



Palatin Technologies, Inc.
NYSE American: PTN

CORPORATE PRESENTATION
November 2023

Carl Spana, Ph.D.
President & CEO

Stephen T. Wills, CPA/MST
CFO / COO

Forward Looking Statements

The statements in this presentation that relate to future plans, events or performance are forward-looking statements, which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended. Such forward-looking statements involve significant risks and uncertainties, and actual results, events and performance may differ materially from those expressed or implied in this presentation. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include, but are not limited to, statements concerning the following: (i) estimates of our expenses, future revenue and capital requirements; (ii) our ability to obtain additional funding on terms acceptable to us, or at all; (iii) our ability to advance product candidates into, and successfully complete, clinical trials; (iv) the initiation, timing, progress and results of future preclinical studies and clinical trials, and our research and development programs; (v) the timing or likelihood of regulatory filings and approvals; (vi) our expectations on sales and market acceptance for bremelanotide (Vyleesi®) for hypoactive sexual desire disorder (HSDD), a type of female sexual dysfunction (FSD), including our licensees outside North America jurisdictions; (vii) our expectation regarding timelines for development of our other product candidates; (viii) the potential for commercialization of our other product candidates, if approved for commercial use; (ix) our ability and the ability of our licensees to compete with other products and technologies similar to our product candidates; (x) the ability of third party collaborators to timely carry out their duties under their agreements with us and our licensees; (xi) the ability of contract manufactures to perform their manufacturing activities in compliance with applicable regulations; (xii) our ability to recognize the potential value of our licensing arrangements with third parties; (xiii) the potential to achieve revenues from the sale of our product candidates; (xiv) our ability to maintain product liability insurance at a reasonable cost or in sufficient amounts, if at all; (xv) the retention of key management, employees and third-party contractors; (xvi) the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology; (xvii) our compliance with federal and state laws and regulations; (xviii) the timing and costs associated with obtaining regulatory approval for our product candidates; (xix) the impact of legislative or regulatory healthcare reforms in the United States; and (xx) other risks disclosed in our SEC filings. The forward-looking statements in this presentation do not constitute guarantees of future performance. We undertake no obligation to publicly update these forward-looking statements to reflect events or circumstances that occur after the date of this presentation.

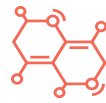
Company Profile

Melanocortin System Drug Development Platform

Therapeutics for inflammatory & Autoimmune Diseases, Sexual Dysfunctions & Obesity



Demonstrated expertise moving programs from discovery to FDA approval



Expertise in the biology and chemistry of melanocortin system (MCS) & natriuretic peptides (NPR)



1st company to gain FDA approval for a melanocortin agent (Vyleesi®)



Strategy leverages our expertise across multiple therapeutic opportunities



MOA with potential to modify underlying disease pathologies – not just treat symptoms

Commercial Product and Development Programs

Commercial Product		
Vyleesi® (bremelanotide) Hypoactive Sexual Desire Disorder	FDA Approval 2Q2019 / Currently Marketed by Palatin	Seeking U.S. and ROW Licenses

Pipeline Development Programs							
Melanocortin Receptor Programs	Pre-clinical	Phase 1	Phase 2	Phase 3	NDA	FDA Approval	Status/Next Steps
PL9643 MCr Agonist Dry eye disease							Phase 3 MELODY-1 Trial Initiated DMC interim analysis completed Phase 3 Data Expected 4Q2023
PL9654 MCr Agonist Retinal diseases							IVT delivery Topical delivery
PL8177 Oral MC1r Agonist Ulcerative colitis (UC)							Phase 2 enrolling Interim data 1Q2024 Final data 1H2024
MCr Agonist Diabetic nephropathy							Phase 2 enrolling Enrollment target completion 4Q2023 Final data 1H2024



Ophthalmology MCr Programs

Dry Eye Disease – PL9643

Glaucoma – PL9588

Retinal Diseases – PL9654

Ophthalmic Diseases with Unmet Medical Need: Front to Back

Conjunctiva/Cornea/Ocular surface

- Dry eye
- Ocular surface protection

Cornea endothelium

- Protect donor corneas for transplantation
- Improve corneal transplant survival
- Protection of cornea with cataract surgery
- Fuchs Dystrophy

Iris/Ciliary Body/Choroid

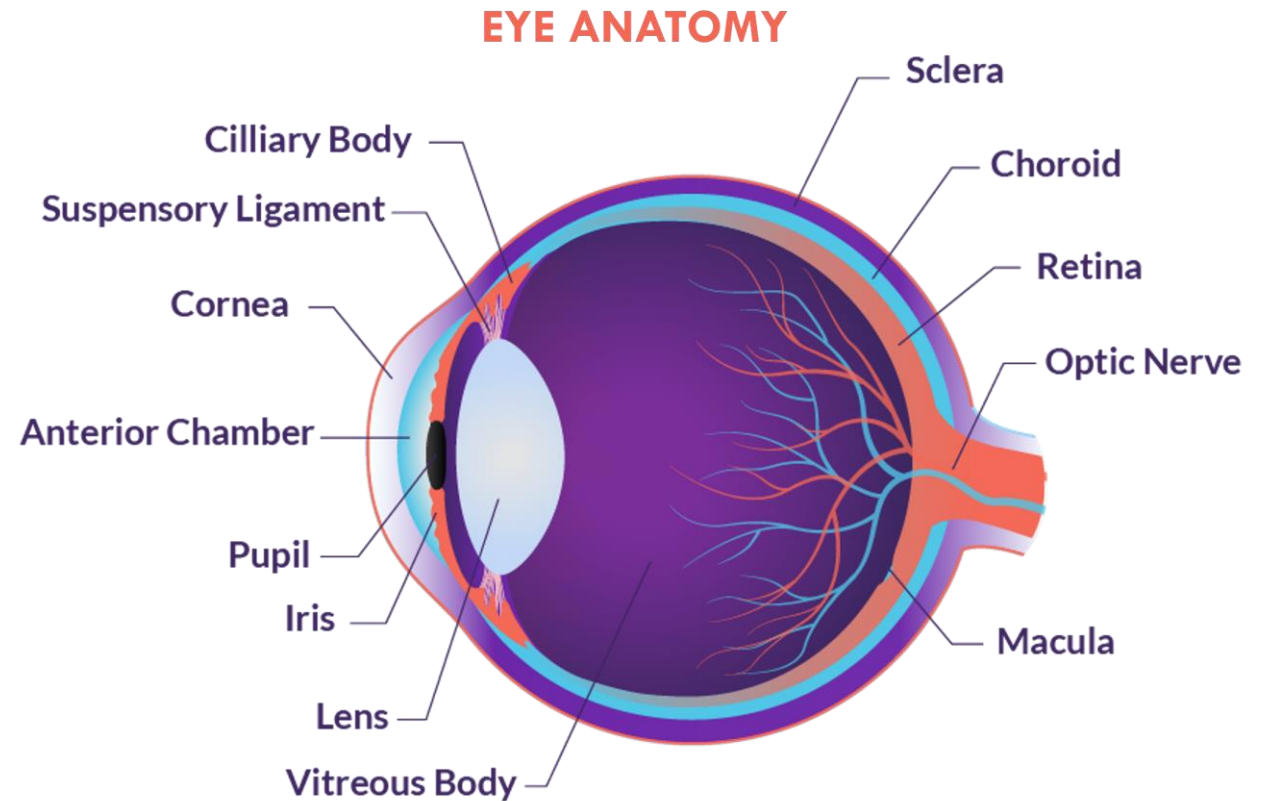
- Non-infectious uveitis

Retina

- Diabetic retinopathy
- Geographic atrophy
- Age-related macular degeneration
- Diabetic macular edema
- Retinal vein occlusion

Optic nerve

- Glaucoma



Dry Eye Overview

Dry eye disease (DED) or **keratoconjunctivitis** is a multifactorial disorder of the tears and ocular surface

