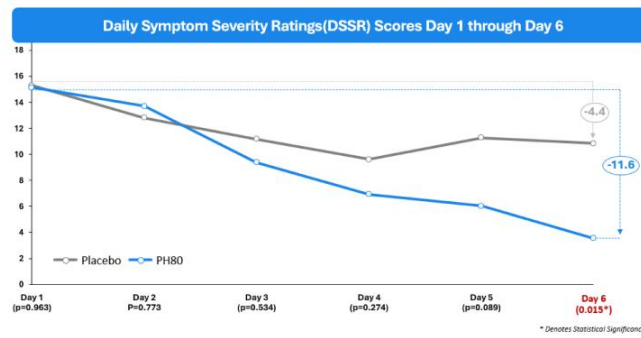


Phase 2a Study Results¹

- Refisolone was administered at 3.2 µg up to 5 times daily.
- Significantly **reduced the frequency of hot flashes** after Week 1 of treatment, with sustained improvement to Week 4.
- Reduced **the severity of hot flashes** after Week 1 of treatment with sustained improvement to Week 4.
- ✓ Statistical significance was demonstrated starting from Week 2.
- Serious adverse events (SAEs) were low and comparable to placebo.

The Phase 2a study demonstrated statistically and clinically significant improvement vs placebo in the frequency and severity of menopausal hot flashes

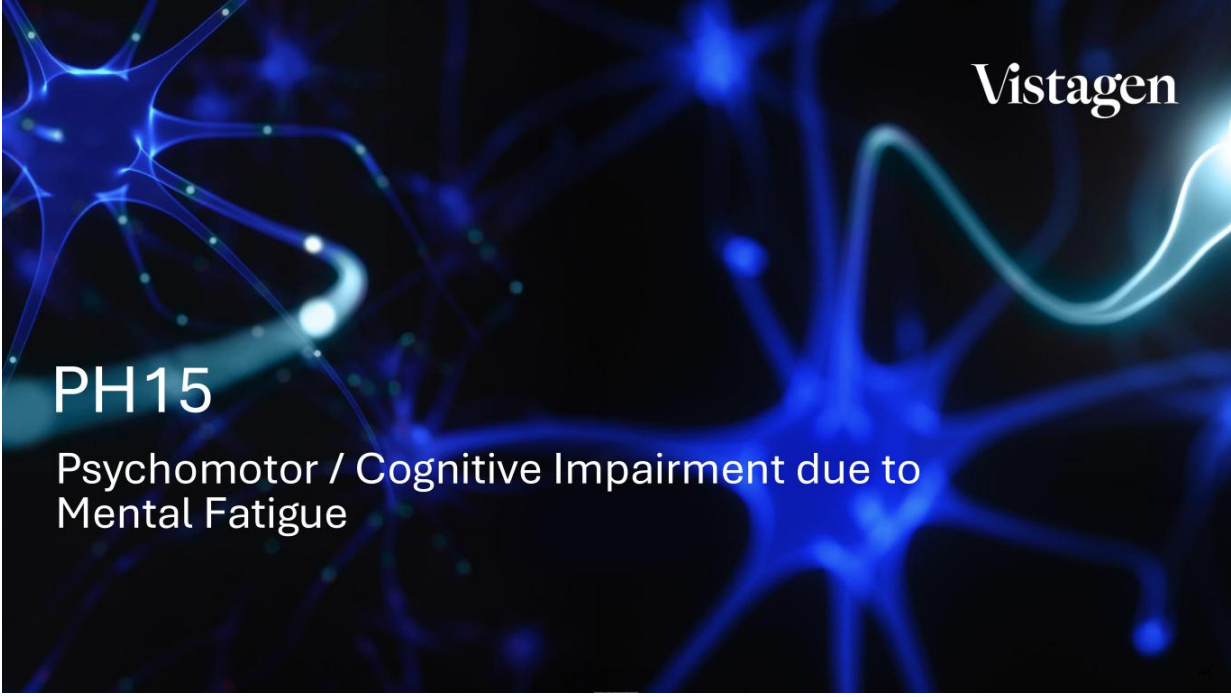
Refisolone Positive Phase 2a Study Premenstrual Dysphoric Disorder (PMDD)



Phase 2a Study Results

- Refisolone was administered at 0.9 µg up to 4 times daily
- Refisolone showed statistically and clinically significant improvement vs placebo in symptoms of PMDD at study endpoint after 6 days of treatment (p=0.015)
- DSR mood items seemed to be the most sensitive to refisolone
- Refisolone was well-tolerated with no serious adverse events (SAEs)

Refisolone showed statistically and clinically significant improvement vs placebo in symptoms of PMDD at study endpoint after 6 days of treatment (n=52) in a Phase 2a study

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PH15

Psychomotor / Cognitive Impairment due to
Mental Fatigue

PH15: A novel, fast-acting, non-systemic clinical-stage product candidate designed for the acute treatment of cognitive/psychomotor impairment due to mental fatigue

PH15

PH15 is **designed to modulate hippocampal activity** and related limbic circuitry, which may support improvements in cognitive and psychomotor function due to mental fatigue.



