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# Palatin Technologies, Inc.

Corporate Presentation (Non-Confidential)

September 2019

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President & CEO*

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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 exclusive licensee for North America, AMAG Pharmaceuticals, Inc. (AMAG), and our licensee in other jurisdiction; (vii) our expectation regarding timelines for development of our other product candidates; (viii) the potential for commercialization of bremelanotide for HSDD and our other product candidates, the potential market size and market acceptance for bremelanotide for HSDD for FSD and our other product candidates, if approved for commercial use; (ix) our ability and the ability of our licensees, including AMAG, 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, including AMAG; (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.

Palatin Technologies, Inc. (NYSE American: PTN) is a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential.

- ❑ Demonstrated expertise/competence to move programs from discovery to development to collaboration to approval
- ❑ Strategy leverages our chemistry and biology research across multiple therapeutic opportunities
- ❑ MOAs with the potential to modify underlying disease pathologies - not just treat symptoms
- ❑ Vyleesi™ (bremelanotide) partnerships provide financial resources to unlock the potential of our pipeline assets

# Corporate/Development Milestones



## Vyleesi (bremelanotide) for Hypoactive Sexual Desire Disorder

<b>FDA Approval</b>	<b>2Q2019</b>
US Vyleesi launch	3Q2019
North American license agreement AMAG	1Q2017
China license agreement Fosun Pharma	3Q2017
South Korea license agreement Kwongdong Pharma	4Q2017
Additional ROW partnerships	2019/2020

## Melanocortin System Anti-inflammatory & Autoimmune Programs

	<b>Initiate</b>	<b>Data</b>
<b>PL8177 – ulcerative colitis and non-infectious uveitis</b>		
Phase 1 SAD/MAD		1Q2019
Phase 1 oral formulation pk study		1Q2019
Non-infectious uveitis FDA OD designation		2Q2019
Phase 2 non-infectious uveitis PoC FPI	4Q2019	4Q2020
Phase 2 ulcerative colitis PoC FPI	1H2020	1H2021
<b>PL9643 – dry eye and retinal diseases</b>		
IND dry eye	4Q2019	
Phase 2 dry eye FPI	1Q2020	4Q2020

## Natriuretic Peptide System Cardiovascular & Fibrosis Programs

PL3994 open label Phase 2a HF-pEF patients FPI	4Q2019	4Q2020
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# Pipeline Overview

## CLINICAL PIPELINE

MCr	INDICATION	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	NDA SUBMISSION	FDA APPROVAL
Vyleesi <i>MC1r Agonist</i>	Hypoactive Sexual Desire Disorder (HSDD)						
PL-8177 <i>MC1r Agonist</i>	Inflammatory Bowel Disease (IBD)						
	Non-infectious Uveitis						
PL-9643 <i>MCr Agonist</i>	Dry Eye Disease						
	Diabetic Retinopathy & Macular Edema						
PL-8905 / 9610 <i>MC1r Agonist</i>	Rare Genetic Metabolic and Obesity Disorders						

NPA	INDICATION	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	NDA SUBMISSION	FDA APPROVAL
PL-3994 <i>NPR-A</i>	Heart Failure						
PL-5028 <i>NPR-A/C Agonist</i>	Fibrosis						

## OVERVIEW

- Licensees: AMAG (NA), Fosun (China, Taiwan, HK, Macau) and Kwangdong (S. Korea)
- Phase 1 SAD/MAD completed
- Phase 1 oral formulation completed
- FDA Orphan Drug Designation June 2019
- IND enabling activities ongoing
- Preclinical development candidate evaluated in multiple models of DR/DME
- Preclinical SC and oral development candidates for treating rare forms of obesity

## INFLECTION POINTS

- Approval granted 6/21/2019
- Vyleesi sales 3Q2019
- Additional ROW licenses
- Initiate ulcerative colitis Phase 2 PoC 1H2020
- UC Phase 2 data 1H2021
- Phase 2 initiation 4Q2019
- Data 4Q2020
- Initiate Dry Eye Phase 2 1Q2020
- Data 4Q2020
- Initiate Phase 3 1Q2021
- Phase 3 data 1Q2022
- Initiate DR/DME Phase 2 PoC 2H2021
- Phase 2 data 2H2022
- Seeking collaboration and development partners