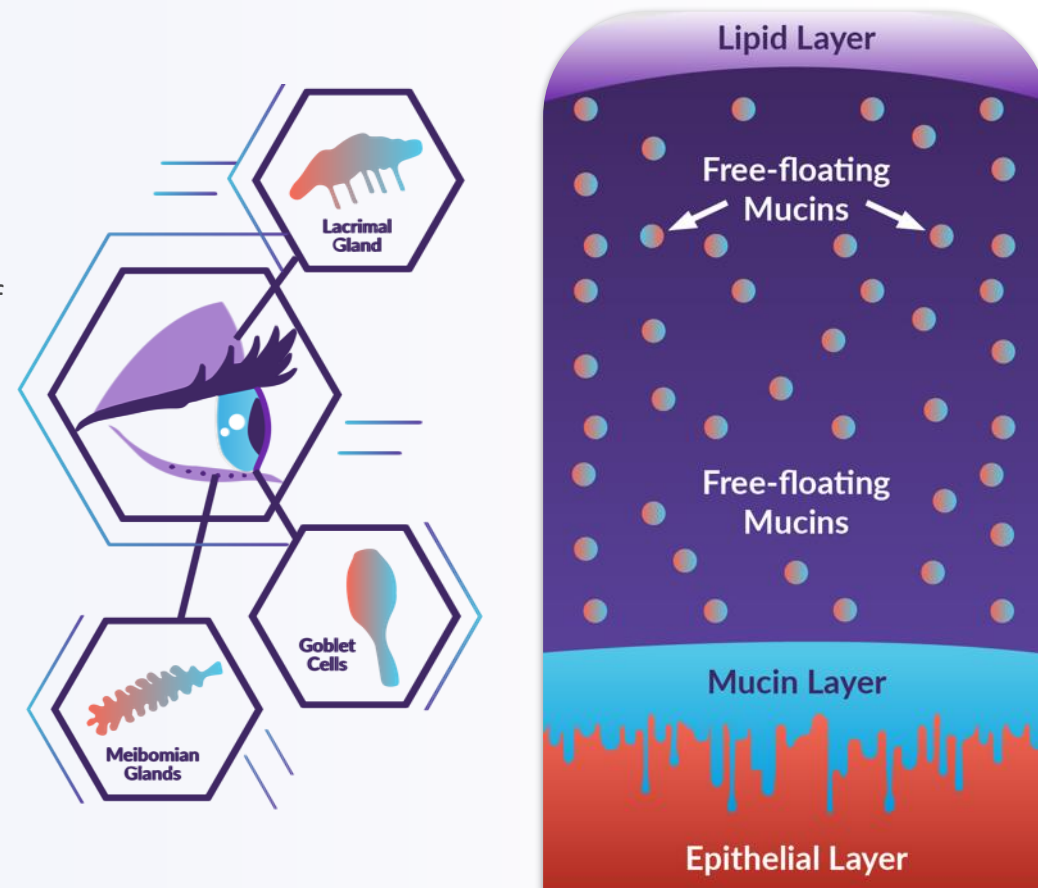
Symptoms include dryness, irritation, redness, discharge and blurred vision

Inflammation plays a prominent role in the development and amplification of the signs and symptoms of DED

A few of the approved **Treatments** within the current global dry eye products market ~\$6.8 billion²⁰²¹ projected to reach ~\$9.7 billion²⁰²⁸.

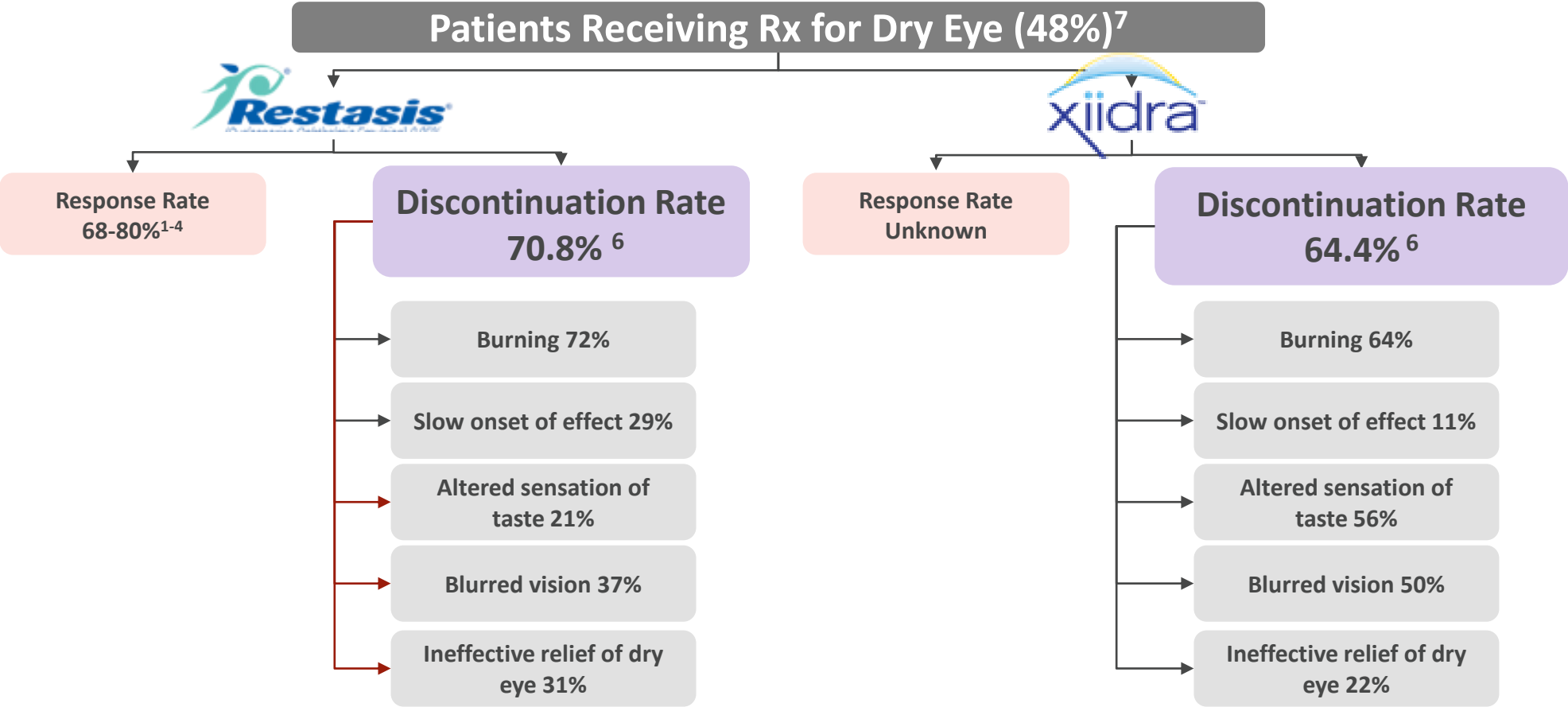
- Restasis® / Cequa® - topical cyclosporine
- Xiidra® - topical integrin inhibitor
- Tyrvaya® - nasal varenicline
- Eyesuvis® other topical steroids
- Miebo – perfluorohexyloctane
- Artificial tears

Current treatments have **efficacy and tolerability issues**, so there is a high medical need for innovative treatments that affect underlying disease processes with better ocular tolerability – **PL9643**



Patient Satisfaction is an Issue with Current Therapies

Poor tolerability leads to high discontinuation rates



Side effects such as burning, blurry vision, and bad taste are main reasons for poor compliance, while lack of efficacy is also a main driver for discontinuation of Restasis

Sources: 1. Sall K et al., (2000); 2. Schultz et al., (2014); 3. Torricelli et al., (2014); 4. Williamson et al., (2015); 5. Mah et al., Clin Ophthalmol (2012); 6. White et al. Clin Ophthalmol (2019); 7. Lum et al. Amer. Academy of Optometry (2018), 8. White et al. Clin Ophthalmol (2020)

PL9643 Safety & Ocular Tolerability Comparability

<u>Approved Products</u>		<u>PL9643</u>			
		Phase 2 Study (N=160)		Phase 3 Lead-In Cases (N=120)	
Restasis		PL9643 (N=80)	Vehicle (N=80)	PL9643 (N=60)	Vehicle (N=60)
Ocular Burning	17%	0%	0%	0%	3%
Xiidra					
Instillation Site Irritation	18%	0%	0%	0%	0%
Dysgeusia	13%	0%	0%	0%	0%
Reduced Visual Acuity	4.7%	0%	1%	0%	0%
Cequa					
Instillation Site Pain	22%	0%	9%	0%	0%
Conjunctival hyperemia	6%	0%	0%	0%	0%
Eysuvis					
Instillation Site Pain	5%	0%	9%	0%	0%
Tyrvaya					
Sneezing	82%	0%	0%	0%	0%
Cough	5-16%	0%	0%	0%	0%
Throat Irritation	5-16%	0%	0%	0%	0%
Site Instillation Irritation	5-16%	0%	0%	0%	0%

