



Palatin Technologies, Inc.  
NYSE American: PTN

CORPORATE PRESENTATION  
September 2022

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President & CEO

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CFO / COO

# Forward Looking Statements

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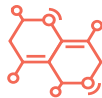
The statements in this presentation that relate to future plans, events or performance are forward-looking statements, which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended. Such forward-looking statements involve significant risks and uncertainties, 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

Targeting the Melanocortin System is a platform for the development of drugs treating inflammatory & autoimmune diseases



Demonstrated expertise moving programs from discovery to FDA approval



Expertise in the biology and chemistry of the melanocortin system



1<sup>st</sup> company to procure FDA approval for a melanocortin agent (Vyleesi®)



Strategy leverages our chemistry and biology across multiple therapeutic opportunities



MOAs with the potential to modify underlying disease pathologies - not just treat symptoms

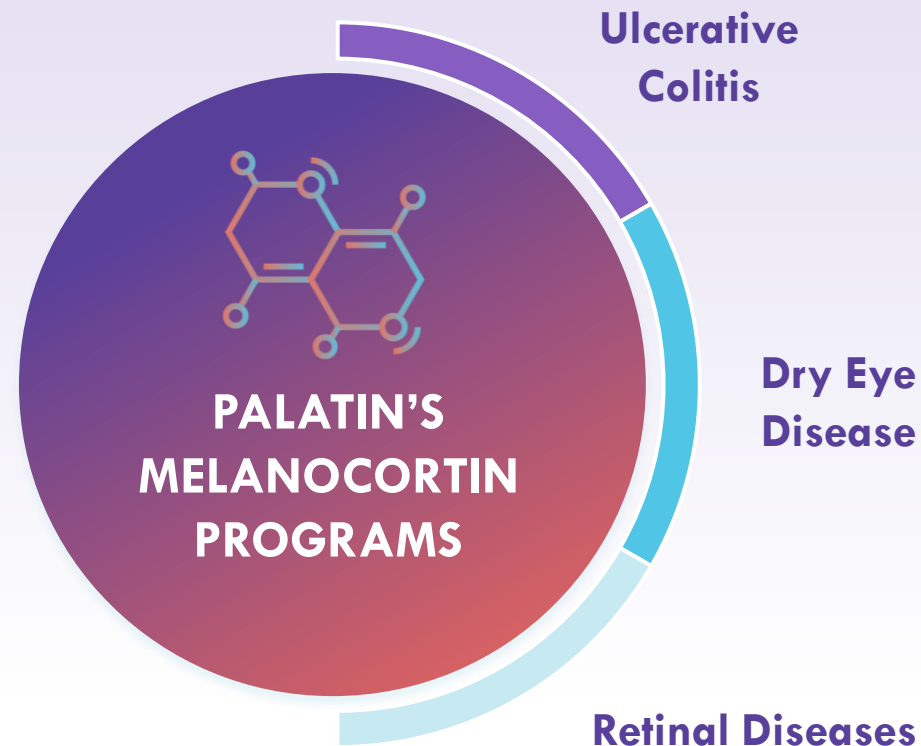
# Commercial Product and Development Programs

Commercial Product							
Vyleesi® (bremelanotide) Hypoactive Sexual Desire Disorder		FDA Approval 2Q2019					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 4Q2021 DMC interim assessment completed August 2022 Phase 3 Data Expected 1H2023
PL9654 MCr Agonist Retinal diseases							IVT Formulation Under Development SC delivery under final evaluation IND filing 2023
PL8177–Oral MC1r Agonist Ulcerative colitis (UC)							Phase 2 enrolling Interim data (n=16) 1H2023 Final data (n=28) 2H2023
MCr Agonist Diabetic Nephropathy							Open label trial (n=30) Phase 2 Trial Initiates 4Q2022 Interim data 1H2023

# Developing Drugs to Address Unmet Clinical Need

Total Market Size of Palatin's Clinical Programs (2021) ~ \$20 Billion

Addressing *unmet and unsatisfied medical needs*, through safer better tolerated drugs in large markets.



- Need for safer, more tolerable UC products prior to steroids & biologics especially for pediatric patients
- Market Size (2021) ~\$5.5 Billion

- Need for treatments with efficacy and better ocular tolerability
- Market Size (2021) >\$5.0 Billion

- Need for safer, more tolerable DR/DME products after or with anti-VEGFs
- Market Size (2021) ~\$10 Billion

# Target Milestones

Melanocortin System Inflammatory & Autoimmune Disease Programs		Date
<b>PL9643 – Dry Eye</b>		
Phase 3 Melody 1 <b>Initiated</b>		4Q2021
Phase 3 Melody-1 <b>Interim Assessment</b>		Completed
Phase 3 Melody-1 <b>Data</b>		1H2023
<b>PL8177-Oral – Ulcerative Colitis</b>		
Phase 2 Proof-of-Concept <b>initiated and enrolling patients</b>		Started 3Q2022
Phase 2 Proof-of-Concept <b>Interim data</b>		1Q2023
Phase 2 Proof-of-Concept <b>Data</b>		1H2023
<b>MCR Agonist - 2<sup>nd</sup> front of eye indication</b>		
Target IND filing		1H2023
<b>PL9654 Retinal indication</b>		
Target IND filing		2H2023
<b>Natriuretic Peptide System Cardiovascular &amp; Fibrosis Programs</b>		
<b>PL3994 – Heart Failure Preserved Ejection Fraction</b>		
Open label Phase 2 <b>Data</b>		2H2022
<b>Vyleesi (bremelanotide) for Hypoactive Sexual Desire Disorder</b>		
North American rights regained		3Q2020
S. Korea licensee PK study <b>enrolling Data</b>		1H2023
Re-license North American rights / Additional ROW partnerships		2H2022



# Melanocortin Inflammatory & Autoimmune Disease Programs

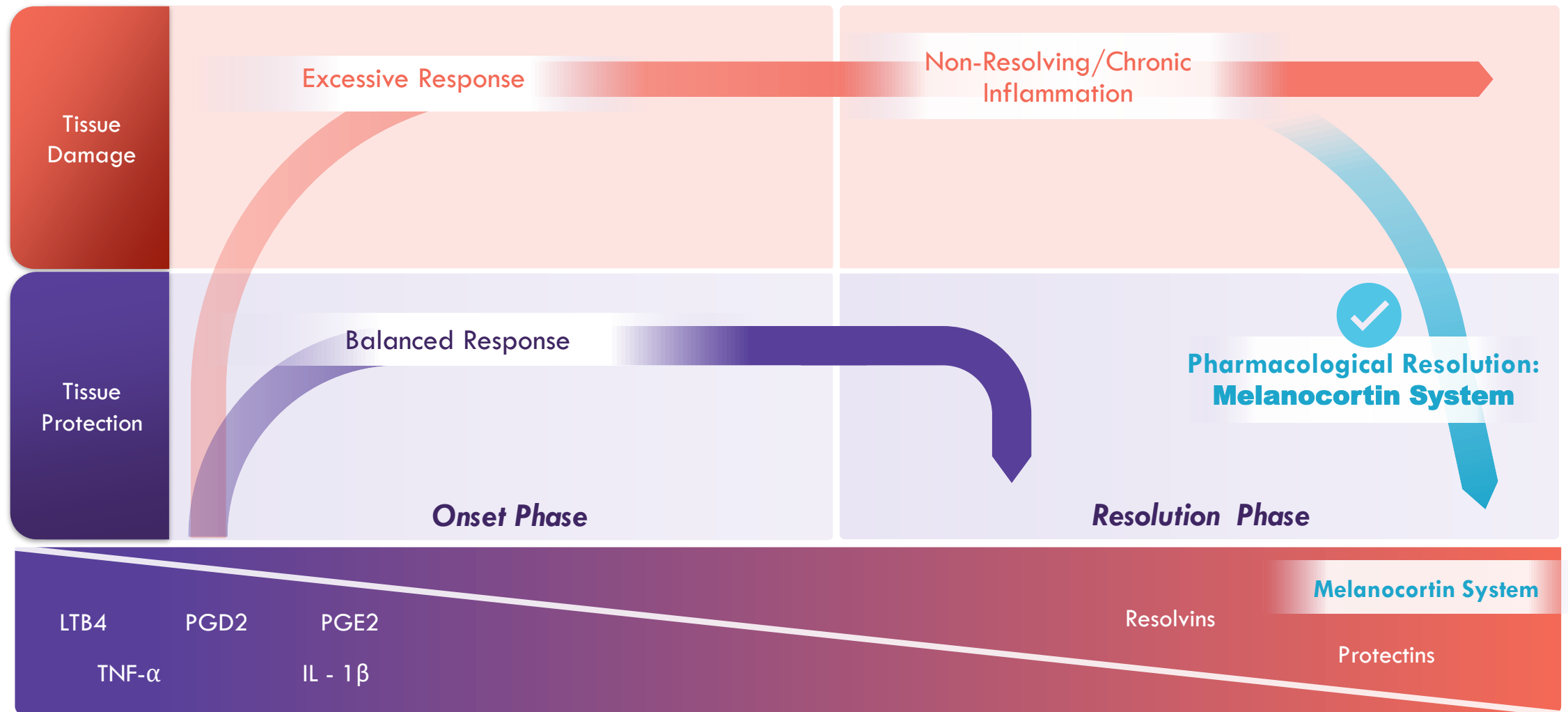
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Pioneering a new way to treat patients, and  
meeting the need for safe effective treatments.