- Synthetic mimetic of neuropeptide hormone ANP in development for heart failure
- Preclinical development fibrosis and cardiovascular diseases

- Entering Phase 2a clinical trial supported by a grant from the American Heart Association in 2H2019
- Complete preclinical work
- Evaluate options 1H2020

## Now Available!

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

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

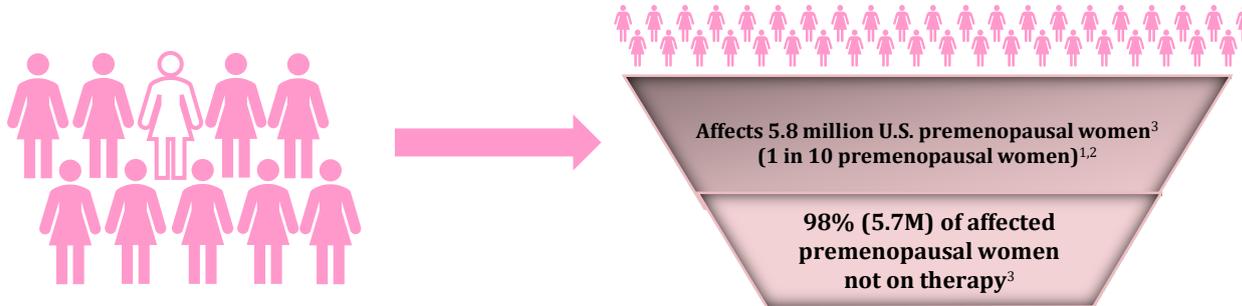
Vyleesi is the first and only as-needed\* treatment for premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD).



**\*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.**

## Helping Premenopausal Women with Hypoactive Sexual Desire Disorder (HSDD)

# HSDD is a Significant Market Opportunity



**1/10<sup>1,2</sup>**

Number of premenopausal women who have low desire with associated distress

- ▶ 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.

# North American Vyleesi Licensing Agreement



- ▶ AMAG Pharmaceuticals - specialty pharmaceutical company focused on developing and commercializing innovative healthcare solutions
  - Annual sales > \$400M
- ▶ Dedicated sales, marketing and commercial teams focused on female health
- ▶ Committed and capable partner to commercialize Vyleesi
- ▶ Exclusive licensing agreement covers NA market
  - \$165M in milestones received as of 3Q2019
  - Up to \$300M in sales milestones (1<sup>st</sup> milestone \$25M at \$250M annual sales)
  - Royalties from high single to low double digits starting 3Q2019
  - AMAG responsible for pre-launch, launch and commercial activities



# ROW Vyleesi Licensing Agreements



- ▶ **Fosun Pharma – Chinese pharmaceutical company focused on developing and commercializing innovative healthcare solutions with >\$2B in annual sales**
  - Exclusive licensing agreement covers China, Hong Kong, Taiwan and Macau markets
  - \$5M upfront payment, \$7.5M regulatory milestone
  - Up to \$92.5M in sales milestones plus tiered royalties from high single digits to low double digits
  - Fosun responsible for all development, regulatory and commercial activities
- ▶ **Kwangdong Pharmaceutical Co. – Republic of Korea leading pharmaceutical company with >\$900M in annual sales**
  - Exclusive licensing agreement for the Republic of Korea
  - \$500,000 upfront, ~\$40M in regulatory and sales milestones plus royalties on sales
  - Kwangdong responsible for all development, regulatory and commercial activities