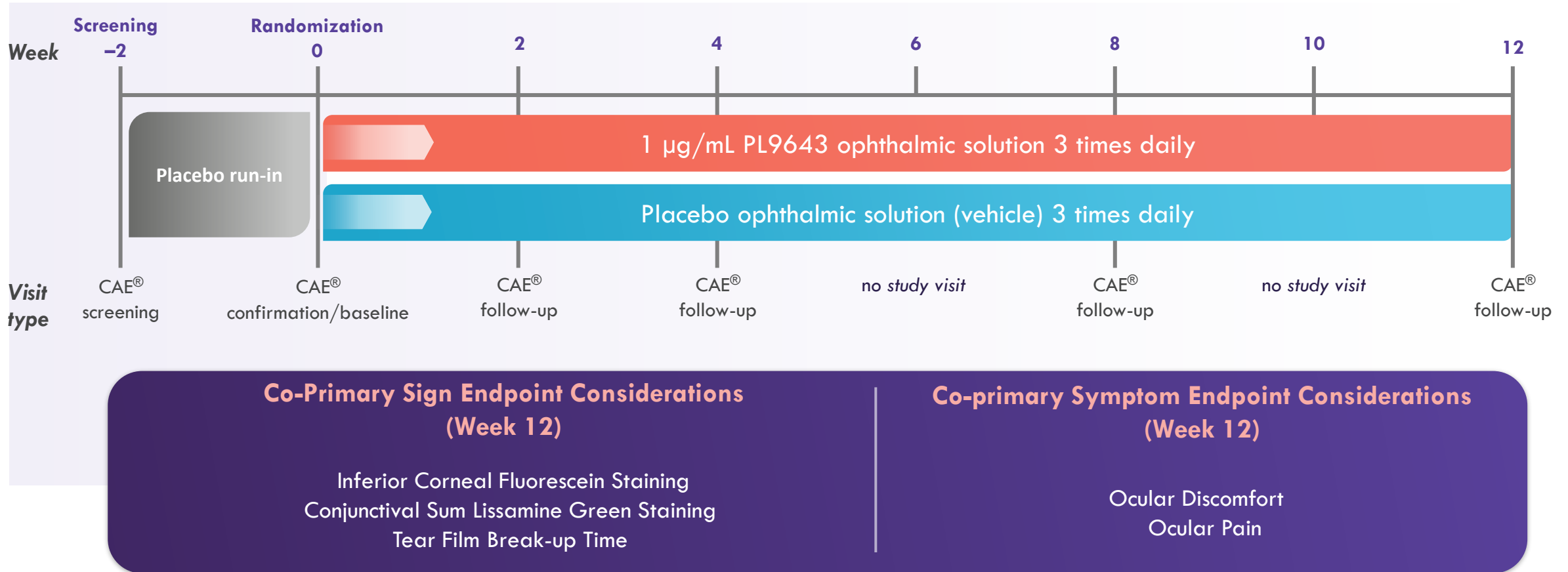
- Phase 2 n=160
 - No** treatment-related serious AEs or ocular AEs were observed with PL9643 treatment
- Drop tolerability** similar to artificial tears
- Phase 3 MELODY-1 Lead-In Population (N=120), confirms Phase 2 study results
 - NO patient receiving PL9643 had an ocular AE**

PL9643 Phase 3 Study Design*

12-week, Multicenter, 1:1 Randomized, Double-Masked, Vehicle-Controlled Adaptive Design Study

Evaluate the efficacy and safety of PL9643 in up to 600 adults with moderate or severe dry eye disease defined as:

Disease duration ≥ 5 years; Inferior Corneal Staining score >1 ; Eye Discomfort score ≥ 25 as measured by the Visual Analog Scale (VAS)



Secondary endpoints include TFBUT, Conjunctival Redness, Schirmer's Test, and Ocular Discomfort Scale

CAE[®], controlled adverse environment

* Reflects Interim Analysis

Interim Analyses Lead-In Population: Clinical Signs & Symptoms

- PL9643 was superior to Vehicle for all 13 Clinical Signs

Nasal Lissamine Green Staining *	Inferior Corneal Fluorescein Staining *
Corneal Sum Lissamine Green Staining	Temporal Fluorescein Staining
Conjunctival Sum Lissamine Green Staining *	Nasal Fluorescein Staining *
Total Staining Score Lissamine Green Staining **	Corneal Sum Fluorescein Staining
Central Fluorescein Staining **	Conjunctival Sum Fluorescein Staining
Superior Fluorescein Staining	Total Staining Score Fluorescein Staining
Tear Film Break-Up Time**	

- Symptom responder sub-population and primary endpoint identified: Ocular pain (VAS)

Pain (VAS) 12-Weeks: PL9643 showed difference of 15.4 points; a clinically meaningful change; change at 12 weeks

Treatment Assignment	N	Least Sq. Mean	Standard Deviation	Standard Error
PL9643	33	8.7*	16.15	2.66
Vehicle	33	24.1	27.80	4.84

- Surveillance indicates double-blind segment of MELODY-1 is on track for success

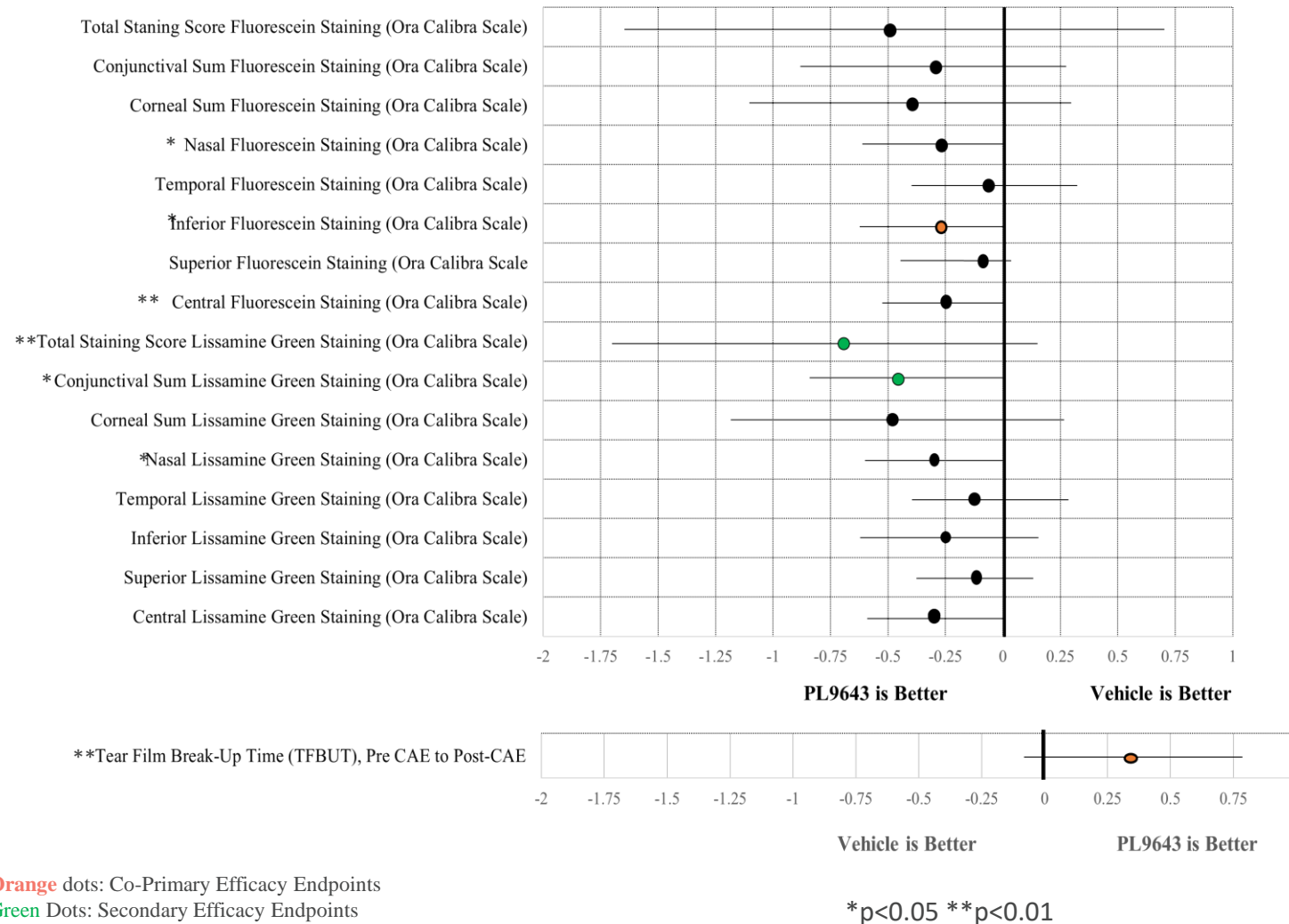
Pain (VAS) comparison between the Lead-In Population and the Phase 3 Double Blind Population

	N	Least Sq. Mean	Standard Deviation	Standard Error
Lead-In	61	45.41	32.408	4.309
Phase 3 Double Blind	54	45.28	35.019	4.58

*p<0.05, **p<0.1 Assessed at 12 weeks (Day 85)

