# Saturn-2 Phase 3 Pivotal Trial Topline Data Presentation and Corporate Update

May 2022



## **Legal Disclaimer**

This presentation contains forward-looking statements that involve risks and uncertainties. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based 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. All statements other than statements of historical facts contained in this presentation, including any statements regarding our expectations of the potential market opportunity and patient populations for our product candidates, including TP-03, TP-04, and TP-05 if approved for commercial use, including comparisons between the market for treating blepharitis and the market for treating dry eye disease; the inability to grow the market in a similar way to the dry eye market may occur due to differences in the underlying diseases, different eye care professionals or patient attitudes towards the diseases, symptoms or treatment, regulatory approval, market dynamics, differences in company strategy, marketing or operations and differences in key assumptions which we have not taken into account in our analysis; the ability of our clinical trials to demonstrate acceptable safety and efficacy of our product candidates, and other positive results; the timing, progress and results of clinical trials for our product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs; the timing, scope and likelihood of regulatory filings, NDA submissions and approvals; our ability to obtain marketing approvals of our product candidates and to meet existing or future regulatory standards or comply with post-approval requirements; our expectations regarding the potential advantages of our product candidates over existing therapies; the impact of COVID-19 on our business, clinical development programs and operations; the receipt by Tarsus of payments and achievement and timing of milestones under the terms of the LianBio collaboration, the ability of LianBio to commercialize TP-03 in the Greater China territory; our potential to enter into new collaborations; our expectations with regard to our ability to develop additional product candidates or product candidates for other indications; our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives; our ability to develop, acquire and advance additional product candidates into, and successfully complete, clinical trials; the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs; the commercialization and market acceptance of our product candidates; our marketing and manufacturing capabilities; the pricing of and reimbursement for our product candidates; the implementation of our business model and strategic plans for our business and product candidates; regulatory development in the United States. Europe and other jurisdictions; our ability to effectively manage our anticipated growth; our financial performance and projections relating to our competitors and our industry, including competing therapies are forward-looking statements. The words "may," "will," "expect," "anticipate," "aim," "estimate," "intend," "plan," "believe," "is/are likely to," "potential," "continue" and other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements may involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. Important factors that could cause our actual results to differ materially are detailed from time to time in the reports we file with the Securities and Exchange Commission, copies of which are posted on our website and are available from us without charge. However, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties.

We are currently finalizing our interim financial results as of and for the quarterly period ending March 31, 2022. The results presented in this presentation reflect preliminary estimates. Preliminary estimates represent the most current information available to management and do not present all necessary information for an understanding of our results of operations for such period and have not been reviewed or audited by our independent registered public accounting firm. As a result, final results may vary from these preliminary estimates. We currently expect that final results will be within or near these preliminary estimates. However, it is possible that actual final results may differ materially from these estimates due to the completion of our financial closing procedures, final adjustments, and other developments that may arise and these estimates should be read together with the discussion of forward-looking statements included above as well as the reports we file with the Securities and Exchange Commission, copies of which are posted on our website and are available from us without charge. We have based these forward-looking statements largely on our current expectations, assumptions, estimates and projections as of the date of this presentation. While we believe that these expectations, assumptions, estimates and projections are reasonable, such forward-looking statements are only predictions and involve known and unknown risks and uncertainties, many of which are beyond our control. New risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. This presentation also contains estimates and other data related to the industry in which the Company operates. This data involves a number of assumptio



## **Today's Agenda**

Welcome and Introductions	Bobby Azamian
Tarsus – Revolutionizing Treatment for Demodex Blepharitis	Bobby Azamian
Saturn-2 Phase 3 Topline Data	Bobby Azamian and Elizabeth Yeu
Patient Journey - Clinical Perspective	Paul Karpecki
Conclusion	Aziz Mottiwala and Bobby Azamian
Q&A	All