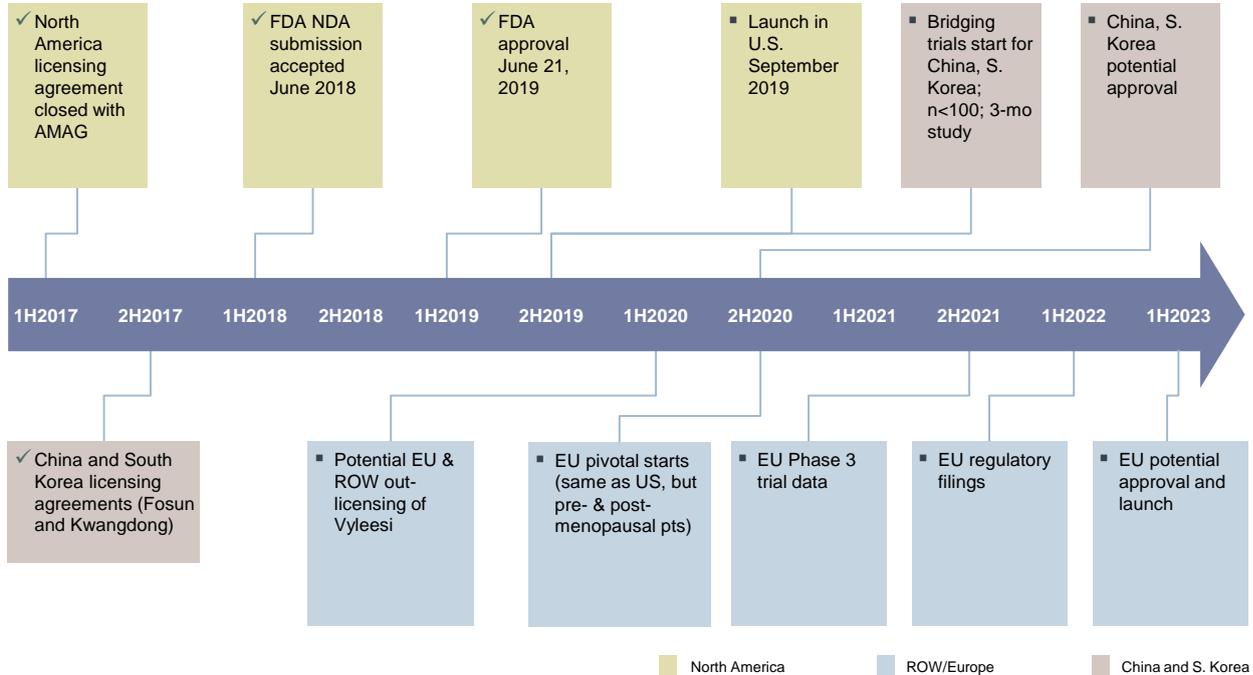


# Vyleesi Milestones



Significant tailwinds are behind Palatin as key Vyleesi inflection points are quickly approaching

## VYLEESI FOR HSDD



# Melanocortin

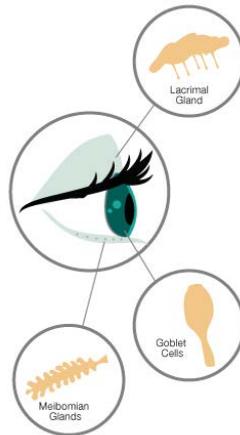
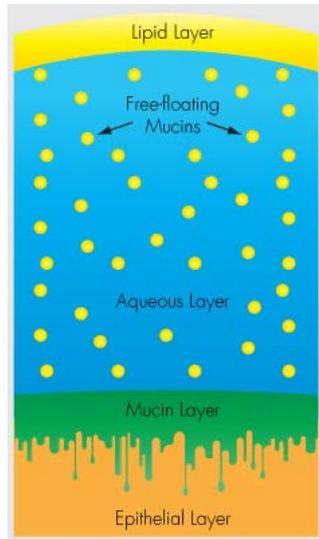
Autoimmune  
&  
Anti-Inflammation Programs