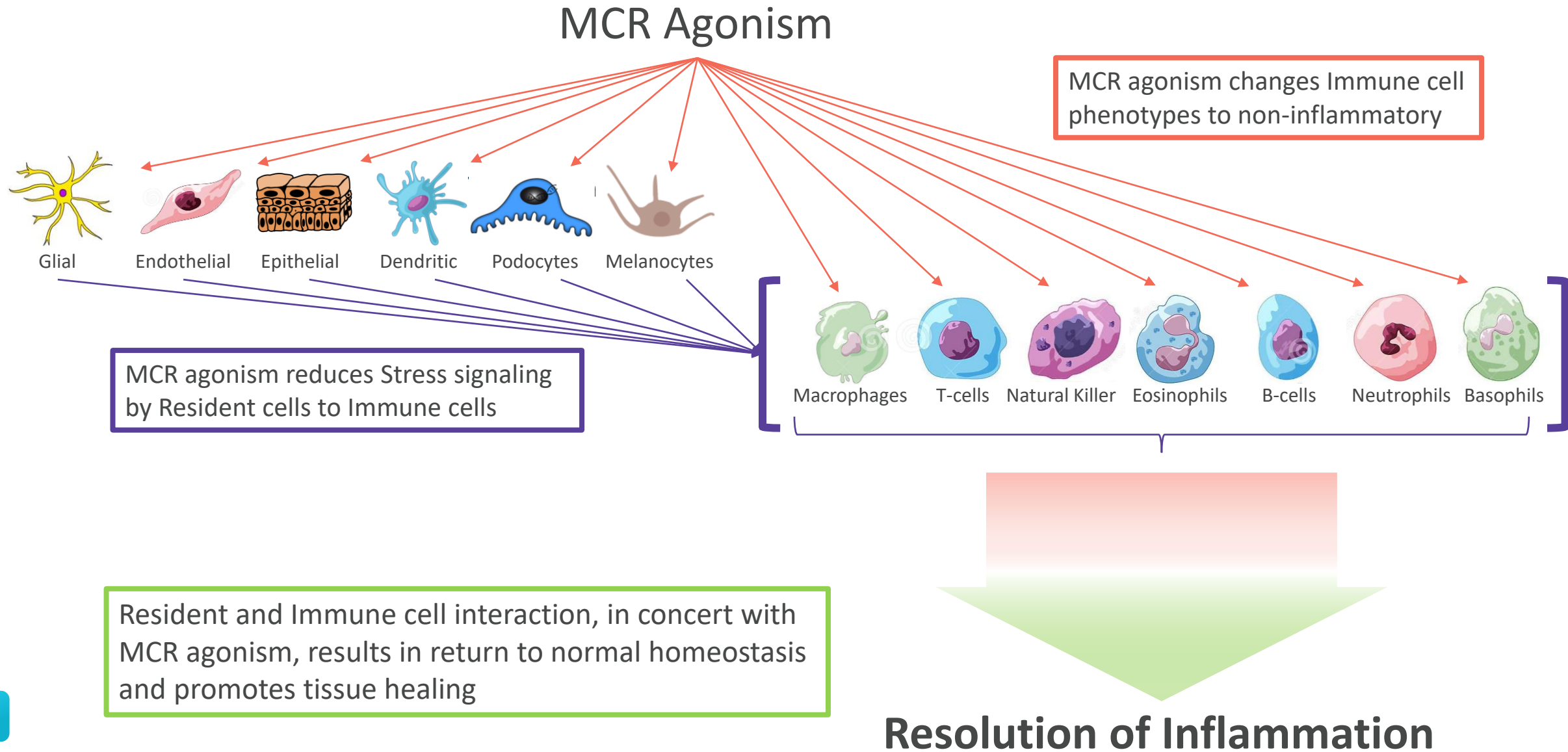


# The Inflammatory Process in Health and Disease





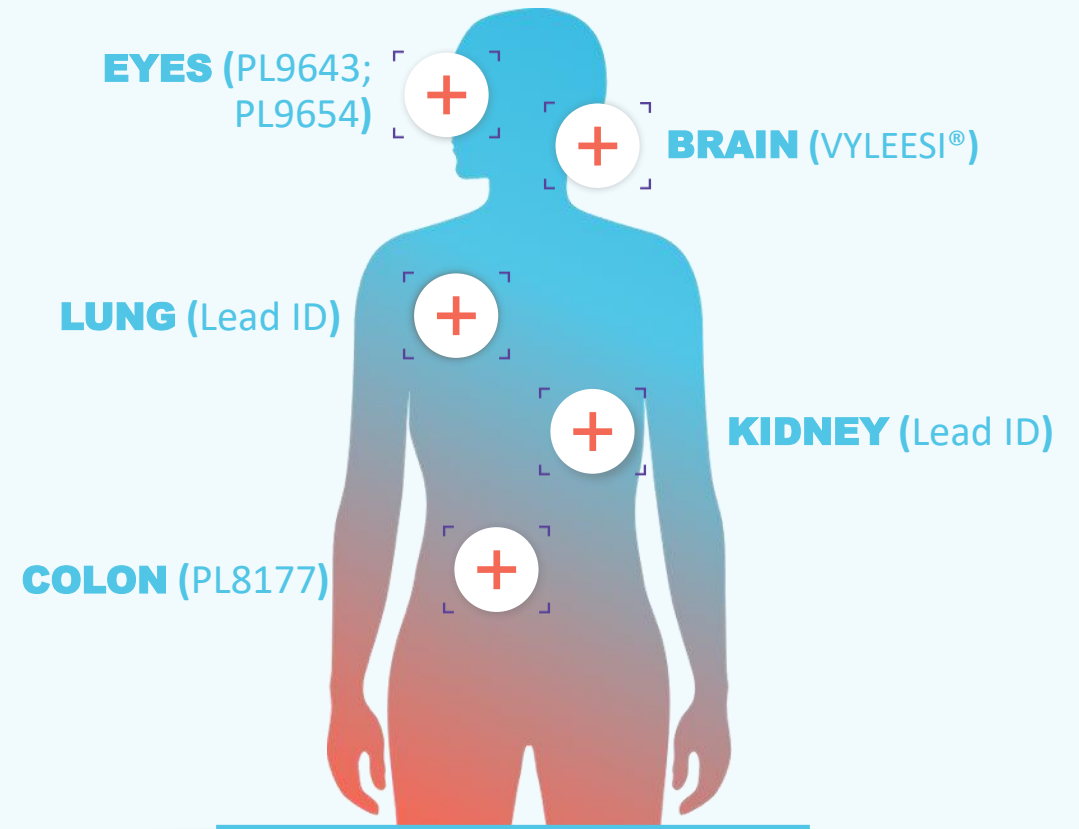
# Multiple Pathways From MCR Agonism to Resolution of Inflammation



# Melanocortin Therapeutics Have Broad Utility

Targeting the Melanocortin System a platform for drugs to treat inflammatory diseases

Palatin's therapeutics work by **activating** endogenous melanocortin pathways to **resolve** damaging inflammation and promote tissue healing



# Validating the Melanocortin System

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**Goal:** Validate the Melanocortin system as a new target for the development of drugs to treat multiple inflammatory and autoimmune diseases

**Why:** Potential for a new class of drugs not based on immune suppression with better efficacy, tolerability and safety to address significant unmet medical need in large markets

## Strategy

- Advance the science using the latest in genomic and proteomic technologies
  - Multiple publications and presentations
- Translate preclinical findings into clinical data in multiple indications to demonstrate depth of mechanism
  - Ph. 3 dry eye disease, Ph. 2 ulcerative colitis & ph. 2 diabetic nephropathy
- Build a portfolio of drugs for ocular indications