Analyses Lead-In Population: Clinical Signs

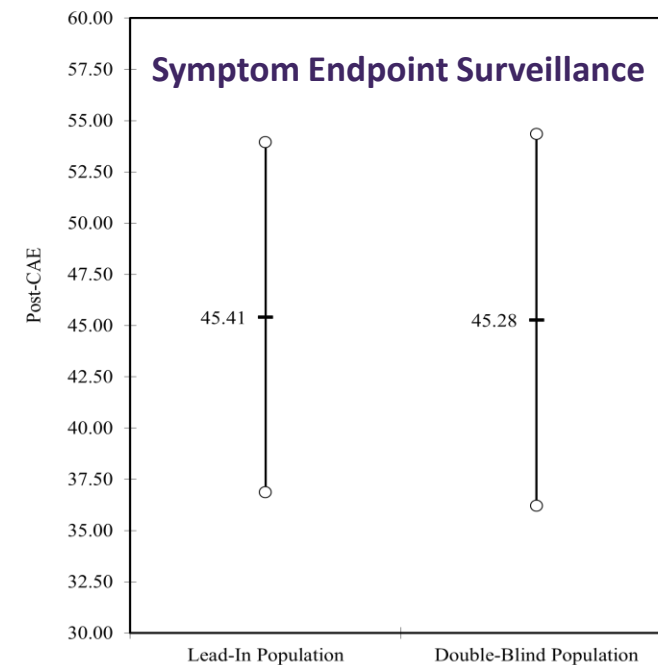
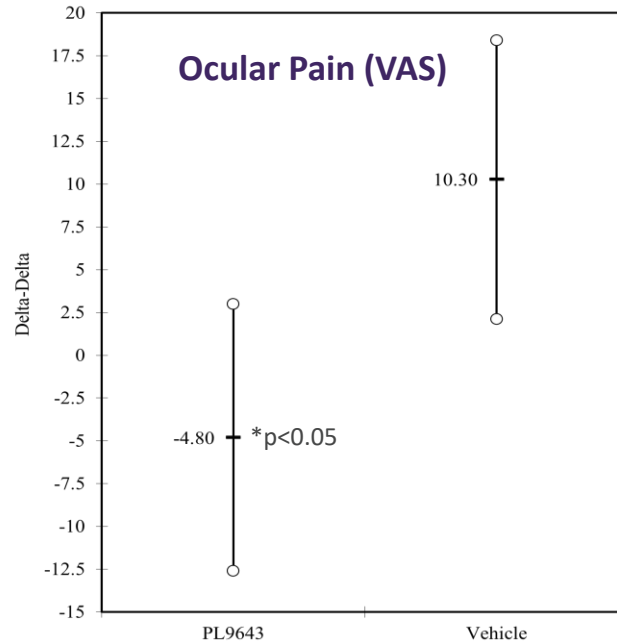
LIP analysis of clinical signs following 12 weeks of treatment



- PL9643 was superior to vehicle for **all** 13 clinical signs evaluated
- Multiple clinical signs were statistically significant
- PL9643 has a “global effect” on improving the clinical signs of DED

Analyses Lead-In Population: Clinical Symptom

Identified clinical symptom responder population and primary endpoint: Ocular Pain



- Ocular pain visual analogue scale (VAS) - at 12 weeks PL9643 had a statistically significant and clinically meaningful change over vehicle of 14.5 points
- PL9643 would be the only treatment for DED with a primary effect on ocular pain
- Data from the LIP symptom analysis allows for surveillance of on-going double-blind segment of MELODY-1 and indicates the study is on track for success

PL9643 Topical Treatment for Dry Eye Disease

Emerging profile indicates PL9643 will be the best approved DED treatment

PL9643	Category	Attribute
	Indication	Dry Eye Disease
	Product Overview	PL9643 is a melanocortin agonist which resolves inflammation and promotes tissue healing
	Safety/Ocular tolerability	Based on Phase 2 clinical trial data and Phase 3 Lead-in population none anticipated
	Efficacy	Broad efficacy in multiple signs and symptoms, including inferior corneal staining, lissamine green staining, ocular discomfort, burning and TFBUT
	Dosing	Topical: TID administration
	Differentiating Factors	Superior safety, ocular tolerability and broad efficacy compared to current treatments

- Melody-1 Phase 3 enrollment completed
 - Positive interim analysis – study on track to demonstrate efficacy for multiple signs and symptoms of DED
 - Excellent ocular tolerability & safety
 - Data 4Q23
- MELODY-2 & MELODY-3 – initiate 1H24
- NDA submission targeted 2H25

PL9643 Dry Eye Summary Statements

PL9643 MELODY-1 Phase 3 clinical trial is on track to

- Demonstrate efficacy for multiple sign and symptom endpoints of DED
- With excellent ocular tolerability and safety

Analysis of Lead-In population has identified

- Symptom sub-population and informed primary sign and symptom endpoints
- Ordering of secondary endpoints and optimal analysis approach for blinded ongoing Phase 3 trial

Adaptive design approach

- Has significantly mitigated risk

Emerging and differentiated product profile

- Positioning PL9643 as a leading treatment option for DED patients

PL9643 Dry Eye Commercial Opportunity



DIFFERENTIATED PRODUCT

PL9643 has a superior commercial product profile compared to approved therapies

- Superior efficacy (multiple signs & symptoms)
- Quick onset of efficacy
- Superior ocular tolerability
- Superior safety profile



UNMET MEDICAL NEEDS SPEED/SAFETY/TOLERABILITY

Current FDA approved treatments have poor ocular tolerability onset of efficacy leading to patient and clinician dissatisfaction and high discontinuation rates



LARGE MARKET OPPORTUNITY

DED is estimated to affect over 34 million people in the United States

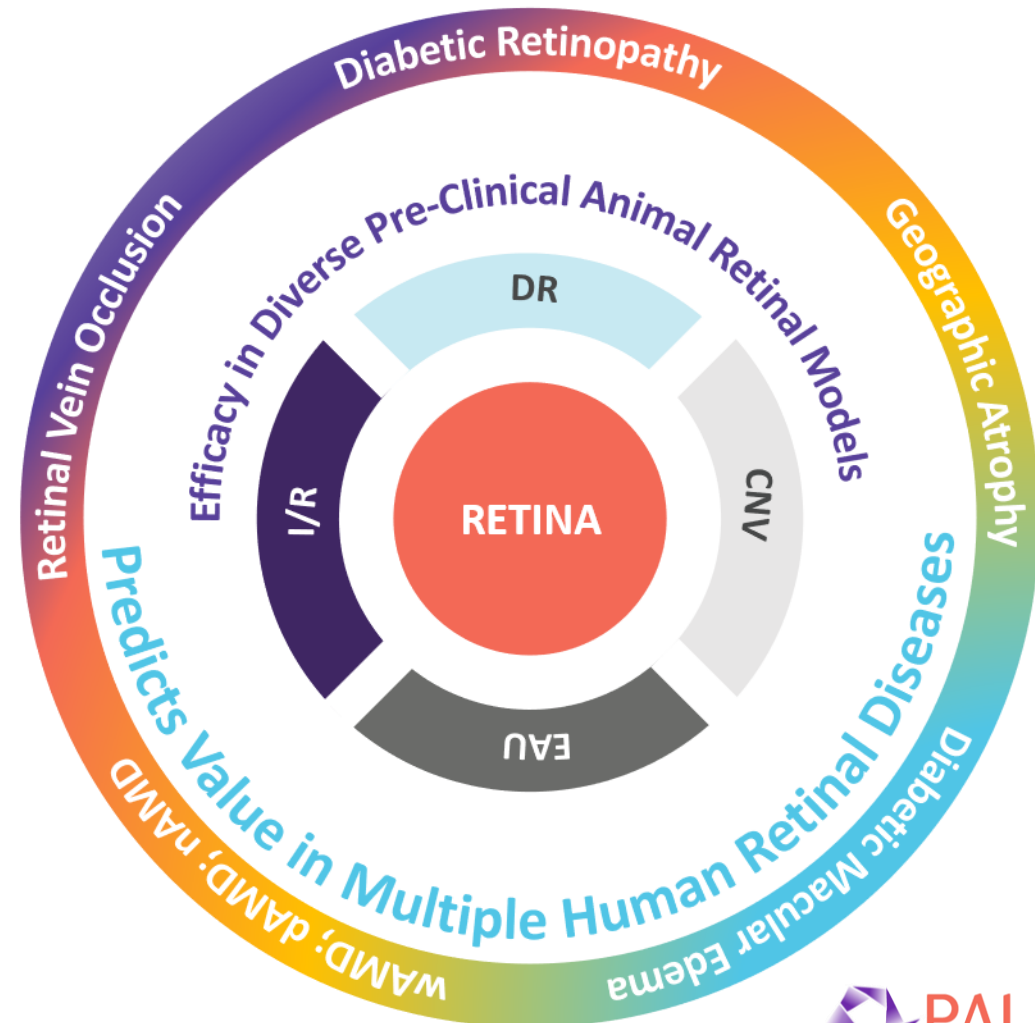
- ~16M people diagnosed with DED in U.S.
- ~7.3M diagnosed patients not satisfied with current treatments and are willing to try new treatments
- Rx market ~\$1.2B in 2021 and projected to be >\$1.6B in 2026

Broad Potential for Retinal Diseases

Retinal disorders current drug market USD **\$20B**, projected to be **\$27B** by 2026

DR/DME estimated ~**\$10B**

- Palatin melanocortin agonists active in 4 pre-clinical retinal disease models*
 - Unprecedented versatility
 - Predictive of potential efficacy across human retinal diseases



Retinopathy – Desired Target Product Profile for Commercial Success

PL9654 Preclinical Data:

- Efficacy in 4 diverse preclinical animal models
- Broad efficacy supports clinical development
- Genomic and proteomic data on MOA
- Topical & SC dosing
- Excellent IP position

Ongoing Activities:

- Expanding preclinical models
- Genomic and proteomic studies to define MOA
- Extensive PK
- Exploring SC and topical delivery

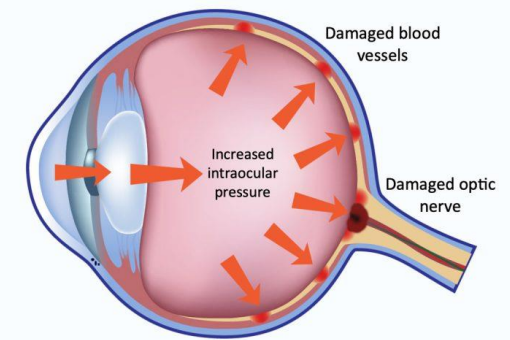
Next Steps:

- IND enabling studies
- Phase 1 SAD/MAD
- 1st Phase 2 efficacy study

Exploring non-IVT patient self-dosing for superior patient comfort and compliance.