- ▶ Melanocortin system is up-regulated by and integral to the resolution of inflammation and autoimmune pathologies
- ▶  $\alpha$ -MSH and MC1&5 receptors expressed by monocytes, macrophages, neutrophils, lymphocytes, dendritic cells, podocytes and mast cells. MC1r agonism also down-regulates fibroblast function and fibrosis
- ▶ Melanocortin agonism activates resolution of proinflammatory processes
  - Inhibition of NF- $\kappa$ B and other proinflammatory cytokines (IL-1, IL-2, IL-4, IL-6, IL-13, TNF- $\alpha$ , IFN- $\gamma$ )
  - Increased production of IL-10, an anti-inflammatory cytokine
  - Mediates antigen specific T-cell and macrophage responses from pro-inflammatory to regulatory
- ▶ MC1r specific peptides and small molecules have demonstrated *in vivo* activity in numerous disease models of inflammation.

\*International Journal of Inflammation, Volume 2013 (2013), Curbing Inflammation through Endogenous Pathways: Focus on Melanocortin Peptides. Tazeen J. Ahmed, Trinidad Montero-Melendez, Mauro Perretti, and Costantino Pitzalis

- ▶ Rational design and synthesis of selective MC1r & MC1/5r agonists
  - PL8177: cyclic peptide selective MC1r agonist
  - PL9643: cyclic peptide MCr agonist
- ▶ PL8177, PL8331 and PL9643 demonstrated reversal of pathology in multiple inflammatory and autoimmune disease models
  - Including inflammatory bowel disease, dry eye, uveitis and diabetic retinopathy
- ▶ PL8177 phase 2 clinical development candidate for indications requiring local or systemic administration
  - Orphan Drug Designation for non-infectious uveitis
  - Oral formulation for ulcerative colitis
  - Preclinical evaluation for atherosclerosis and rheumatic diseases
- ▶ PL9643 topical eye drop or intravitreal administration for ocular indications
  - Phase 2 candidate for dry eye disease as a topical eye drop formulation
  - Preclinical development for retinal diseases

- ▶ Dry eye syndrome or keratoconjunctivitis symptoms include irritation, redness, discharge and blurred vision.



- ▶ **Aqueous-Deficient**
  - Autoimmune disease (e.g. Sjögren's Syndrome)
- ▶ **Lipid-Deficient**
  - Meibomian gland dysfunction, hormonal changes
- ▶ **Mucin-Deficient**
  - Goblet cell loss
- ▶ **Neural Loop-Associated**
  - Blink disorders, abnormal corneal sensitivity
- ▶ **Environmentally-Induced / Exacerbated**



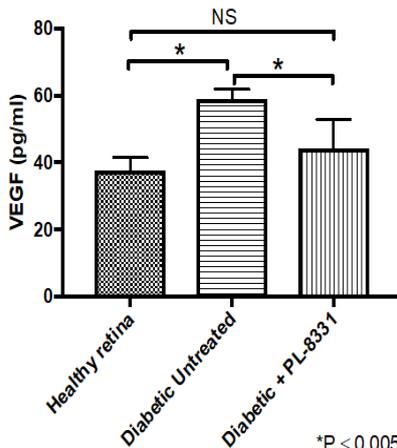
- ▶ PL9643 replaces PL8331 extends patent life
- ▶ Single use aqueous eye drop formulation developed
- ▶ Ora, Inc., world-leading ophthalmic CRO, managing dry eye development program
  - Preclinical IND enabling activities complete 2H2019
  - Pre-IND meeting held agreement on phase 2 study design and overall development program through phase 3 registration studies
  - IND submission and initiation of phase 2 dry eye clinical trial 2H2019
    - Establish clinical proof of concept
    - RCT - placebo and 2 doses of PL9643 / FPI 1Q2020
    - Data anticipated 4Q2020