Ocular

# Ophthalmic Diseases with Unmet Medical Need: Front to Back

## Conjunctiva/Cornea/Ocular surface

- Dry eye

## Cornea endothelium

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

## Iris/Ciliary Body/Choroid

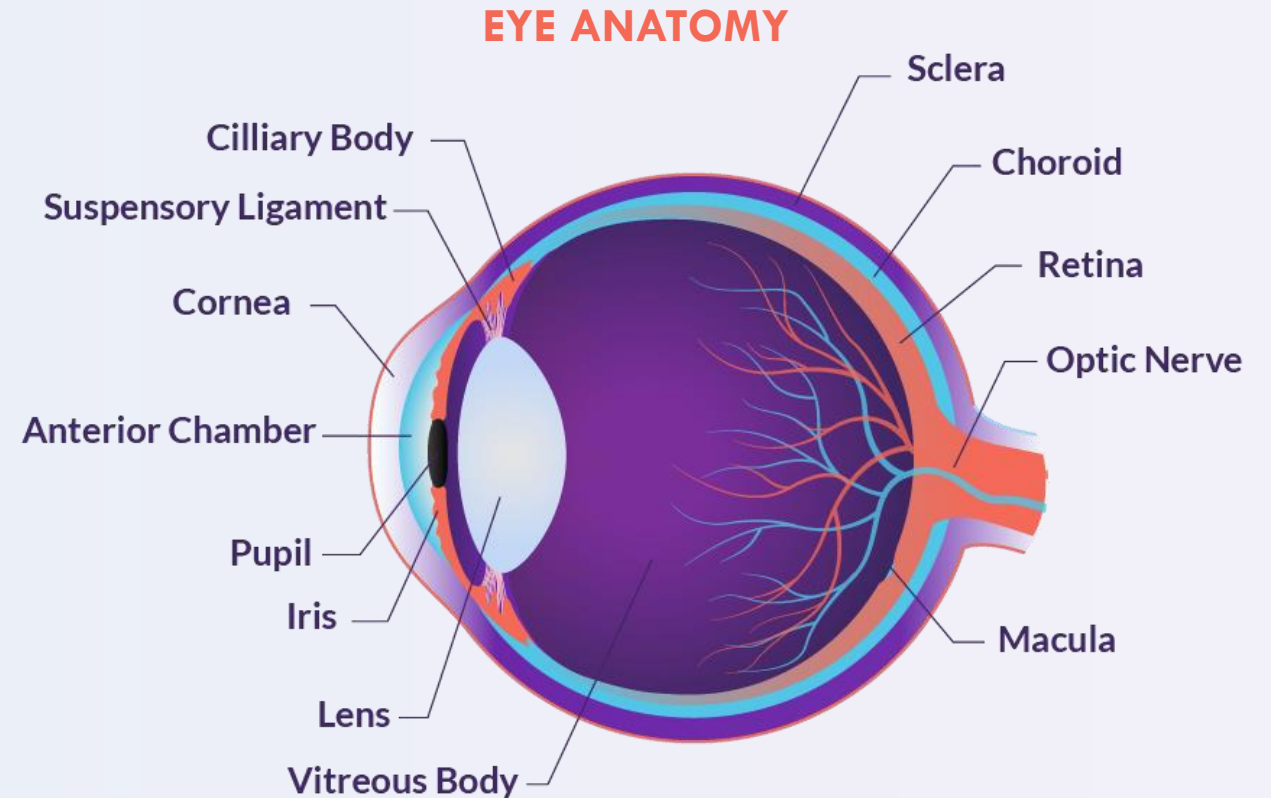
- Non-infectious uveitis

## Retina

- Diabetic retinopathy
- Age-related macular degeneration

## Optic nerve

- Glaucoma



# Dry Eye Overview

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

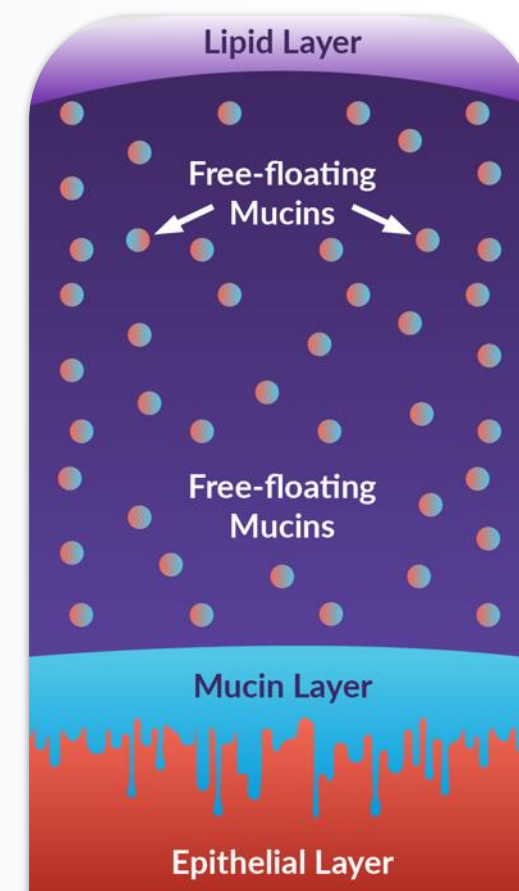
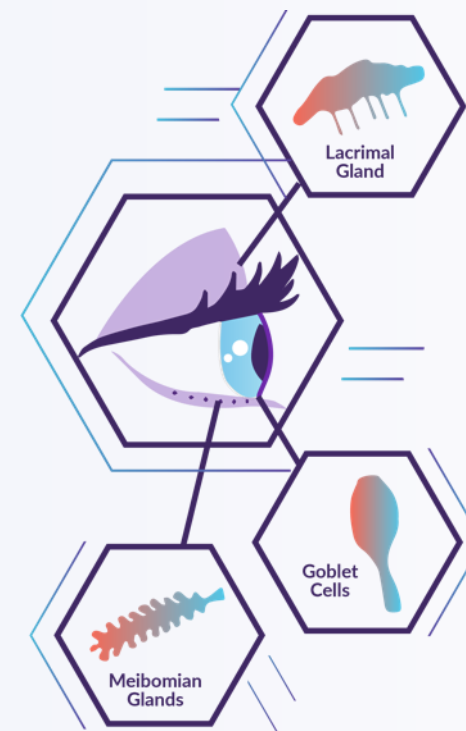
**Symptoms** include dryness, irritation, redness, discharge and blurred vision

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

Current **Treatments** ~\$5 billion in revenue

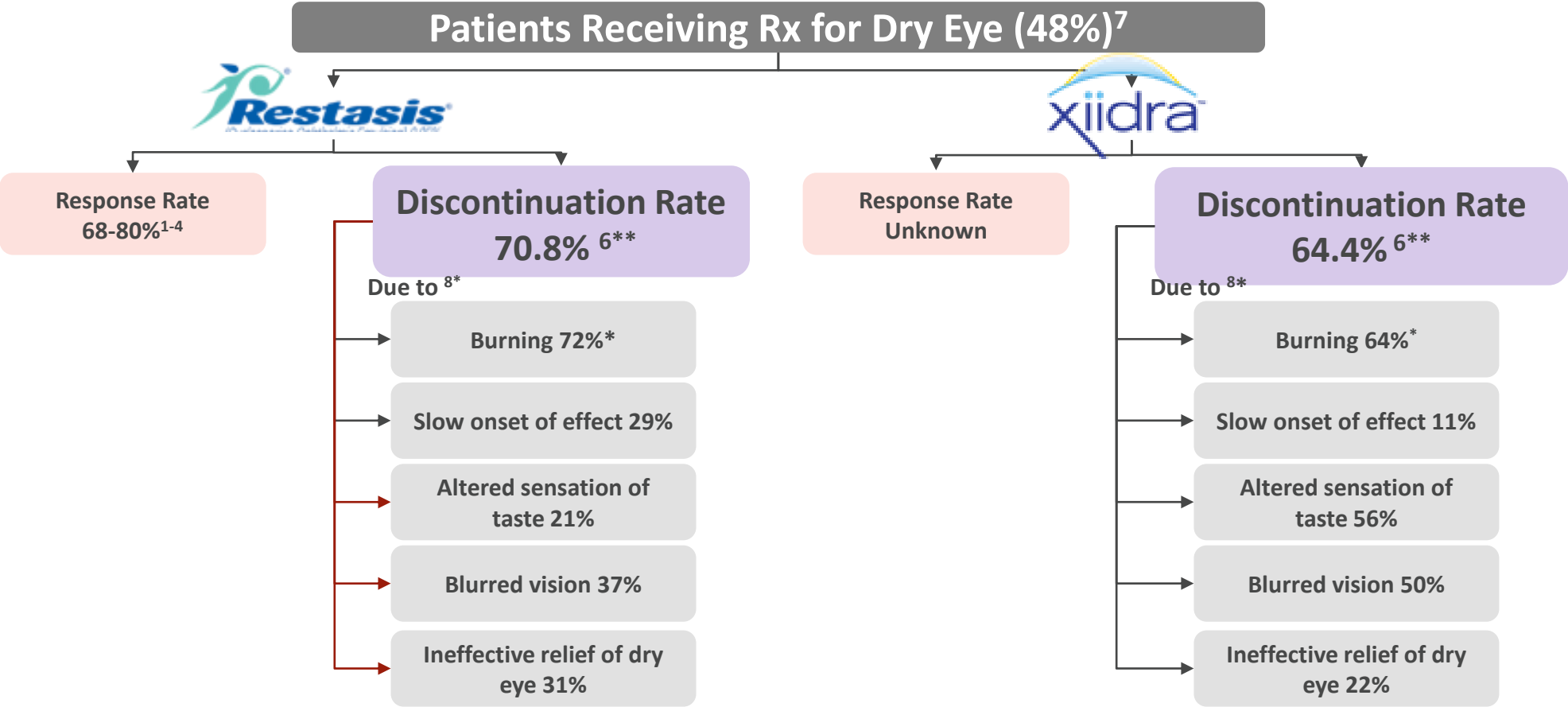
- Restasis®-topical cyclosporin
- Xiidra®-topical integrin inhibitor
- Topical steroids
- Artificial tears

Current treatments have **efficacy and tolerability issues** and there remains a high medical need for new innovative treatments that affect underlying disease processes



# Compliance Remains an Issue with Current SOC 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

\*Note: Percentage value indicates the proportion of participants who experienced the side effect \*\* Note: Discontinuation rates within 12 months based on 2021 Real World study; side effects listed are not directly connected to discontinuation rate

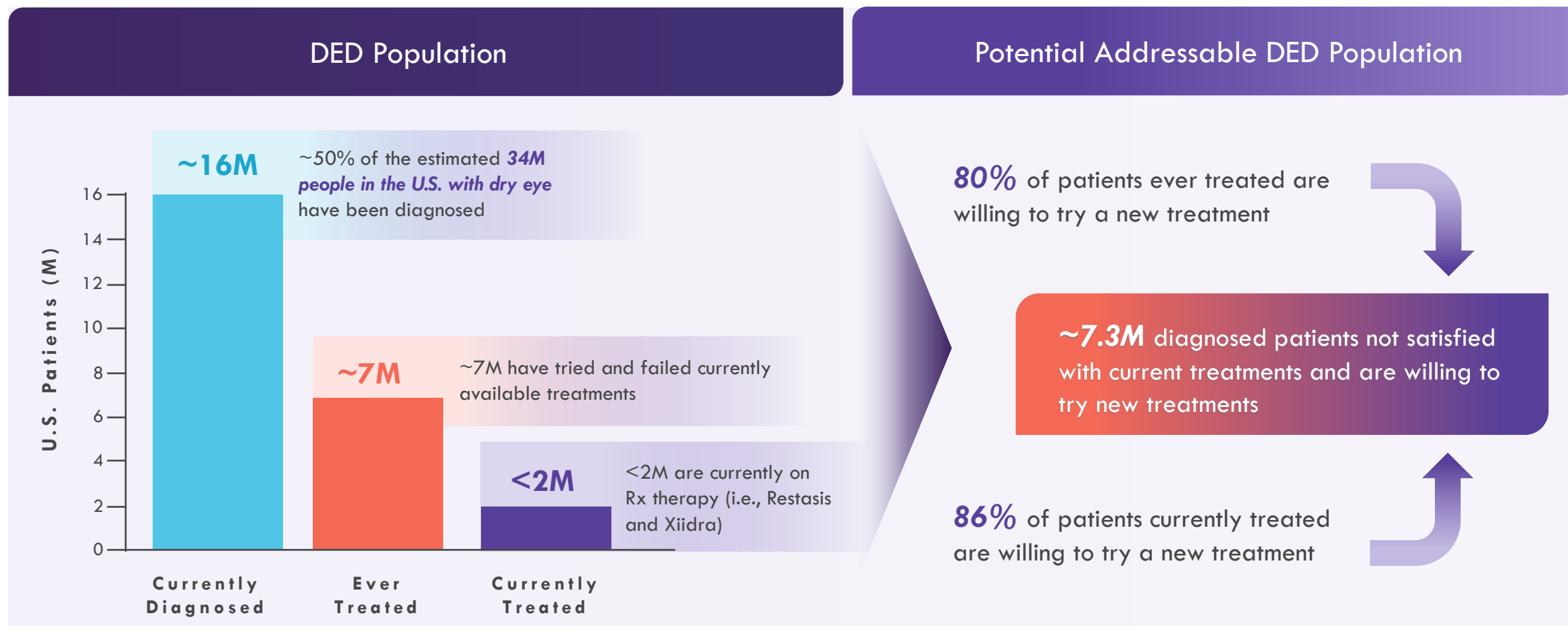
Sources: 1. Sall K et al., (2000); 2. Schultz et al., (2014); 3. Torricelli et al., (2014); 4. Williamson et al., (2015); 5. Mah et al., Clin Ophthalmol (2012); 6. White et al. Clin Ophthalmol (2019); 7. Lum et al. Amer. Academy of Optometry (2018), 8. White et al. Clin Ophthalmol (2020)