PL9588 Treating Glaucoma - Optic Neuropathy

- Group of progressive eye diseases characterized by elevated intraocular pressure (IOP) resulting in or from ocular nerve damage
- Elevated IOP results in loss of retinal ganglion cells and progressive loss of vision (open angle glaucoma), 2nd leading cause of blindness
- In the U.S. there are ~3.4M people with open angle glaucoma
 - ~50% have been diagnosed and on treatment
- Goal of drug therapy is reduction and maintenance of lower IOP
 - Prostaglandins, 1st line therapy [U.S. (2019): \$1.62 billion]*
 - β -agonists and α -agonists, main adjunct treatments [U.S. (2019): \$690 million]*
- New treatments with novel MOA and potential for neuroprotection are desired
- PL9588 novel mechanism for treating glaucoma
 - Lowers IOP & provides neuroprotection
 - Ready to initiate clinical development



* IQVIA 2019 (TD Cowen , March 2023, Thera DED and Glaucoma, p. 35)

Vyleesi® - FDA Approved for HSDD

FDA Approved Vyleesi® For HSDD

Helping Premenopausal Women with Hypoactive Sexual Desire Disorder (HSDD)

vyleesi
(bremelanotide injection)
1.75 mg/0.3 mL for subcutaneous use only

**Hey, you. Meet Vyleesi.
...it's Now Approved**

Vyleesi is the first and only as-needed* treatment for premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD).



**Reconnect with
your desire**



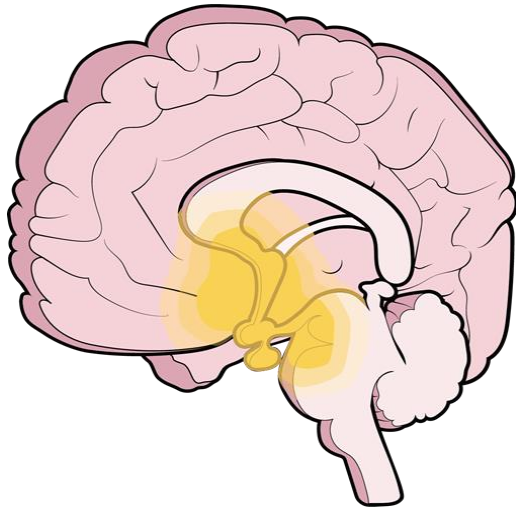
*Administer subcutaneously as needed at least 45 minutes before anticipated sexual activity. The duration of its effect after each dose is unknown. Do not administer more than one dose within 24 hours or more than 8 doses per month.



Visit: www.vyleesi.com / www.vyleesipro.com

Vyleesi – Melanocortin Receptor Agonist

Women with HSDD may have an imbalance of neurotransmitter activity in the brain that impacts sexual desire: too few excitatory signals, too many inhibitory signals, or both.²



Excitatory Signals

- + Dopamine
- + Norepinephrine
- + Oxytocin
- + **Melanocortins (MCs)**

Inhibitory Signals

- + Serotonin (5-HT)
- + Opioids
- + Endocannabinoids

Vyleesi is a **melanocortin receptor agonist** that non-selectively activates several receptor subtypes, with sexual effects mediated by Melanocortin 4 receptor.^{1,2}



1. VYLEESI® (bremelanotide injection) Prescribing Information. 2019.

2. Kingsberg SA, et al. *CNS Drugs*. 2015;29(11):915-933.

HSDD is a Significant Market Opportunity

1/10^{1,2}



Number of premenopausal women who have low desire with associated distress



Affects 5.8 million U.S. premenopausal women³
(1 in 10 premenopausal women)^{1,2}

98% (5.7M) of affected premenopausal women not on therapy³

Focused on relevant digital channels

Creating an online community for HSDD patients

- Provide accurate information
- Tools to support the HSDD patient - symptom check, speaking with your doctor and additional resources

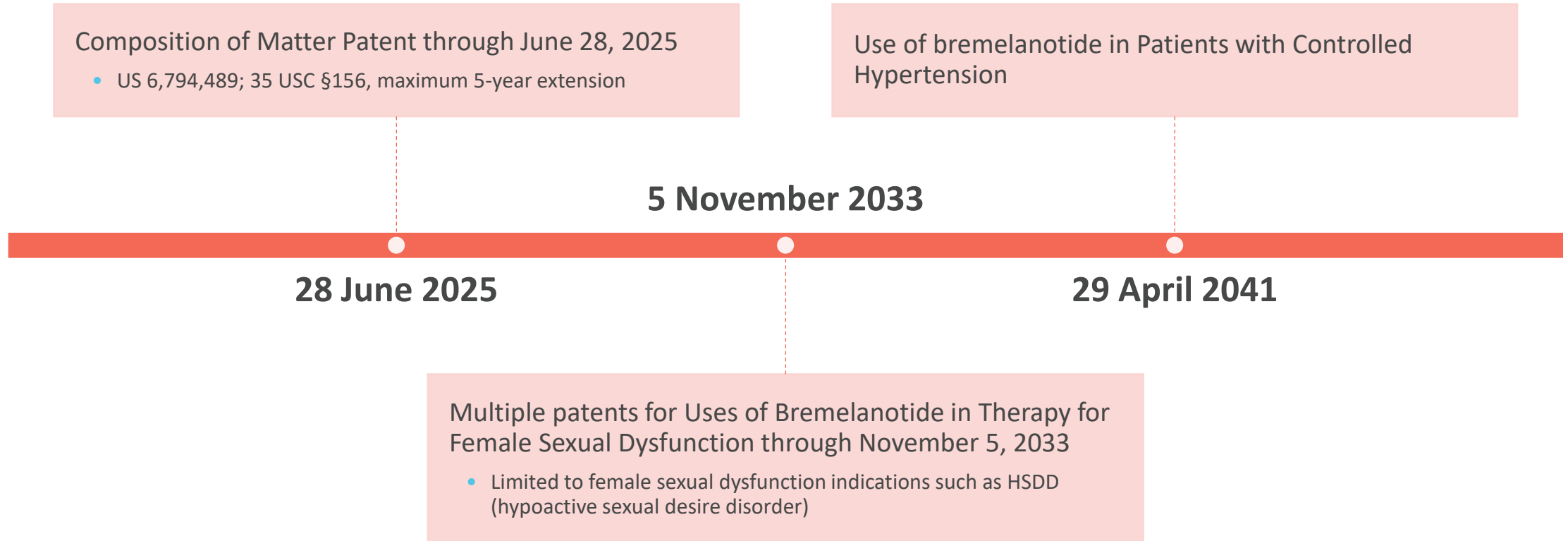
Ensure HCP readiness, provide information and tools to diagnose and treat HSDD patients with Vyleesi

¹ Shifren JL, Monz BU, Russo PA, Segreti A, Johannes CB. Sexual problems and distress in United States women: prevalence and correlates. *Obstet Gynecol.* 2008;112(5):970-978.

² Goldstein I, Kim NN, Clayton AH, et al. Hypoactive sexual desire disorder: International Society for the Study of Women's Sexual Health (ISSWSH) expert consensus panel review. *Mayo Clin Proc.* 2017;92(1):114-128.

³ Palatin supported research that was performed by Burke, Inc., an ISO 20252-certified company, in compliance with the established standard for market, opinion, and social research.

Intellectual Property Position



Vyleesi® / Addyi® Comparison / Differentiating Factors

Competitive Advantage

Single competitor with
suboptimal label and treatment
regimen

Prescription / Use

- Addyi®
 - Oral / chronic use - must be taken once daily
 - Month supply of pills / WAC \$400
 - Requires 4-6 weeks before initial onset of efficacy
- Vyleesi®
 - SC / on-demand treatment taken as-needed
 - Pack of 4 single-use auto injectors / WAC \$899
 - Onset of efficacy in ~30-45 minutes
 - Treatment effect for 8-10 hours

Label

- Addyi®
 - HSDD in premenopausal women
 - **Boxed Warning** for hypotension, syncope, and alcohol consumption / **REMs** program
- Vyleesi®
 - HSDD in premenopausal women
 - **No** Boxed Warning / **No** REMS

Vyleesi Product Revenue Results First Quarter FY 2024 (9/30/23)