# Diabetic Retinopathy & Macular Edema



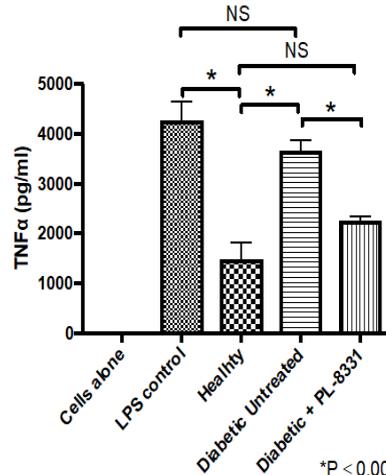
- ▶ By 2050, the number of Americans with diabetic retinopathy is expected to nearly double, from 7.7 million to 14.6 million
- ▶ DME affects ~10% of people with diabetic retinopathy
  - ~750,000 in the USA & 2.2 million people in the EU
- ▶ IVT VEGF antagonists and steroids are the only treatments for DME
  - Annual global sales for DR/DME estimated at \$1.85b
- ▶ There is a high need for additional treatments
  - Novel MOA to improve visual acuity
  - Replacement for steroids without glaucoma or cataract side effects
- ▶ Palatin has evaluated melanocortin agonist in multiple models of DR/DME
  - Suppresses VEGF production and reduces vascular leakage
  - Preserves retinal structure
  - Suppresses inflammation and promotes resolution of inflammatory activity
  - Comparable efficacy to anti-VEGF therapy in DME model