# Approximately 16MM People Diagnosed with DED in U.S.

*An estimated ~7MM may be open to new treatment*

## DED EPIDEMIOLOGY



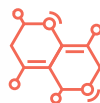
# PL9643 DED Program Summary

PL9643 a **novel approach** to treat Dry Eye Disease (DED) targeting the melanocortin system to resolve pathological inflammation and promote tissue healing



**MELODY-1** phase 3 study innovative adaptive design  
Interim analysis completed August 2022  
Data 1H2023

PL9643 peptide **agonist** at the melanocortin receptors 1&5, pending patent application runs to 2041



PL9643  
Eye Drops



**Positive phase 2 study** significant efficacy for multiple sign and symptom end points, with excellent ocular safety and tolerability

PL9643 **treats inflammation** underlying the development and maintenance of DED, addressing both signs and symptoms of DED



**MELODY Phase 3** registrational Program is evaluating multiple signs and symptoms of DED

# PL9643 Dry Eye Phase 2 Results



Met primary objective of providing data required to advance into registration studies



Statistical significance for the primary endpoints was not achieved in the ITT population that included mild, moderate, and severe patients



In the sub-population of moderate to severe patients (N=53), PL9643 achieved statistical significance (P value <0.05 vs. vehicle) at week 2 and week 12 for multiple signs and symptoms



PL9643 demonstrated excellent ocular safety and tolerability

- No drug related serious adverse or adverse events
- No drug related discontinuations
- High ocular comfort



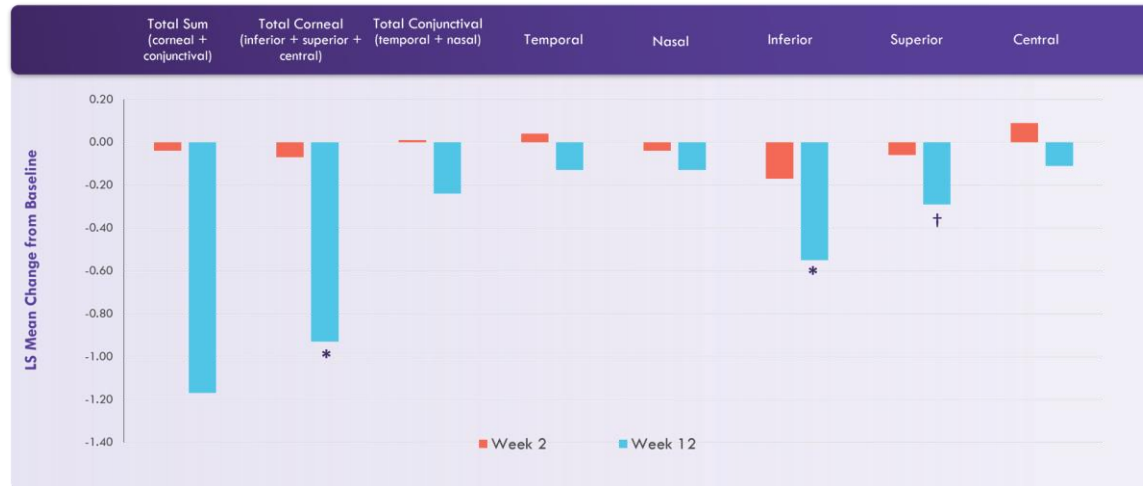
Differentiated & Favorable emerging product profile

- Rapid onset, excellent tolerability, safety and global efficacy

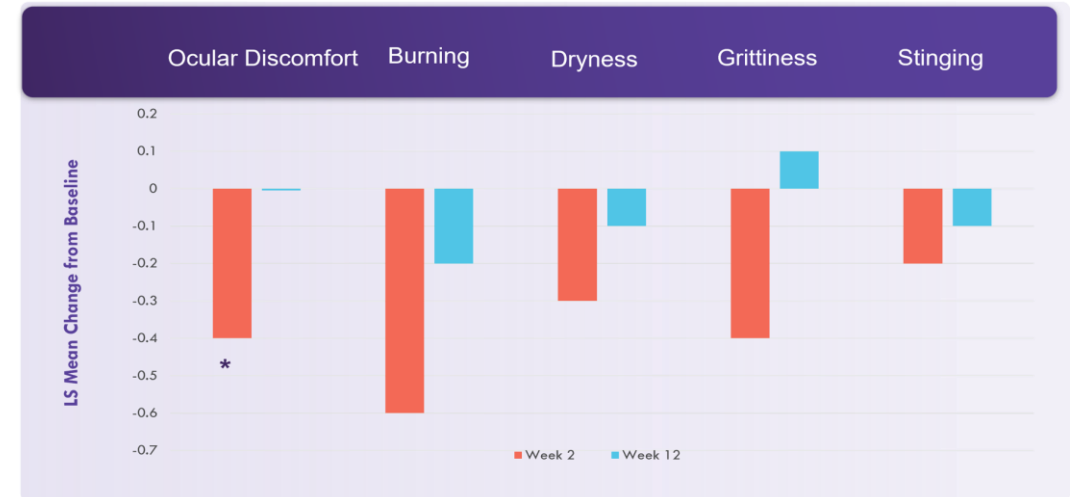
# Phase 2 Study - Signs Differences Between PL9643 and Vehicle

Least squares change from baseline moderate/severe subgroup (n=53)

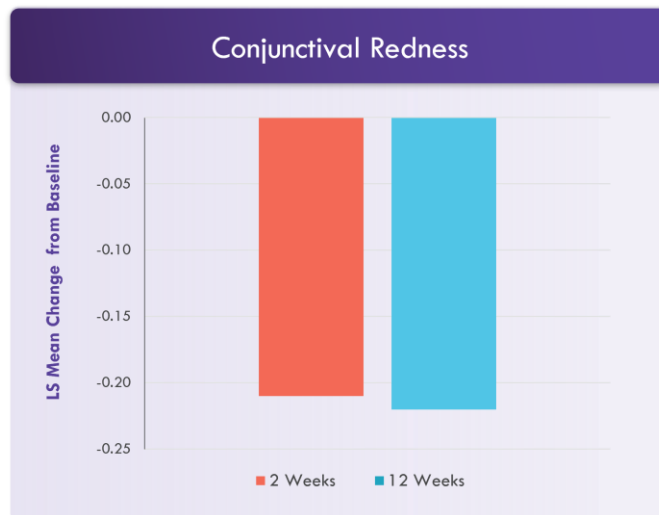
Fluorescein staining



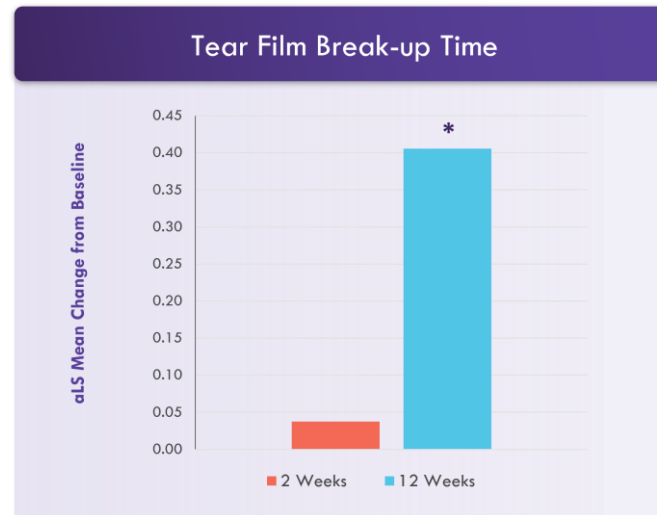
Ora Calibra® Ocular Discomfort and 4-Symptom Questionnaire scores



Conjunctival Redness



Tear Film Break-up Time

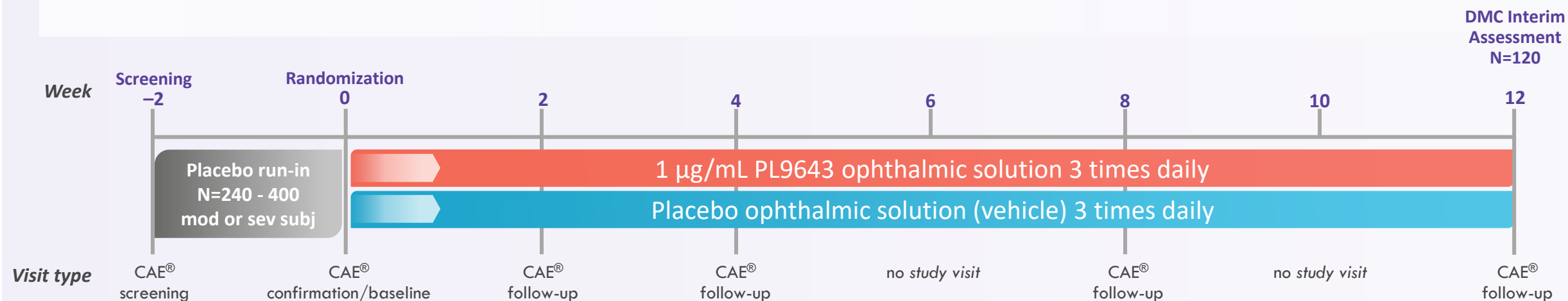


\* $P < 0.05$ ; † $P < 0.1$

# Phase 3 Study Design & Endpoints Based on DMC Recommendations

12-week, multicenter, 1:1 randomized, double-masked, vehicle-controlled adaptive design study