\$4.6 million in Gross Product Revenue

11% growth over prior quarter

100% growth over FY 2023 1Q



\$2.1 million in Net Product Revenue

20% growth over prior quarter

142% growth over FY 2023 1Q



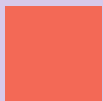
Prescriptions dispensed

14% growth over prior quarter

88% growth over FY 2023 1Q

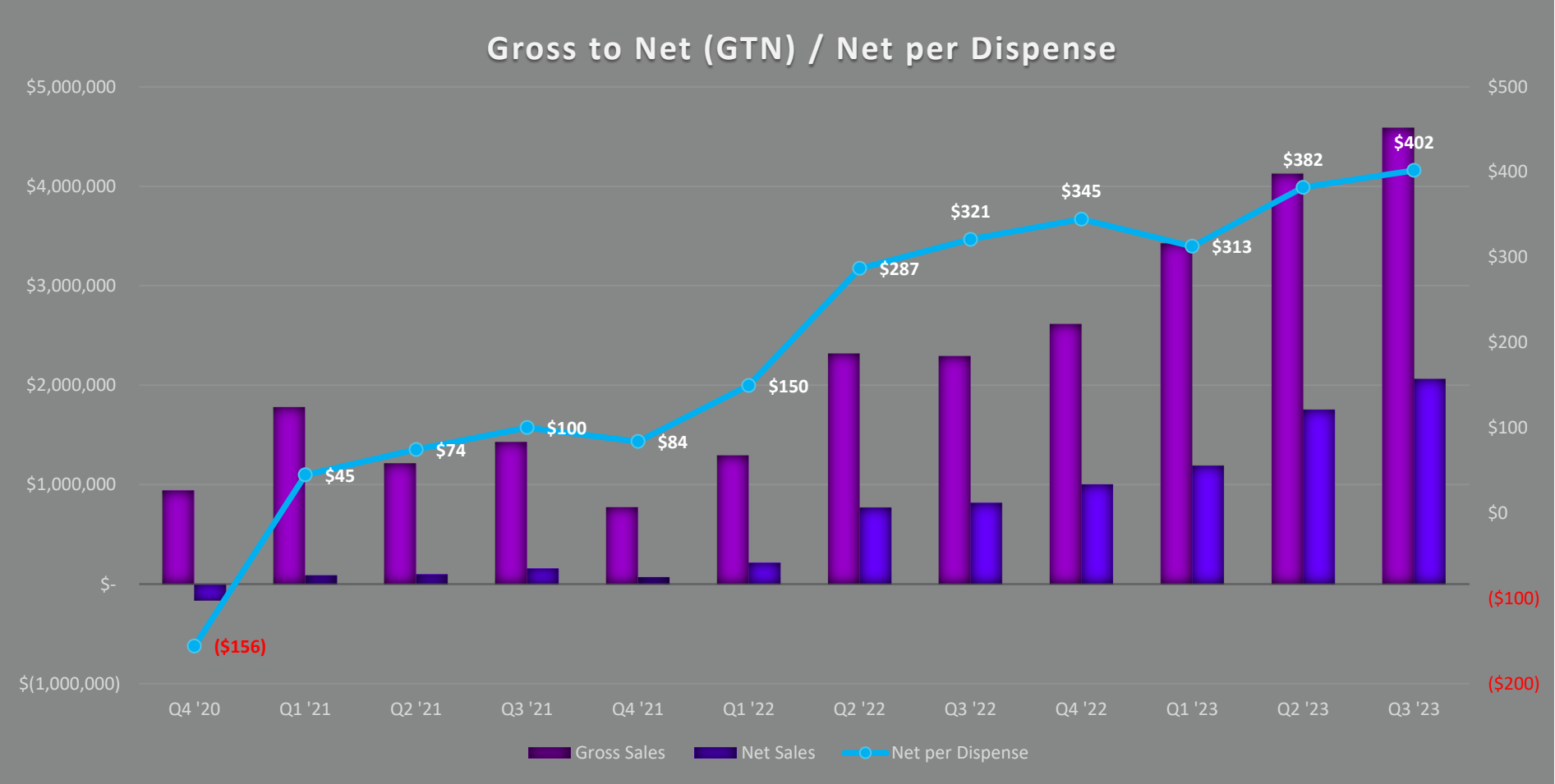


7 consecutive quarters of double-digit growth



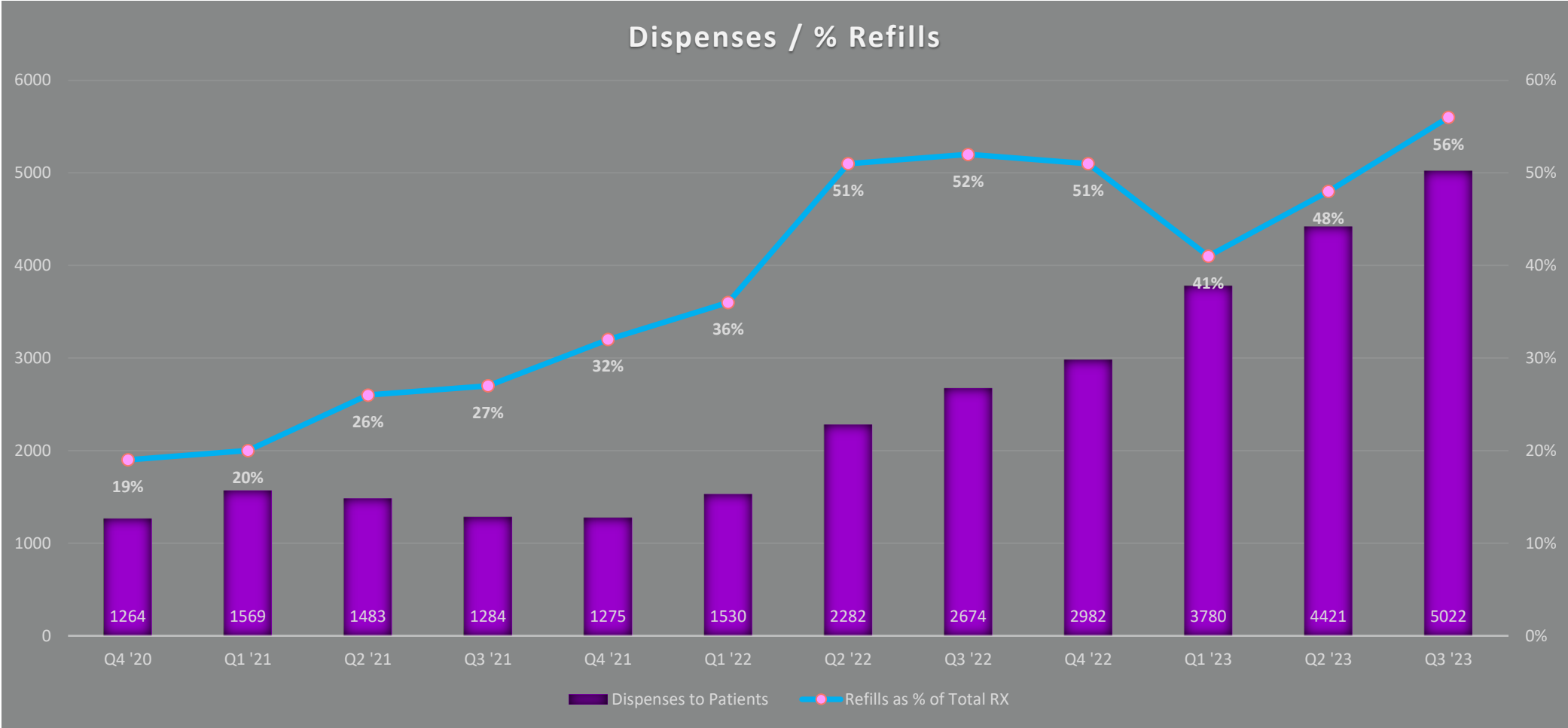
~270 new healthcare prescribers added

Net Sales Analysis (GTN)