# MCr Agonist Streptozotocin Diabetic Mouse Model



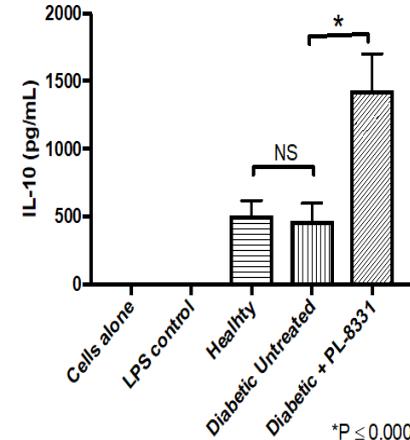
\* $P \leq 0.005$

NS = No significant difference



\* $P \leq 0.001$

NS = No significant



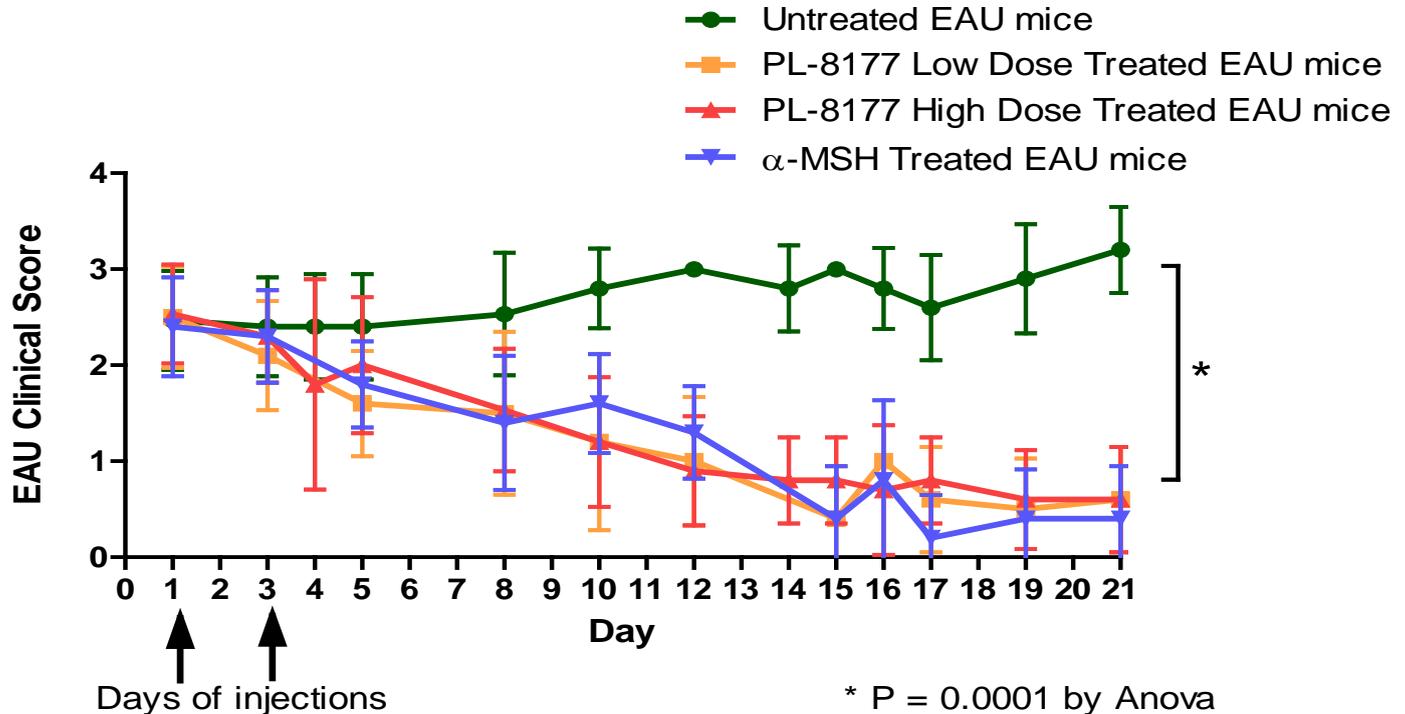
\* $P \leq 0.0001$

NS = No significant difference

- ▶ VEGF and TNF- $\alpha$  levels are similar to healthy mice even though the diabetic mice remain hyperglycemic throughout the study
- ▶ IL-10 is a marker of inflammation resolution

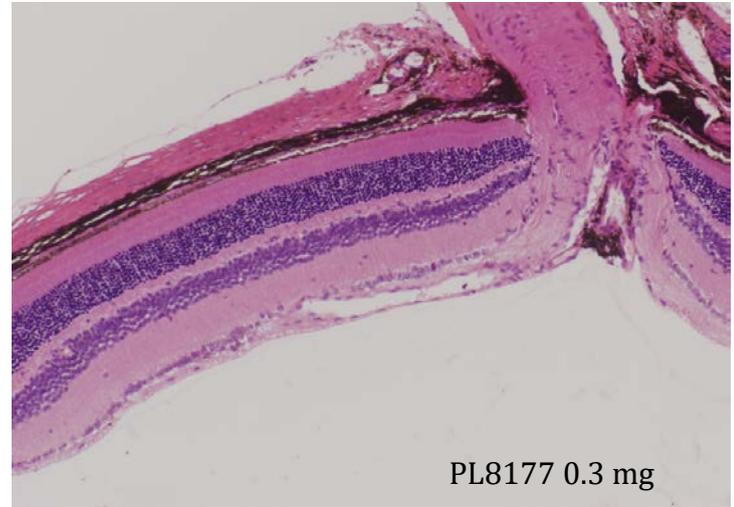
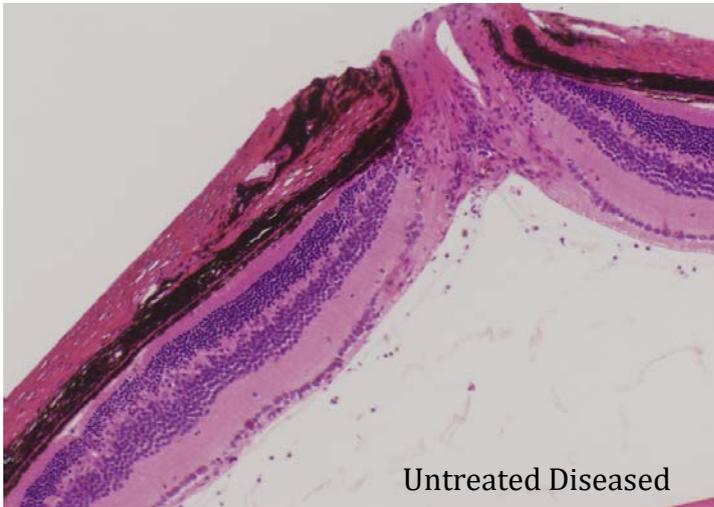
- ▶ Non-Infectious uveitis (NIU) is a potentially blinding intraocular inflammatory disease that arises without a known infectious trigger and is often associated with immunological responses to unique retinal proteins
- ▶ Prevalence of NIU in N. America
  - Adults: ~72,000
  - Pediatric: ~21,000
- ▶ NIU causes bilateral legal blindness in 6% of patients and unilateral blindness in 18% of patients
- ▶ Only 2 FDA approved treatment options
  - Ozurdex (dexamethasone intravitreal implant)
  - Humira (adalimumab)
  - Significant off-label treatments – steroids, Infliximab, methotrexate, azathioprine etc.
- ▶ There remains a high need for new safer treatments
  - Use of steroids leads to glaucoma and cataracts and has systemic toxicities
  - Humira increases rates of serious infection and has substantial contraindications