Evaluate the **efficacy** and **safety** of PL9643 in up to **350 adults (initial target N=240)** with moderate or severe dry eye disease  
Disease duration  $\geq 5$  years; Inferior Corneal Staining score  $>1$ ; Eye Discomfort score  $\geq 25$  as measured by the Visual Analog Scale



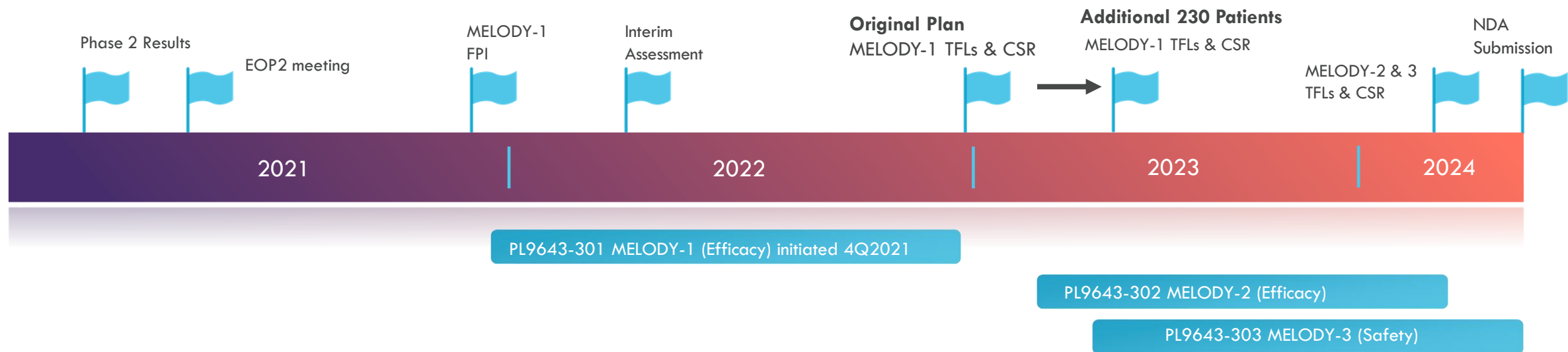
## Sign Endpts

- Inferior corneal fluorescein staining
- Total conjunctival lissamine green staining (Nasal + Temporal Regions)

## Symptom Endpt

- Ocular discomfort

# PL9643 DED Program Timelines Adjusted for DMC Recommendations



# PL9643 Dry Eye Commercial Opportunity



## DIFFERENTIATED PRODUCT

**PL9643 has a very favorable commercial product profile compared to approved therapies**

- Quick onset of efficacy
- Superior safety profile
- Superior patient tolerability
- Ideal profile for chronic use



## UNMET MEDICAL NEEDS SPEED/SAFETY/TOLERABILITY

**Current FDA approved treatments have high discontinuation rates due to high rates of side effects and slow onset of efficacy leading to patient and clinician dissatisfaction**



## 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



# PL9654 for Retinal Diseases

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# PL9654 for Retinal Disorders

The total retinal disorders drug market, USD **\$20 billion** in 2021, projected to be **\$27 billion** by 2026; DR/DME estimated **~\$10 billion**

Retinal disorders can **significantly impair vision** **preservation of vision** is the key outcome for drug treatment

PL9654 is a **highly potent** melanocortin agonist with potential for less frequent IVT dosing, once every ~3-6 months

## Why a Melanocortin Peptide for Retinal Disorders?

High need for new products with **enhanced safety** and efficacy to delay progression, maintain and improve visual acuity, rescue treatment failures

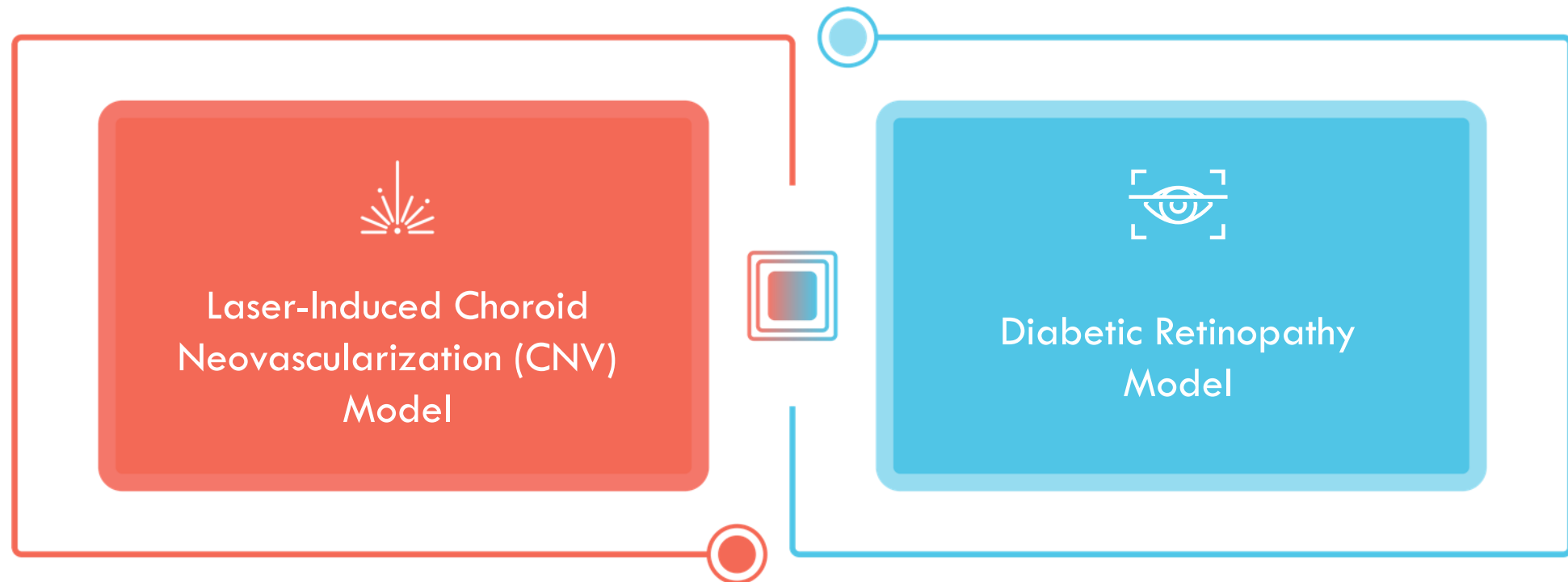
Market is seeking replacement for steroids **without glaucoma or cataract side effects**

PL9654 is **not systemically absorbed** allowing potential for excellent efficacy without safety concerns

Our melanocortin receptor agonists have been **evaluated in multiple animal models** of retinal disease where preservation of vision was demonstrated

# Preclinical Proof-of-Concept

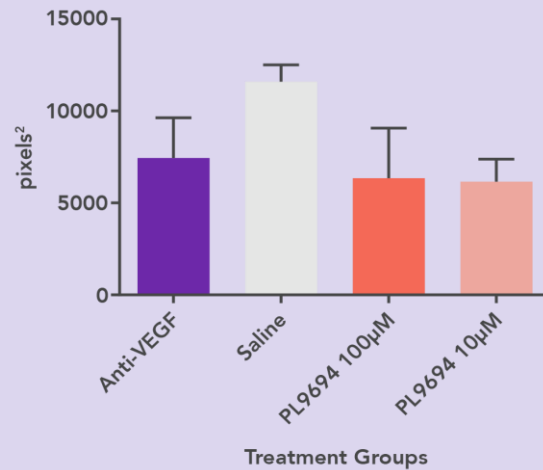
To **validate** melanocortin receptors as therapeutic targets for retinal diseases, Palatin's melanocortin agonist compounds were tested in **two relevant animal models**



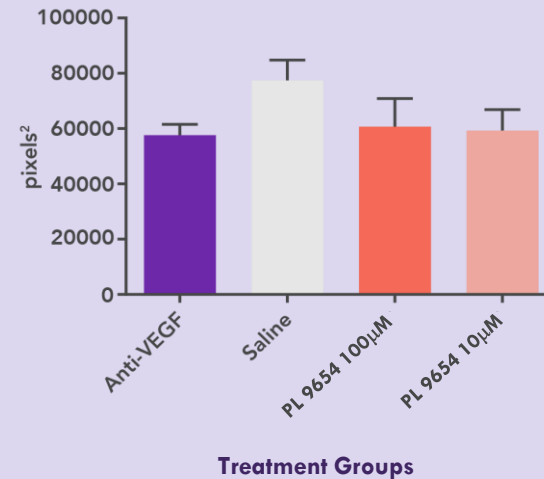
# PL9654 Laser Induced Choroid Neovascularization Model

Model recapitulates main features of human age-related macular degeneration (AMD)

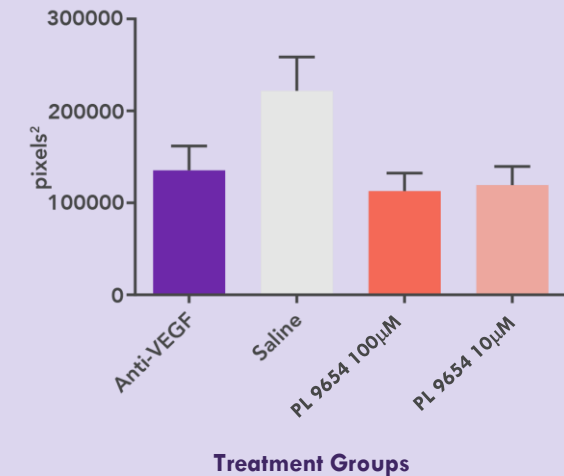
MEAN LEAKAGE AREA



MEAN AREA OF ANGIOGENESIS



MEAN AREA OF FIBROSIS



- PL9654 showed therapeutic activity comparable to anti-VEGF positive control
  - CNV leakage area reduced
  - Angiogenesis area reduced
  - Fibrosis area reduced (better than anti-VEGF)