## **Participants on Today's Call**



Bobak Azamian, MD, PhD
President and CEO
Tarsus



Elizabeth Yeu, MD
Chief Medical Advisor
Tarsus



Paul Karpecki, OD, FAAO Kentucky Eye Institute Lexington, KY



Aziz Mottiwala, MBA
Chief Commercial Officer
Tarsus





# Our Vision is to become a leading eye care pharmaceutical company...

addressing important diseases with impactful therapeutics



## **TP-03**

Designed to provide complete resolution of Demodex blepharitis

# **TP-03 for Demodex Blepharitis Standard of Care Potential**

- Strong and consistent Saturn-2 data
  - Complete collarette cure in 56% of patients
  - Clinically meaningful collarette cure in 89% of patients
  - Mite eradication in 52% of patients
  - Lid erythema (redness) cure in 31% of patients
  - Lid erythema (redness) improvements in 54% of patients
- Consistent cures and responses demonstrated in two pivotal trials involving > 800 patients
- Generally safe and well tolerated, similar to Saturn-1
- NDA submission expected in 2H 2022



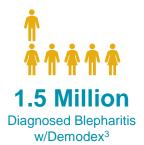
## **Demodex Blepharitis is a Large and Underserved Market in Eye Care**





**Demodex Blepharitis Patients in the U.S.**<sup>1,2</sup>

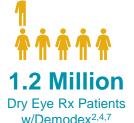
> 7 Million proactively seeking an effective treatment





















Patients with Demodex<sup>2,6</sup>





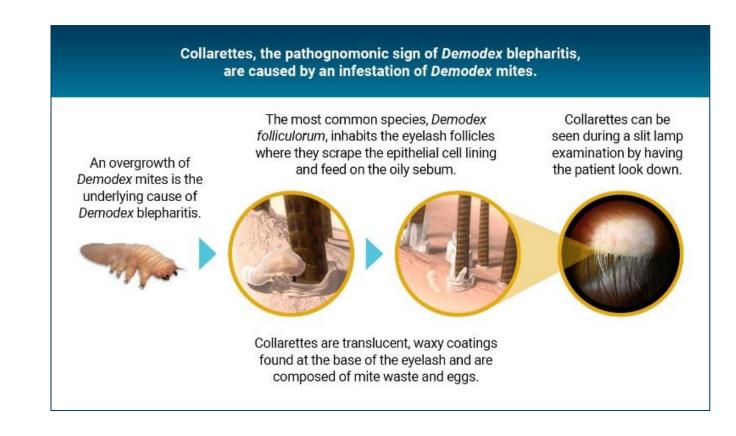
**Demodex Patients** Visiting Eye Doctors



## Demodex Blepharitis is a Pervasive and Damaging Eye Disease

## Demodex blepharitis (DB) is caused by an infestation of Demodex mites, which leads to collarettes, can carry bacteria and induce inflammation

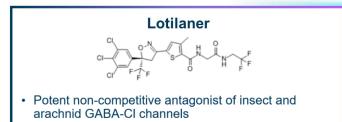
- Diagnosed by collarettes, a waxy, cylindrical plaque at the base of the eyelashes, composed of mite waste, and a sure sign of DB
- DB patients suffer from eyelid margin inflammation, redness and ocular irritation
- 80%\* of DB patients report a negative impact on daily life including itching/burning and blurred vision
- No approved therapeutics





# TP-03 is a Novel Therapeutic Designed to Eradicate Demodex Mites and Treat Demodex Blepharitis

## First-in-class eye drop drug to selectively eradicate Demodex mites



- · Highly lipophilic molecule
- Projected Orange Book Exclusivity to at least 2038<sup>1</sup>



Product Form	Multi-dose eye drop solution bottle
Targeted Use	Treatment of Demodex blepharitis
MOA	Paralysis and death of Demodex mites
<b>Diagnosis</b>	Collarettes identified in standard eye examination
Dosing	BID* for 6 weeks
<b>Efficacy</b>	Collarette cure rate, mite eradication, lid erythema (redness) cure
Consistency	85% of patients show meaningful collarette response, 50% cured
Safety	Well-tolerated safety profile





TP-03 Product profile based on Saturn-1 and Saturn-2 results. 1. The patents and patent applications owned by or licensed to us worldwide include approximately 40 issued patents and approximately 3 pending patent applications; the issued patents and at least some of the pending patent applications include composition of matter claims.