# PL8177 Experimental Autoimmune Uveitis



- ▶ MC1r agonism has significant effects in reversing uveitis
- ▶ Conducted in collaboration with Dr. A. Taylor at Boston University School of Medicine

## Cross section of the eye

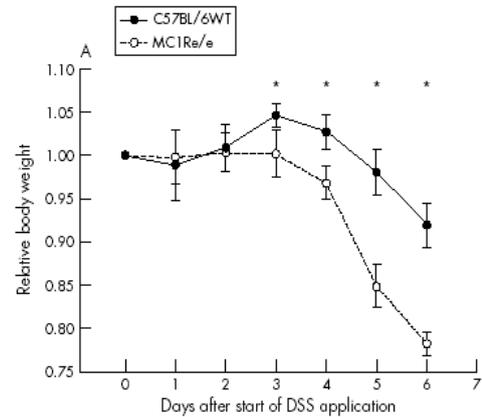
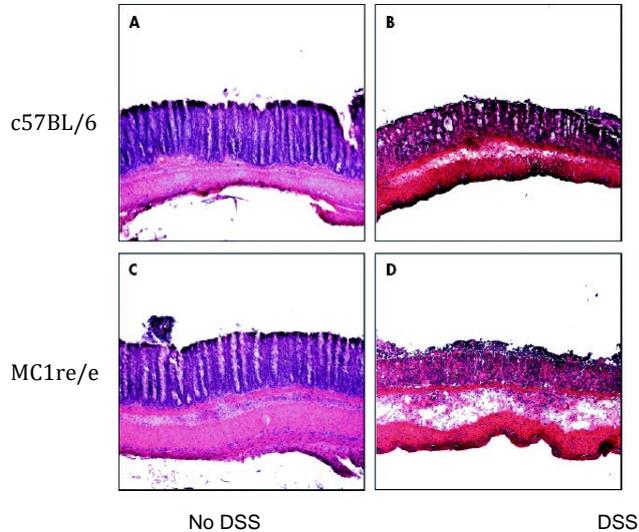


- ▶ Treatment with PL8177 results in reversal of the disease process with return to normal phenotype
- ▶ Reversal of immune cell infiltration and restoration of tissue morphology