PH15 Design Traits



Novel neurocircuitry-focused proposed MOA differentiated from all other approved treatments



Rapid-onset potential to be taken as-needed to provide relief in the moment

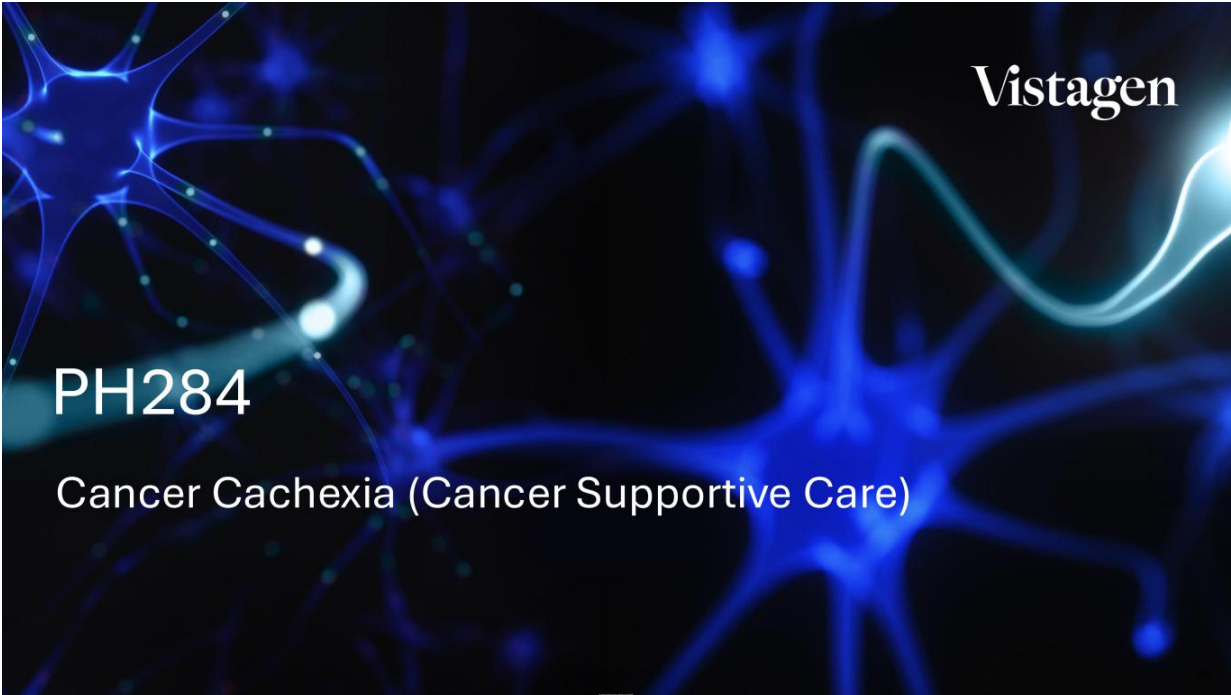


Favorable tolerability results observed in studies completed to date



Potential new treatment to **improve psychomotor impairment** and potentially cognitive impairment due to mental fatigue from sleep deprivation¹

Positive Phase 2a pilot study (n=10) demonstrated significant improvement in reaction time vs placebo and oral caffeine, including during peak fatigue



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PH284

Cancer Cachexia (Cancer Supportive Care)

PH284: An innovative non-systemic clinical stage product candidate designed for the acute treatment of cancer cachexia

PH284

Potential to non-systemically **modulate hypothalamic pathways** that regulate appetite and energy balance.



PH284 Design Traits



Novel neurocircuitry-focused proposed MOA differentiated from all approved treatments



Innovative, non-systemic neurocircuitry-focused pherine product candidate with rapid-onset potential for **appetite enhancement**



Intranasal administration with the potential to increase subjective feelings of hunger and caloric intake in patients diagnosed with wasting syndrome due to cancer treatment



Favorable tolerability results observed in studies completed to date

The Phase 2a study (n=40) demonstrated a strong cumulative increase in subjective hunger with PH284 and no treatment-related adverse events

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Harnessing the power and therapeutic potential of brain regulation.

Advancing a Differentiated Neuroscience Pipeline

- ✓ Differentiated intranasal mechanism
- ✓ Phase 3 opportunity in social anxiety disorder
- ✓ Multiple Phase 2 neuroscience assets with established clinical proof-of-concept
- ✓ Near-term regulatory and strategic catalysts
- ✓ Experienced CNS team

The background of the slide is a dark blue field filled with glowing, interconnected neuron-like structures. These structures consist of central cell bodies with multiple branching processes, some of which are highlighted with bright blue and white light effects, creating a sense of dynamic activity and connectivity.

Vistagen

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