## Saturn-2 Phase 3 Topline Data

Bobak Azamian, MD, PhD Elizabeth Yeu, MD



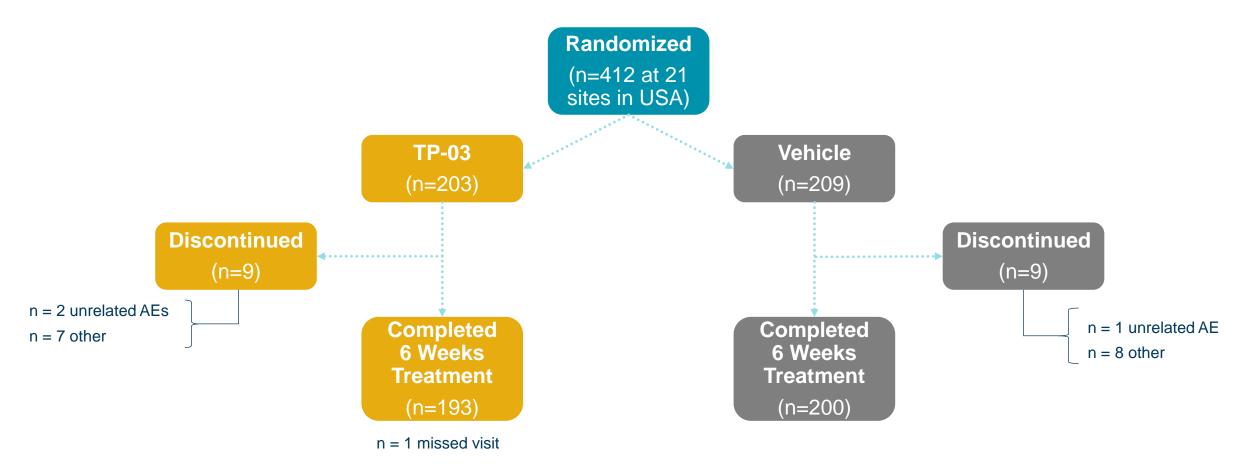
# TP-03 Met All Primary and Secondary Endpoints Again in Saturn-2, with a Complete Resolution of Demodex Blepharitis

- Efficacy: Met all pre-specified primary and secondary endpoints
  - ✓ Primary Endpoint: Complete Collarette Cure p < 0.0001
    </p>
  - ✓ Secondary Endpoint: Mite Eradication p < 0.0001
    </p>
  - ✓ Secondary Endpoint: Erythema Cure p < 0.0001
    </p>
  - ✓ Secondary Endpoint: Erythema/Collarette Composite Cure p < 0.0001
    </p>
- Safety: Generally safe and well tolerated, similar to Saturn-1
  - ✓ Low rates of TP-03 related AE's, vast majority were mild



## **Patient Enrollment and Follow-up**

6 Week Treatment and Follow-up, Twice Daily Drop Without any Touching or Wiping of Lid Margin





## **Collarette Grading Scale Used in Saturn-2**

## Non-linear Scale for Counting Collarettes Performed by Each Site Investigator

# Grade 4

- >2/3 of lashes on lid with collarettes
- Approximately 150 collarettes/lid

#### Average baseline



- Between 1/3-2/3 of lashes on lid with collarettes
- Approximately 100 collarettes/lid



- Between 10 collarettes to 1/3 of lashes on lid with collarettes
- · Approximately 50 collarettes/lid



• 3-10 collarettes on the lashes



- 0-2 collarettes on the lashes
- · Cure of collarettes

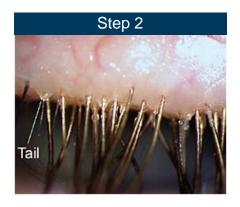


## Mite Density Determination Used in Saturn-2

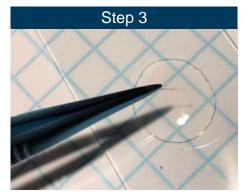
## Trained Mite-counters (CRO) Used for Consistency Across Sites



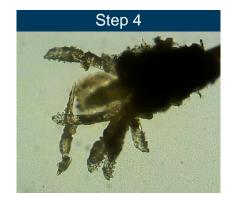
Two or more lashes from each of the upper and lower eyelids, one from each half of each lid, should be twirled with gentle tensioning for at least 10 seconds and removed using fine forceps