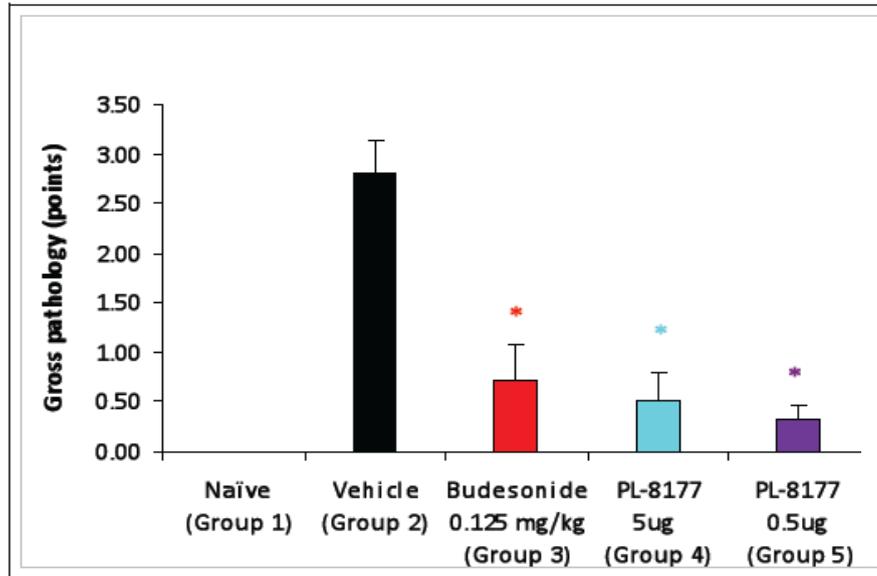
- ▶ Demonstrated efficacy in experimental autoimmune uveitis model
- ▶ Orphan Drug Designation received for non-infectious uveitis
- ▶ Phase 1 SAD and MAD studies completed
- ▶ Phase 2 proof-of-concept study to be scheduled to begin patient enrollment in 4Q2019, data anticipated in 4Q2020

- ▶ MC1r agonism is an endogenous mechanism that downregulates and resolves inflammatory/immune responses
  - MC1r are expressed on the cell surface of intestinal epithelia in UC patients and normal subjects
  - Numerous animal IBD models have demonstrated that the endogenous neuropeptide hormone  $\alpha$ -MSH prevents and reverses intestinal inflammation and supports tissue healing
- ▶ Phase 1 SAD and MAD completed
- ▶ Phase 1 micro-dose study with oral formulation completed
  - Delivery of PL817 to colon demonstrated
  - No systemic uptake
- ▶ Oral formulation phase 2 study in ulcerative colitis scheduled to start in the 1H2020

# Crucial Role of MC1r in Experimental Colitis



C Maaser, K Kannengiesser, C Specht, A Lügering, T Brzoska, T A Luger, W Domschke, T Kucharzik, *1<sup>st</sup> OnLine Gut* 2006;55:1415-1422. doi: 10.1136/gut.2005.083634



## Mean Gross Pathology (Groups 1-5)

\*  $p < 0.05$  vs. Vehicle (Group 2) using T-test

- ▶ PL8177 delivered topically to the colon. Budesonide oral delivery.
- ▶ PL8177 0.5  $\mu\text{g}/\text{rat}$  is 60X more potent than budesonide 0.125mg/kg.

# Corporate/Development Milestones



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## Natriuretic Peptide System Cardiovascular & Fibrosis Programs

PL3994 open label Phase 2a HF-pEF patients FPI	4Q2019	4Q2020
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# Financial Snapshot



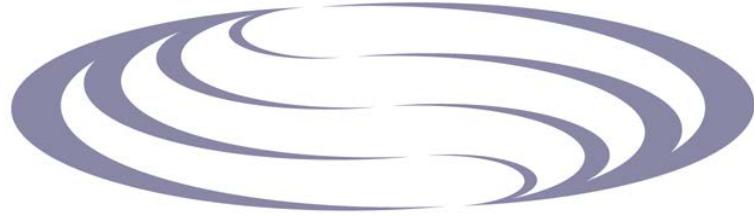
## Financial Highlights as of June 30, 2019

Cash and Cash Equivalents	\$43.5 million
Accounts Receivable	\$60.0 million*
Total Debt (\$0 at July 2019)	\$0.8 million

## Summary Capitalization as of June 30, 2019

	<u>Common Equivalent</u>
Common Stock	227.0 million shares
Preferred	0.1 million shares
Warrants	22.3 million shares
Options	10.3 million shares
RSUs	14.4 million shares
Fully Diluted Shares	273.9 million shares

\*\$60M milestone payment received July 2019 from AMAG upon FDA's approval of Vyleesi™



Thank You