# Diabetic Retinopathy Model

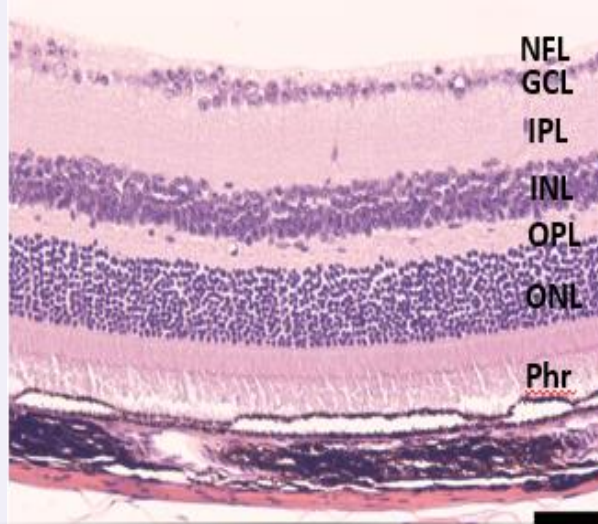
Melanocortin agonist demonstrated key indicators of *improve retinal health*, including:

Preserved retinal anatomy

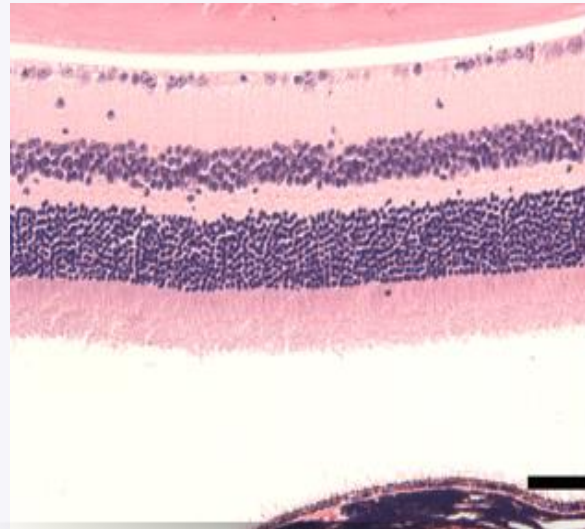
Suppressed pro-inflammatory cytokine to healthy control levels

Increased levels of IL-10, a marker of inflammation resolution

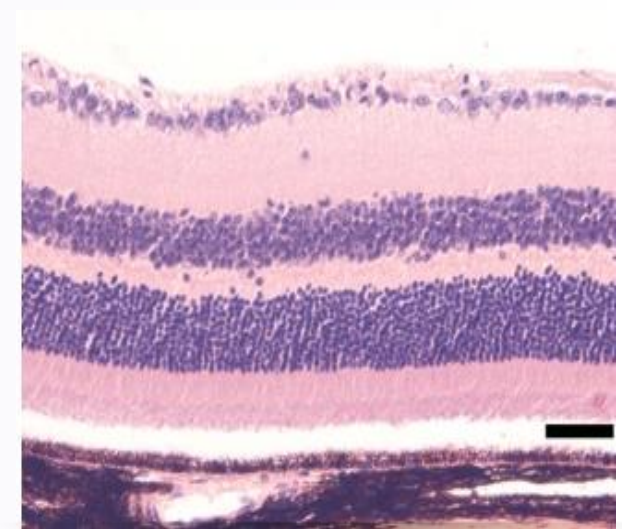
**Healthy Control**



**Diabetic; Untreated**



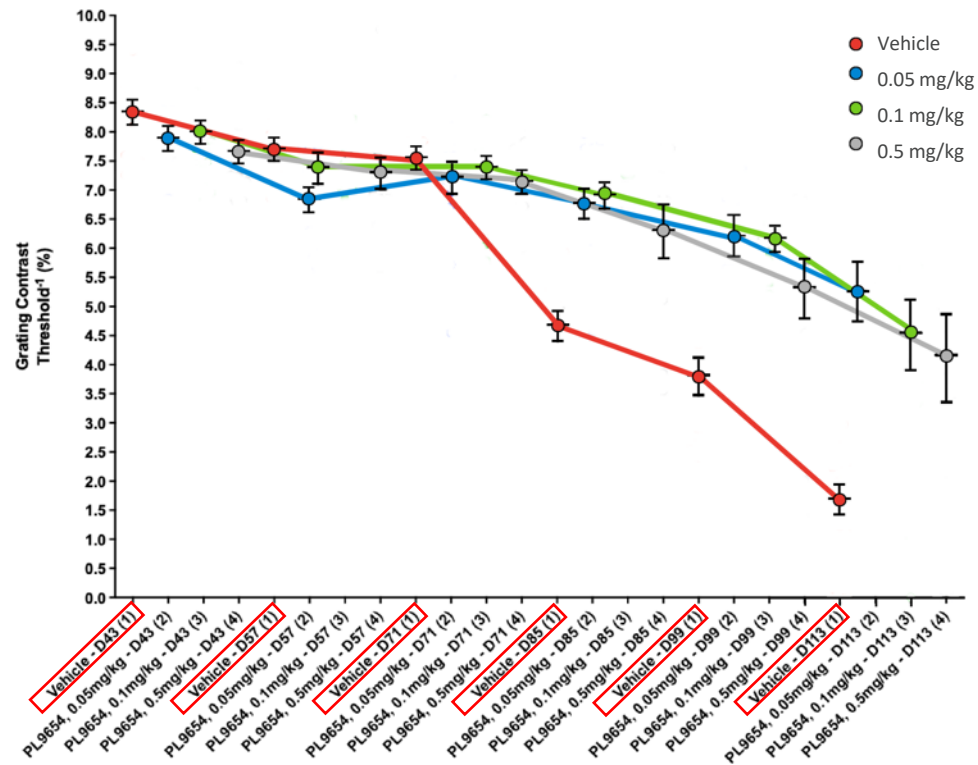
**Diabetic; melanocortin agonist**



*This rodent model develops diabetic retinopathy similar humans*

# PL9654 in a Rat Diabetic In-Life Retinopathy Model

## CONTRAST VISION

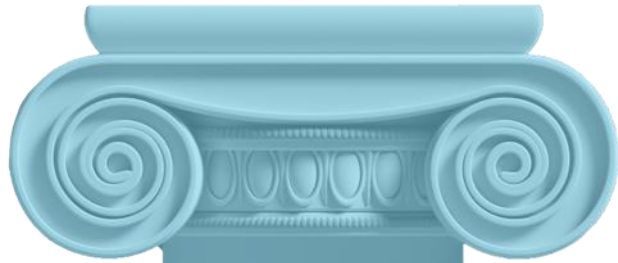


PL9654 *preserves contrast vision* as compared to controls

A 2<sup>nd</sup> measure of visual acuity demonstrated *similar efficacy*

# Retinopathy – Desired Target Product Profile to Determine Commercial Success

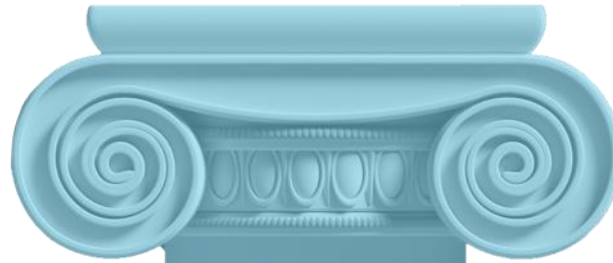
## Efficacy



### PL9654 was chosen based on:

- High potency at melanocortin receptors 1 & 5
  - Enables smaller needle, fewer AEs
- Demonstrated efficacy in preclinical animal models
- Enabling pharmacokinetics
- Desirable solubility profile
- Straight-forward synthesis path
- Excellent IP position

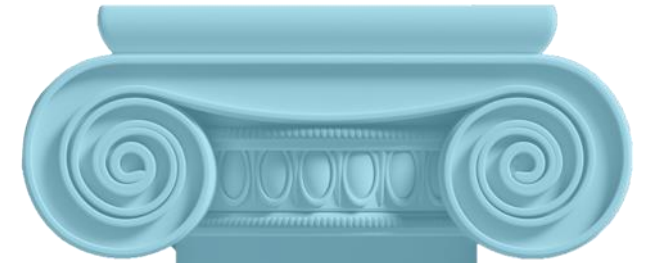
## Pharmacokinetics (ROA)



### PL9654 Ongoing Activities:

- IVT sustained release formulation development (target is 3-6 months sustained dose)
- Additional preclinical models and measurements
- Genomic and proteomic characterization of treated animal models
- Extensive PK
- Validating SC as a delivery option
- Toxicology studies

## Safety



### PL9654

- IND enabling studies and subsequent clinical studies are planned
- IVT formulation minimal/no systemic exposure toxicology studies

**PL9654 IVT *sustained release* formulation under development**  
**Potential for intermittent SC delivery which is preferred by patients**



# PL8177 for Ulcerative Colitis

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# 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 the MCr1

## Why a Melanocortin Peptide for Ulcerative Colitis?

**PL8177-205** ph. 2 study evaluating safety and  
efficacy of PL8177-Oral in UC patients, interim  
assessment 1H2023 final data 2H2023