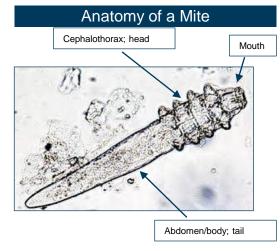
- Lashes with collarettes, if present, should be selected
- Occasionally, tails of mites can be observed in slit lamp examination



- Lashes from each lid are placed on a separate glass slide resulting in eight lashes on four slides
- An artificial tear with an emulsifier (Refresh Optive® Advanced or Refresh Optive Mega 3®) should be applied prior to the placement of the lashes and then a coverslip is placed
- The sample is allowed to sit for approximately 15 minutes to allow the drop to penetrate the collarettes and let the mites disperse



- Using a microscope, the number of *Demodex* observed and the number of lashes epilated are counted for each eye
- Mite density is determined by dividing the number of Demodex observed by the number of lashes epilated for each eye





## Lid Margin Erythema (Redness) Scale Used in Saturn-2

Established and Validated Scale Used in Blepharitis Studies, Performed by Each Investigator

Average baseline 1.6









3 (Severe)\*

2 (Moderate)

1 (Mild)

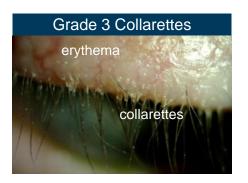
0 (None)

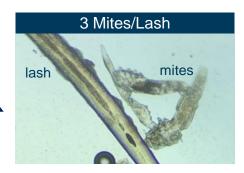


## **Saturn-2 Baseline Characteristics**

### Similar to Saturn-1

	TP-03	Vehicle
Patients	203	209
Age	64	65
Female %	48	49
Collarette Score	2.9	3.0
Mite Density	3.2	3.4
Erythema Score	1.6	1.6

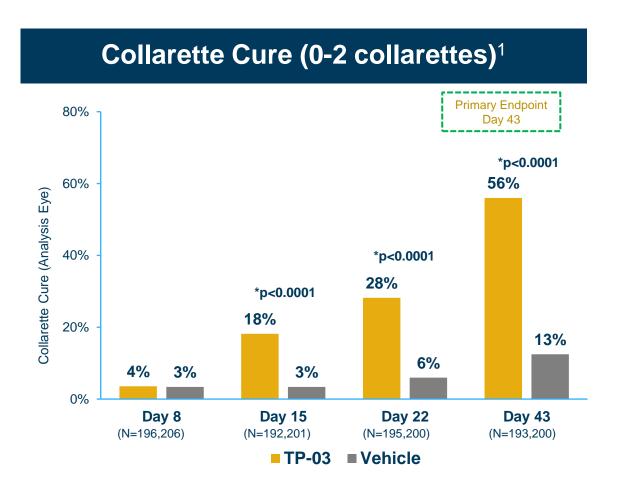


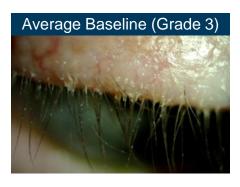




## **Primary Endpoint of Complete Collarette Cure Achieved**

Regulatory Endpoint of Complete Collarette Cure Observed by Week 2





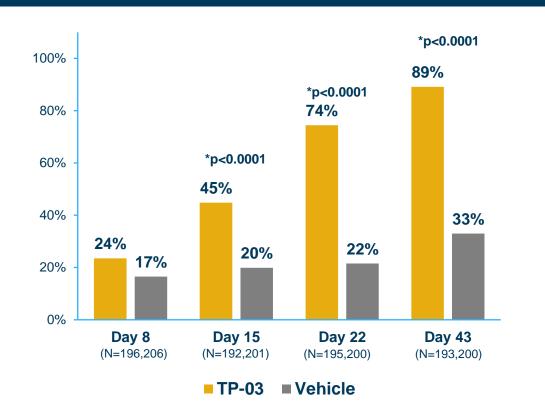




## **Clinically Meaningful Collarette Cure Achieved**

Clinically Meaningful Collarette Cure Observed by Week 2 Over 90% Avg. Reduction in Collarettes (Over 100 to 10 or Less per Lid)