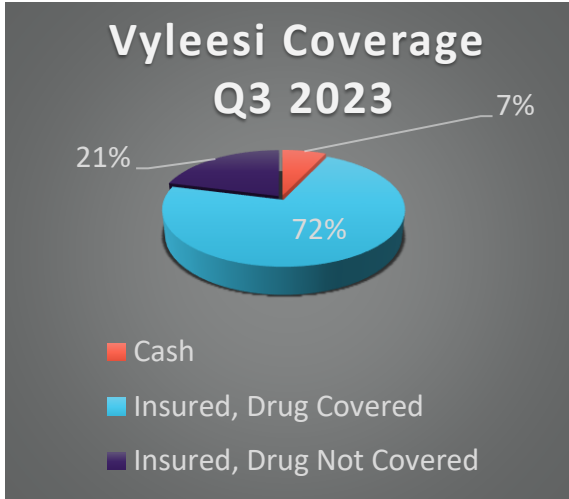
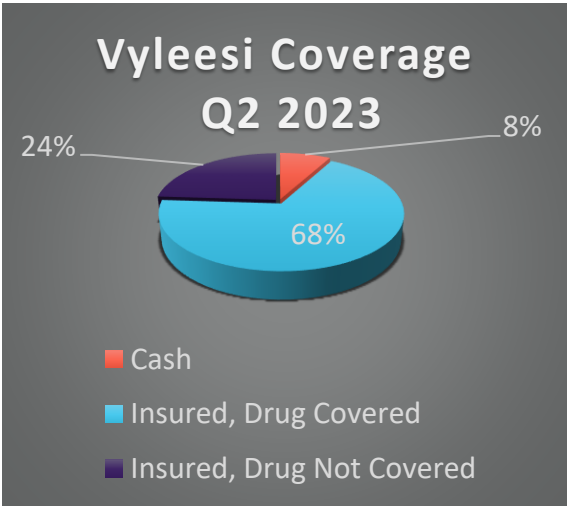
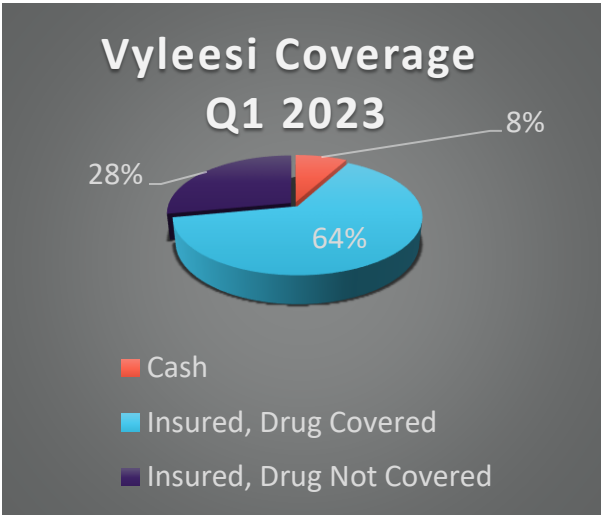
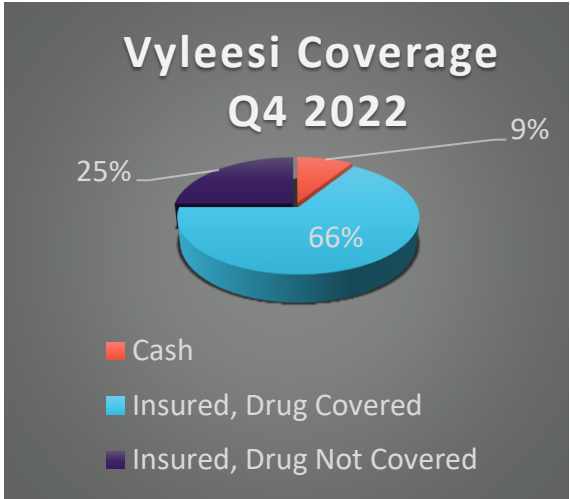
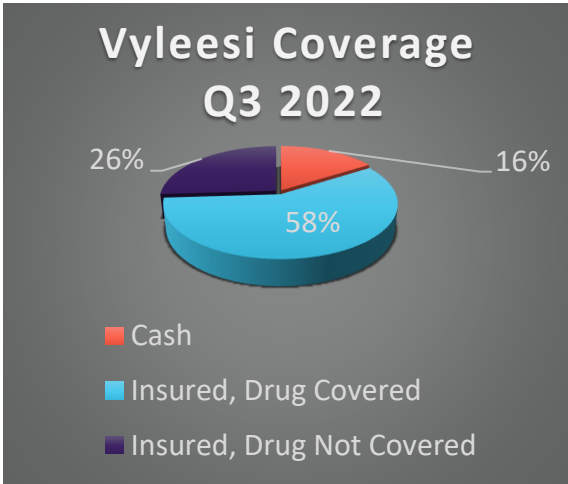
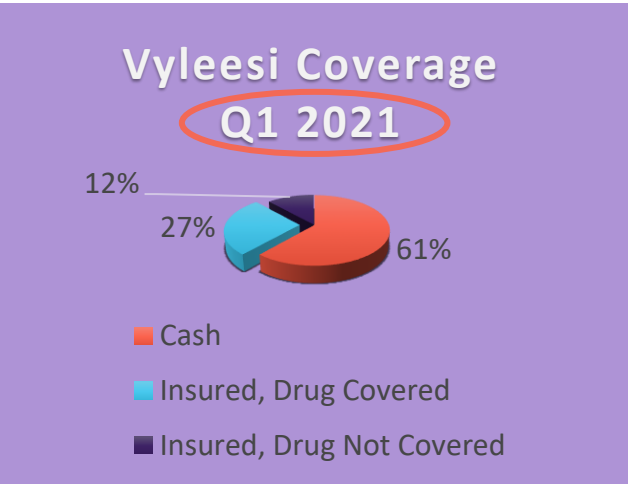


Data presented for calendar year quarters

Patient Distribution Metrics



Significant Growth Within Insured, Drug Covered Segment



PL8177 Oral for Ulcerative Colitis

PL8177 Oral Formulation for Ulcerative Colitis

Global ulcerative colitis (UC) market USD
\$5.5 billion 2021, projected to be **\$8 billion**
by 2026

Most treatments for UC are systemic
and have **tolerability and safety**
limitations

PL8177 is a **highly potent selective**
agonist at melanocortin 1 receptor

Why a Melanocortin Peptide for Ulcerative Colitis?

Phase 2 study evaluating safety and efficacy
of PL8177-Oral in UC patients, interim
assessment 2H23 final data 1H24

MC1r **on colon epithelial cells** is accessible
from the lumen of the colon. PL8177-Oral
demonstrated robust efficacy in UC animal
models

PL8177 is **not systemically absorbed**

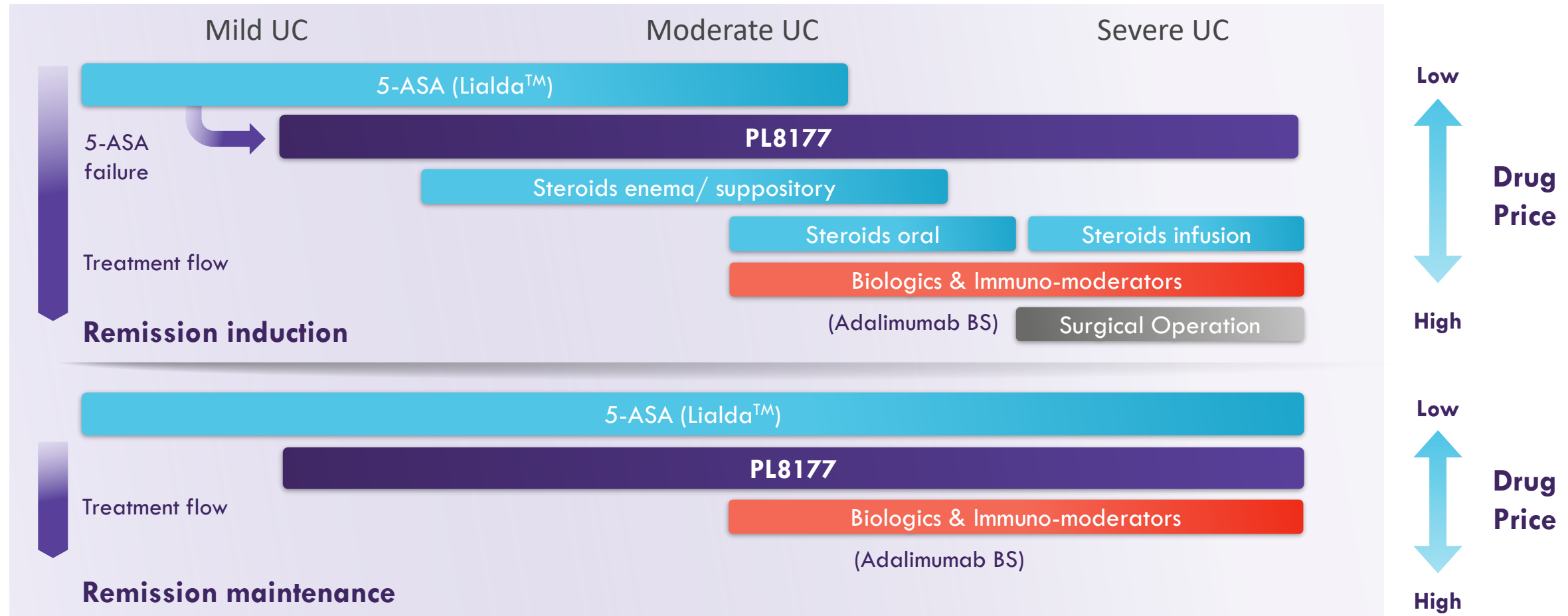
- Potential for excellent efficacy without safety concerns
- Phase 1 SC SAD/MAD study - no significant findings
- Oral Phase 1 study – confirms colon delivery

“Currently available therapies cannot cure IBD, but many of them target various inflammatory pathways, resulting in more or less durable remission. However, these therapies come at a high price economically and physically, with potentially life-threatening side effects.”