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

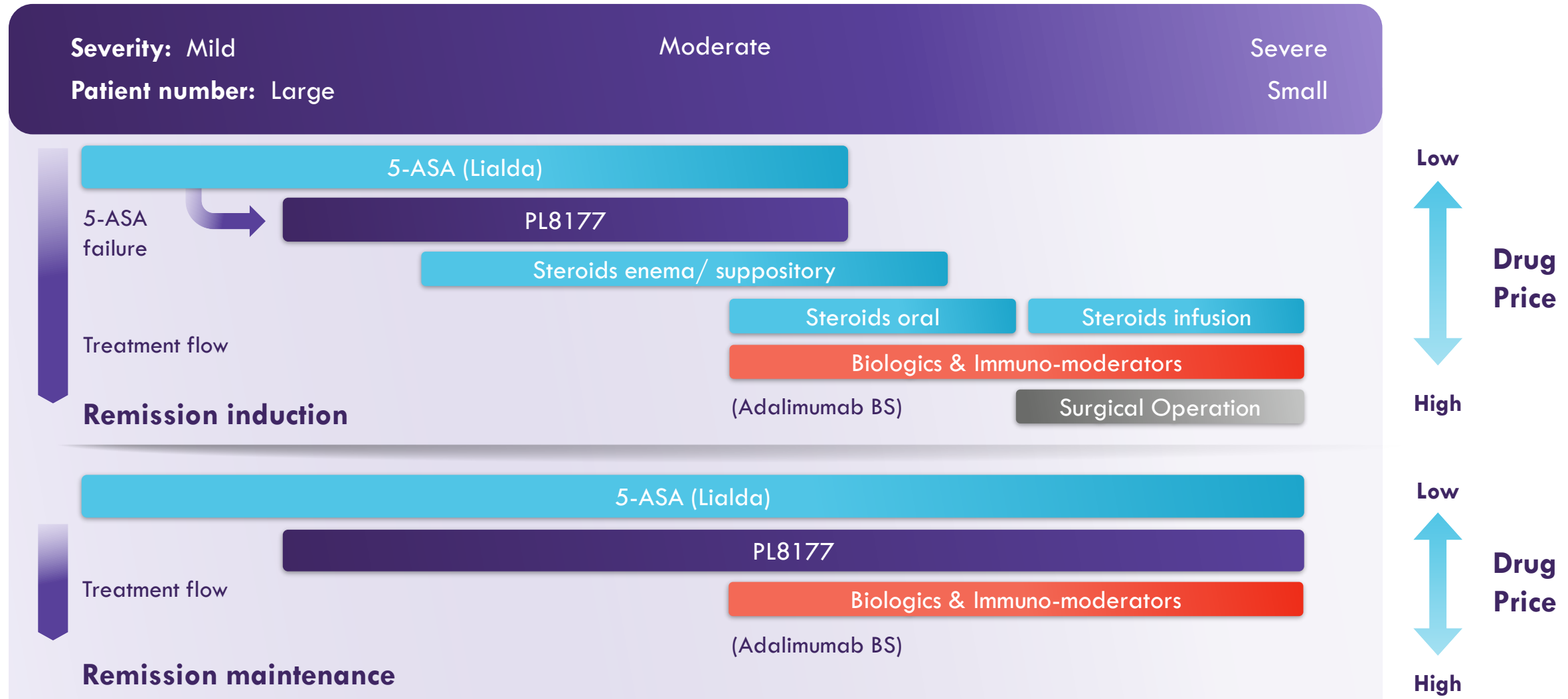
PL8177 is **not systemically absorbed**

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

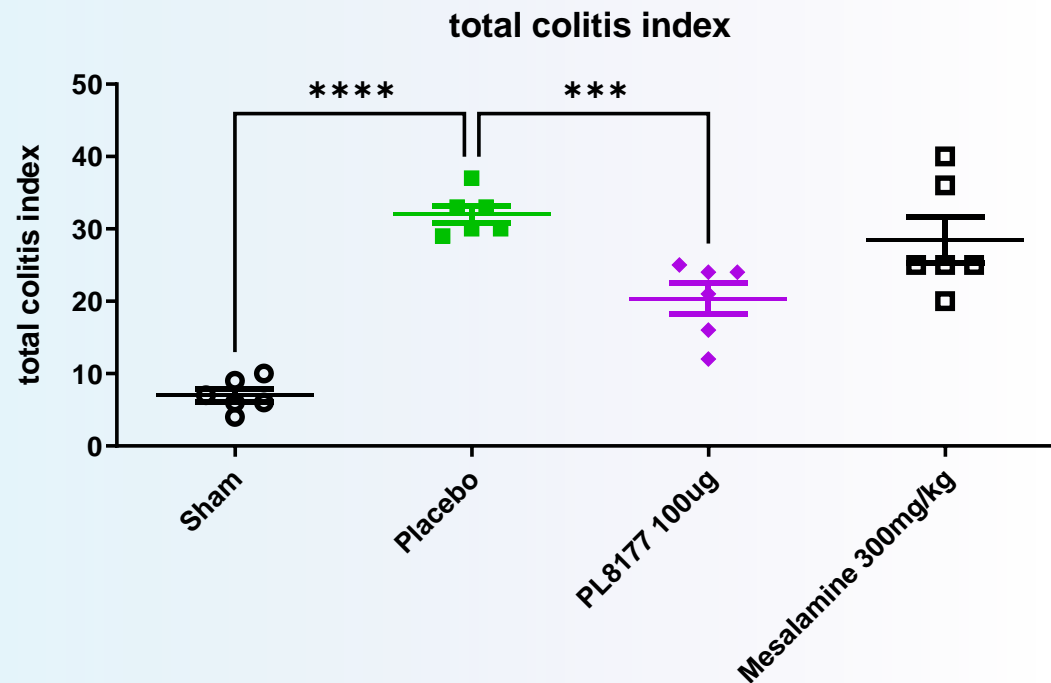
“Currently available therapies cannot cure IBD, but many of them target various inflammatory pathways, resulting in more or less durable remission. However, these therapies come at a high price economically and physically, with potentially life-threatening side effects.”

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

# Opportunity for PL8177 in UC Treatment Landscape



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



- The scoring was based on examining three sections from each colon per animal:
- Sections were taken at the distance of 2.5cm, 5cm and 7.5cm from the anus
- Total colitis index includes observations
  - Abnormalities of mucosal architecture
  - Extent of inflammation
  - Erosion or ulceration
  - Epithelial regeneration
  - Percentage involvement by the disease process

# 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:**

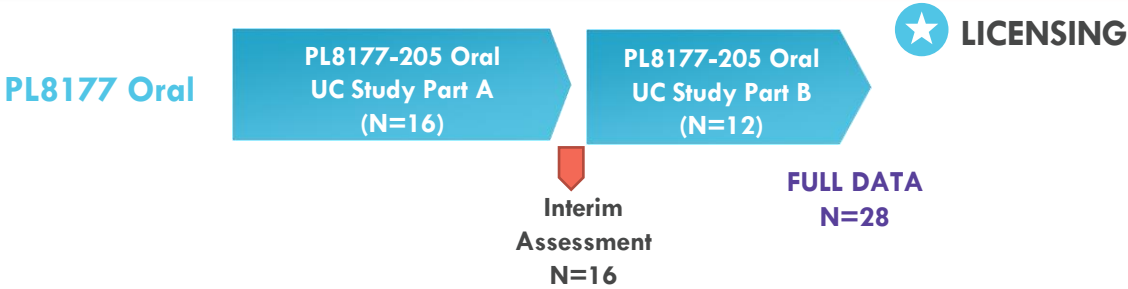
- Adult patients with active UC
- Modified Mayo endoscopic subscore  $\geq 2$ , and Fecal Calprotectin  $> 250$  mcg/g
- Intolerance, lack of response aminosalicylates

**Primary Safety Endpoints:**

- The overall incidence of treatment-emergent adverse event(s) (TEAEs)

**Primary Efficacy Endpoint:**

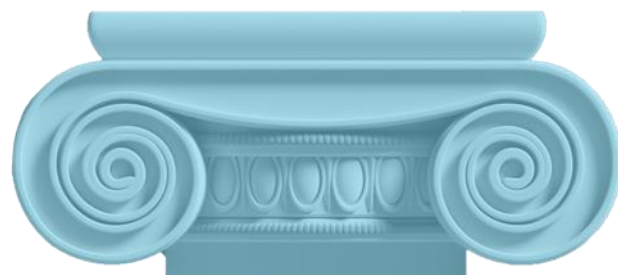
- Proportion of patients that have MES of 0 or 1 (endoscopic improvement)



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

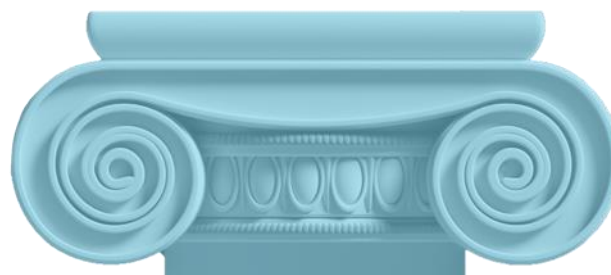
## Efficacy



### PL8177 in animal models and Phase 2 planned:

- High potency at melanocortin receptors 1
- Multiple positive animal models proof of efficacy data in gold standard disease model
- Efficacy as good/better than 5-ASA and glucocorticoids in animal model data
- **Ph. 2 proof-of-concept trial enrolling patients**

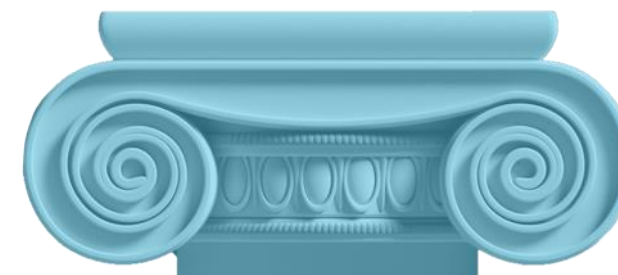
## Pharmacokinetics (ROA)



### PL8177 oral formulation PK:

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

## Safety



- Phase 1 clinical SAD/MAD study with the systemic formulation (SC) completed, no adverse events or safety signals
- No toxicological findings in pre-clinical studies doses >100-fold above planned clinical doses

PL8177 oral formulation meeting the program goals and positioned for success in Phase 2 POC  
Interim data (n=16) 1H2023, final data (n=28) 2H2023



Vyleesi<sup>®</sup>

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# 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

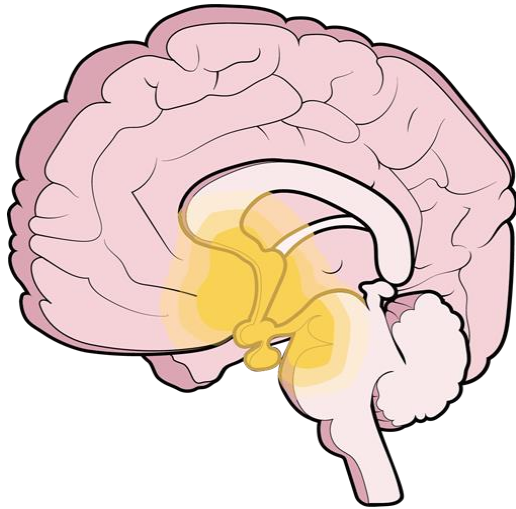


\*Administer subcutaneously as needed at least 45 minutes before anticipated sexual activity. The duration of its effect after each dose is unknown. Do not administer more than one dose within 24 hours or more than 8 doses per month.