## Grade 0 or 1 Collarettes







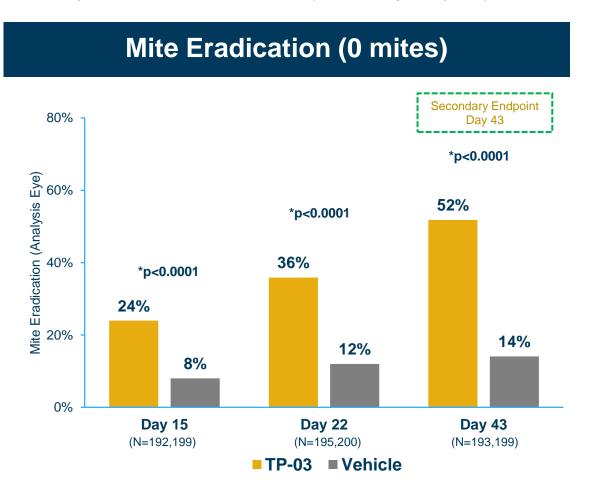




## **Secondary Endpoint of Mite Eradication Achieved**

Complete Mite Eradication Observed by Week 2

Over 50% of Patients Experienced Complete Eradication at Week 6 (Secondary Endpoint)



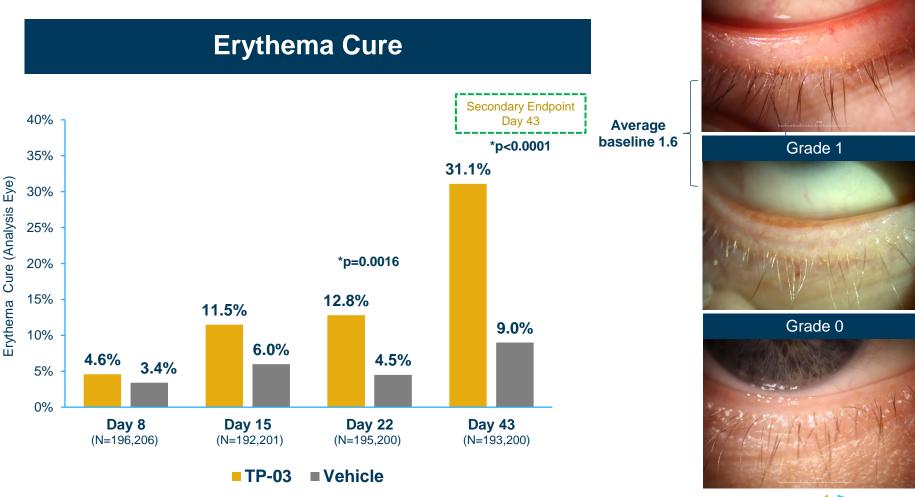






## Secondary Endpoint of Erythema Cure Achieved

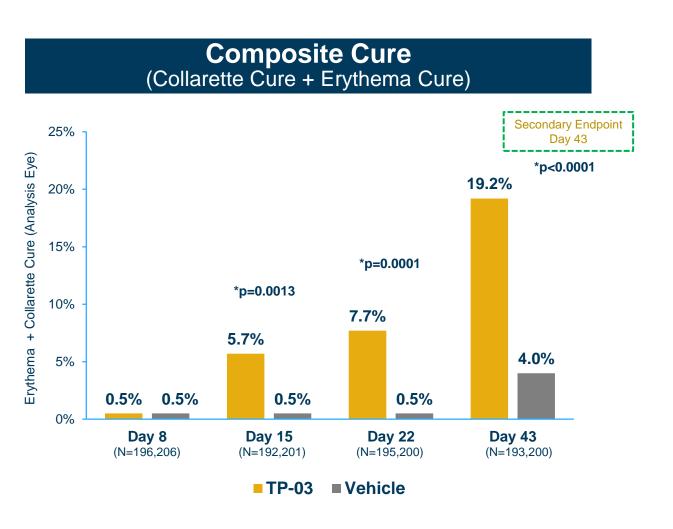
Elevated to Secondary Endpoint in Saturn-2 Complete Erythema Cure Observed by Week 3



Grade 2

## Secondary Endpoint of Complete Composite Cure Achieved

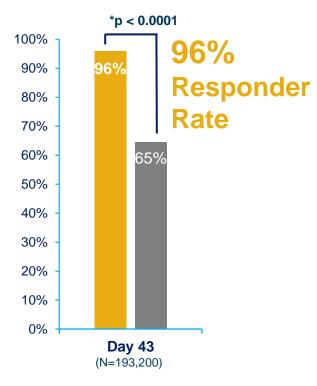
Complete Composite Cure Observed by Week 2