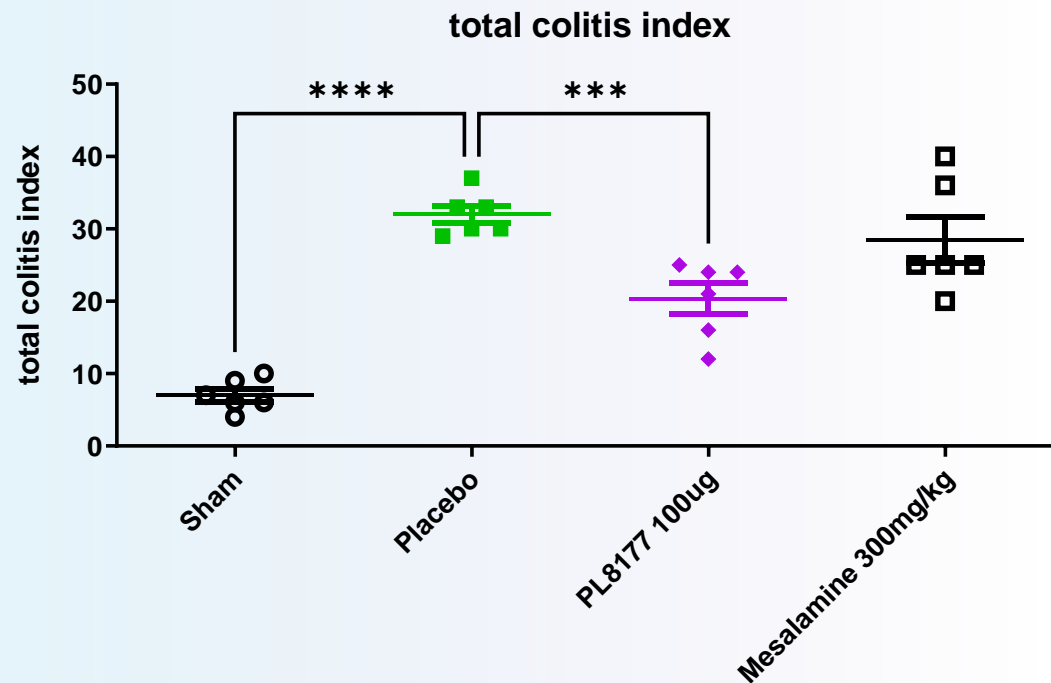
N. ENGL J MED 385:14 September 30, 2021

UC Patient Treatment Paradigm

Opportunity for PL8177 in UC Treatment



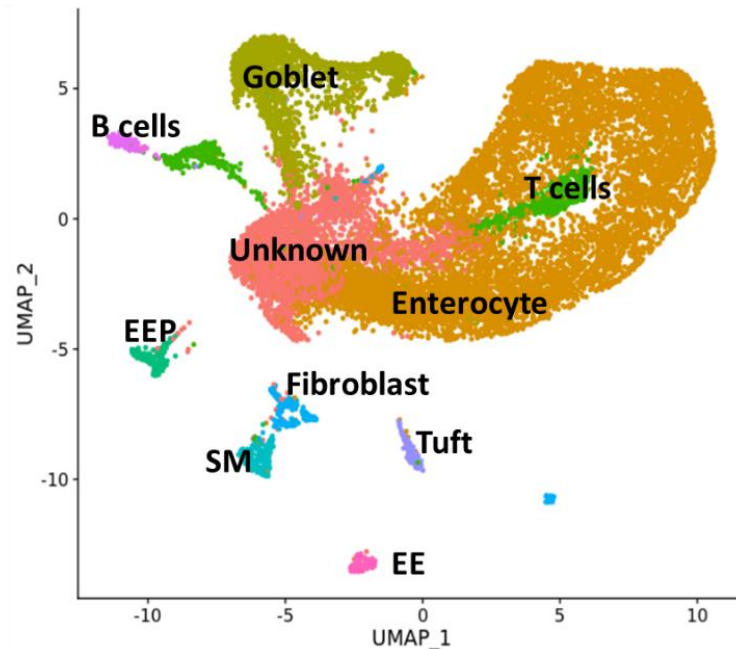
PL8177 Pre-Clinical Histological Findings (Total Colitis Index in Rats)



Total Colitis Index

- Abnormalities of mucosal architecture
- Extent of inflammation
- Erosion or ulceration
- Epithelial regeneration
- Percentage involvement by the disease process
- Superior to mesalamine (SOC) positive control

PL8177-Oral Pre-Clinical Cell Analysis in Rat Ulcerative Colitis Model



Single nuclei RNAseq of rat colon

In a rat DSS colitis model:

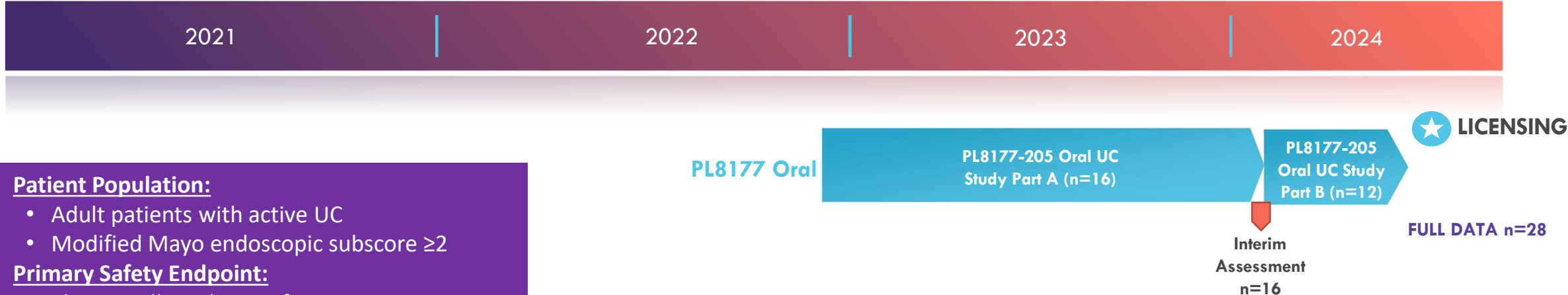
PL8177 **preserves** relative **enterocyte cell** population

PL8177 **prevents increase** in relative **T cell** population

PL8177 **prevents increase** in multiple **inflammatory pathways**

PL8177-205 Phase 2 Study Design & Timelines

Phase 2 RCT Parallel Group Study Using an Adaptive Design to Evaluate Safety, Tolerability and Efficacy



- Patient Population:**
- Adult patients with active UC
 - Modified Mayo endoscopic subscore ≥ 2
- Primary Safety Endpoint:**
- The overall incidence of treatment-emergent adverse events (TEAEs)
- Primary Efficacy Endpoint:**
- Proportion of patients that have MES of 0 or 1 (endoscopic improvement)

Time Point	Dosing Regimen	Placebo	PL8177
Leading into the Interim Assessment	QD	n = 4	n = 12
Target Sample Size Following the Interim Assessment	QD	n = 7	n = 21

Ulcerative Colitis – Target Product Profile for Commercial Success

PL8177 Preclinical Profile

- High potency at melanocortin receptors 1
- Efficacy in multiple animal models including gold standard disease model
- Efficacy as good/better than 5-ASA and glucocorticoids in animal model data
- No toxicological findings in pre-clinical studies doses >100-fold above planned clinical doses

PL8177 Oral Formulation PK

- Phase 1 radiolabeled micro-dose study with the oral formulation, **confirmed colonic delivery** of PL8177
- Orally dosed PL8177 remains in the colon – there is no systemic exposure

PL8177 Clinical

- Phase 1 clinical SAD/MAD study with the systemic formulation (SC) completed, no adverse events or safety signals
- Phase 2 study enrolling UC patients (4Q2022)

PL8177 Oral Formulation – Meeting the Program Goals and Positioned for Success in Phase 2 POC



Milestones Recap Financial / Cap Table Snapshot

Milestones

Melanocortin System Development Programs		Date
PL9643 – Dry Eye Disease (DED)		
Phase 3 Melody1 Interim Analysis / Lead-In Population Analysis Phase 3 Melody1 Data		Completed 4Q2023
PL8177 Oral – Ulcerative Colitis		
Phase 2 Proof-of-Concept Interim Data Phase 2 Proof-of-Concept Data Readout		1Q2024 2Q2024
MC4R Agonist – Diabetic Nephropathy		
Phase 2 Open Label Trial – enrollment completed Topline Data Readout		4Q2023 1H2024
MC4Rr Agonist + GLP-1 – Weight Loss		
Co-administration pre-clinical data shows increased weight loss and greater glucose control above monotherapy Phase 2 clinical study – initiation target		1Q2024
Bremelanotide/MC4R + PDE5i – Erectile Dysfunction (ED)		
Developed a co-formulation of bremelanotide and a PDE5i to be administered as a single injection Phase 2 clinical study in PDE5i non-responder ED patients – initiation target		1Q2024
Vyleesi (bremelanotide) for Hypoactive Sexual Desire Disorder (HSDD)		
Objective to license U.S. Rights		2H2023
7 Consecutive Quarters of Double-Digit Growth in Net Product Revenue and Dispenses		9/30/2023
S. Korea territory and China territory partners advancing regulatory activities - potential approval and sales		2024/2025

Financial / Cap Table Snapshot

Financial Highlights as of September 30, 2023

Cash, Cash Equivalents and Marketable Securities *	\$5.5 million
Accounts Receivable	\$1.3 million
No debt	

* Does not include \$4.5 million of net proceeds from October 2023 Registered Direct Offering

Summary Capitalization as of November 15, 2023

	Common Shares and Equivalent
Common Stock	13.7 million shares
Warrants	4.9 million shares
Options	1.6 million shares
RSUs	0.9 million shares
Fully Diluted Shares	21.1 million shares
Total Shares Authorized	300.0 million shares

Thank You.