# 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.<sup>2</sup>



## 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, the most relevant of which are MC1R and MC4R.<sup>1,2</sup>



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<sup>1,2</sup>



*Number of premenopausal women who have low desire with associated distress*



**Affects 5.8 million U.S. premenopausal women<sup>3</sup>**  
**(1 in 10 premenopausal women)<sup>1,2</sup>**

**98% (5.7M) of affected premenopausal women not on therapy<sup>3</sup>**

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

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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.

# Current Go-To-Market Approach

## Objective: Re-license U.S. rights

- Enhance brand value / improve net ASP, reimbursement, demand

## Commercial Infrastructure

- 3 FTE sales reps (primarily inside / limited office visits)
- 1 FTE business analyst
- 1/2 FTE sales/marketing head / 1/2 FTE market access head / 1/2 FTE digital marketing
- 3rd-party partners enabled for administration and commercial support, media/marketing, and telemedicine
- Palatin cross-functional support: regulatory, quality, CMC, finance, legal

## Promotional Efforts

- Limited FSD market awareness: opportunity for increased efforts/investment
- Field sales and marketing efforts reaching/engaging hundreds of HCPs monthly
- Digital marketing campaign with monthly reach to tens of thousands of target demographic
  - Reduced 3Q/4Q 2021 to review optimization opportunities / Revised target focus 1Q 2022 – 2Q 2022
- Market access efforts prioritized to expand access and reimbursement
- Retention and persistency efforts driving increased refills

# Financial / Operational Fundamentals

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WAC \$899

Package size is a 4-pack (4 single-use autoinjectors)



Net ASP \$275-\$300

Increased execution of Prior Authorizations will drive greater reimbursement/insurance covered prescriptions



COGS ~\$38 (4-pack)

GM ~87% of target net ASP



Distribution

Closed-network through one SP (KnippeRx)



Telemedicine platform

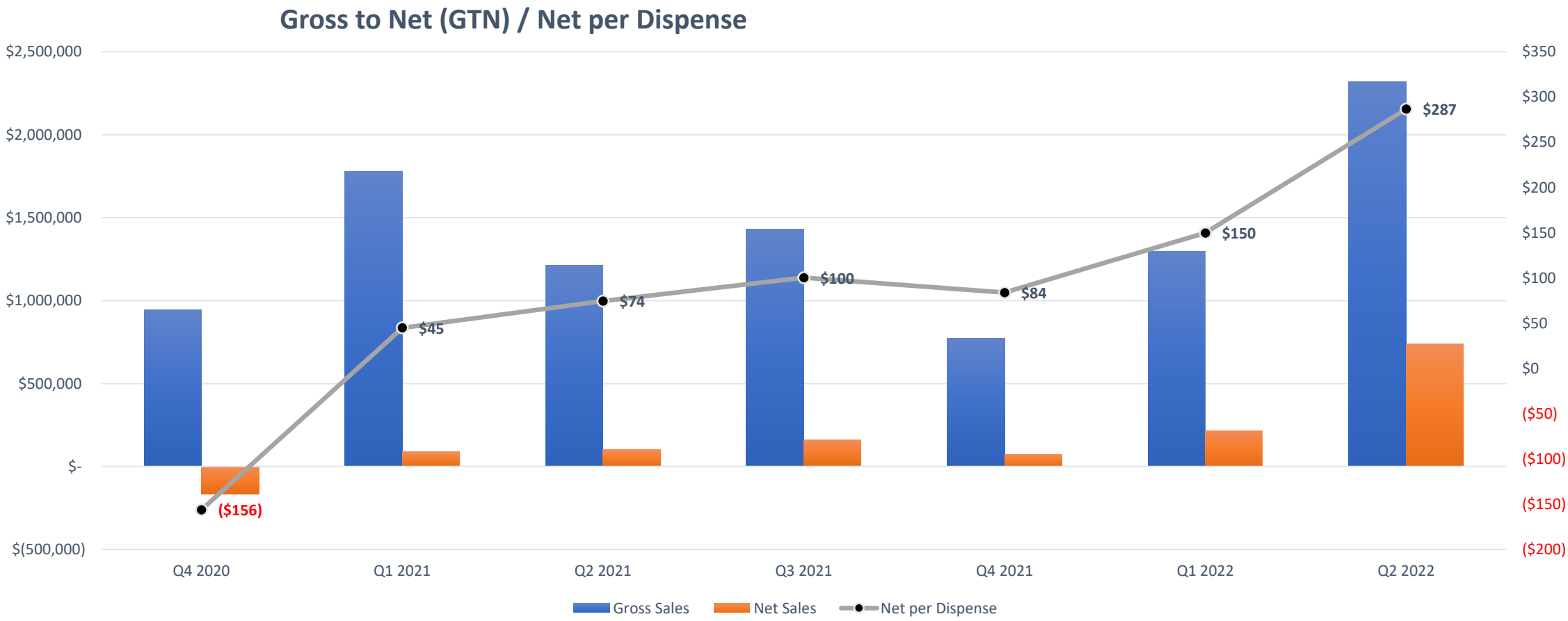
Prescriber- Access via Vyleesi.com



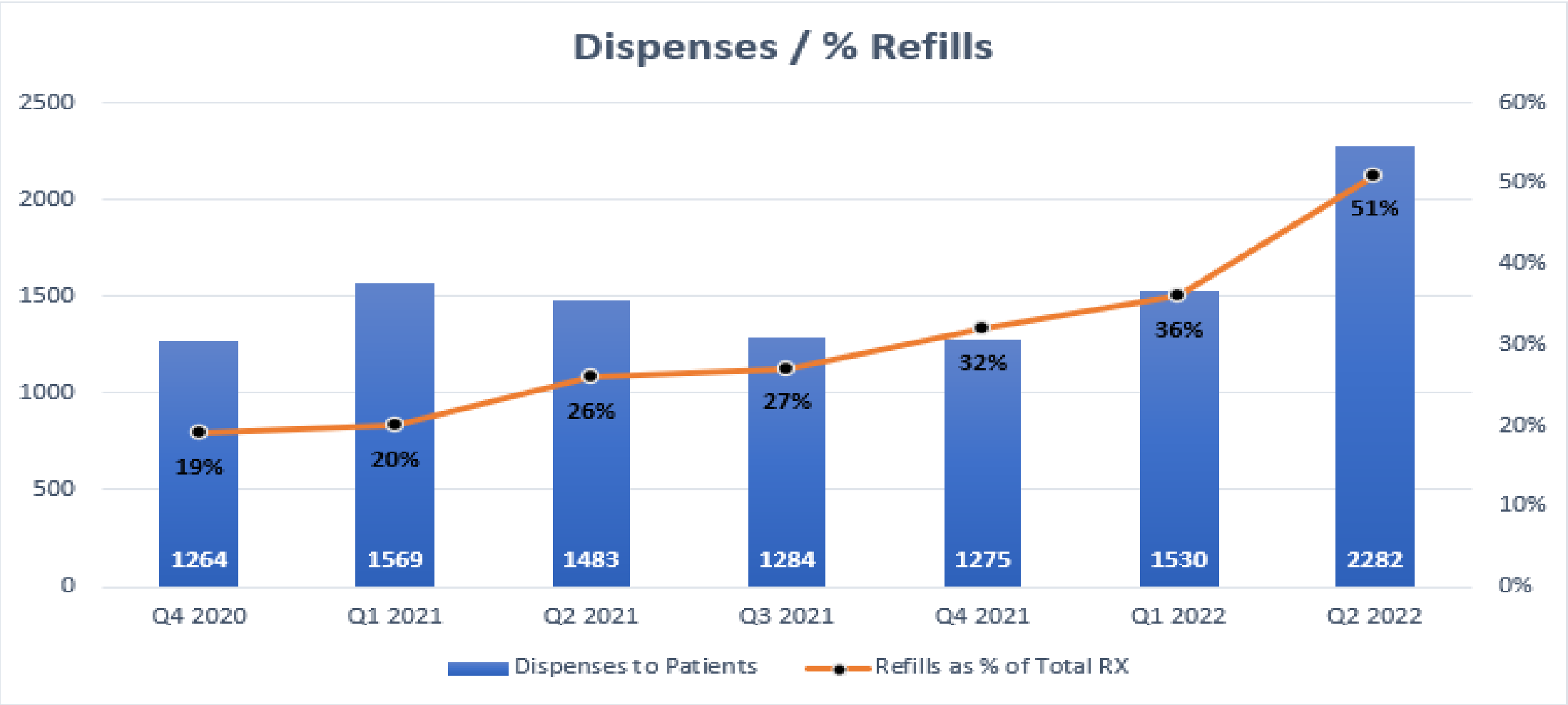
Patient assistance

Patient Pricing strategy – modified December 2021

# Net Sales Analysis



# Dispenses / % Refills



# Financial Snapshot

## Financial Highlights as of June 30, 2022

Cash and Cash Equivalents	\$29.9 million
Accounts Receivable	\$1.8 million
Inventory	\$0.9 million
Inventory Purchase Commitments (over the next 5 years)	\$8.6 million

## Summary Capitalization as of September 20, 2022

### Common Shares and Equivalent

Common Stock	9.3 million shares
Preferred	1.3 million shares
Warrants	0.1 million shares
Options	1.2 million shares
RSUs	0.6 million shares
Fully Diluted Shares	12.5 million shares



Thank You.

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