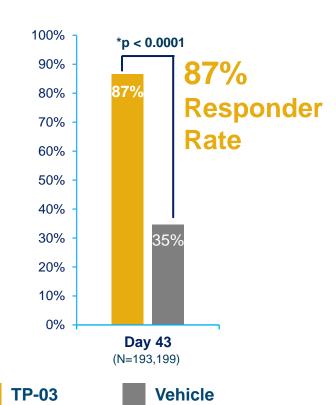


## Collarette, Mite & Erythema Improvement Responder Rates

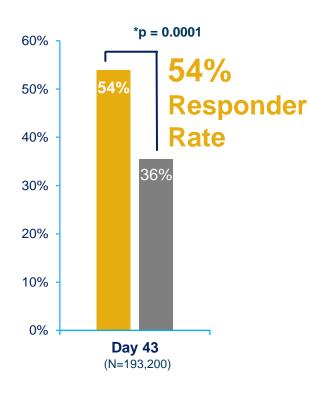




## Patients Achieving ≤ 0.5 Mites/Lash



#### ≥1 Grade Erythema Improvement





## **Adverse Event Summary**

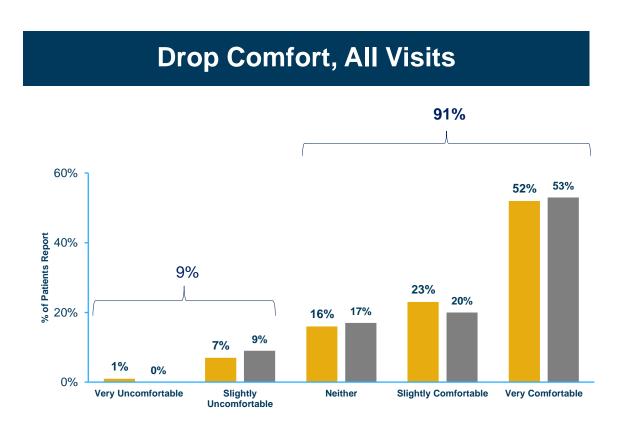
Overall Low Rates of Ocular AEs
All AEs Were Mild or Moderate

Treatment related ocular AE rates ≥ 1%			
	TP-03 (n=203)	Vehicle (n=209)	
Instillation site pain/burning/stinging	16 (7.9%)	14 (6.7%)	
Visual acuity reduced	1 (0.5%)	3 (1.4%)	
Dry eye	3 (1.5%)	1 (0.5%)	
AE Severity	Two moderate All others mild	One moderate All others mild	



## **Drop Comfort Summary**

Over 90% Reported the Drop to be Neutral to Very Comfortable

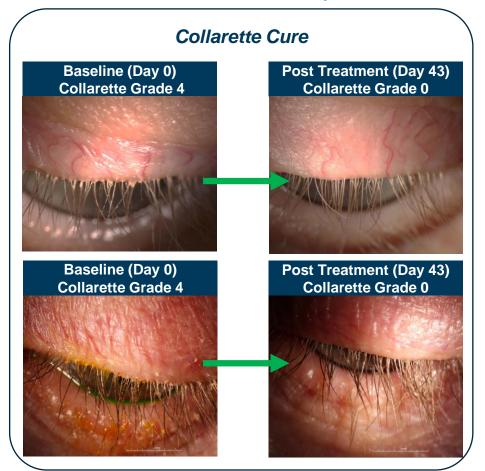


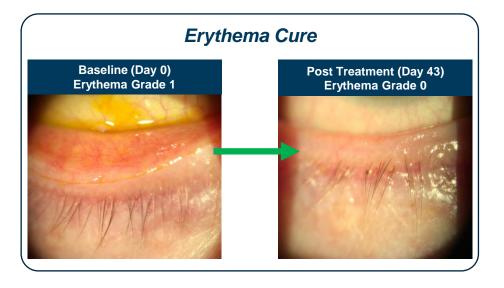


■TP-03 ■ Vehicle

## Significant Clinical Impact Seen After Treatment

## Consistent Collarette Cure and Erythema Cure Rates Observed







## **Saturn-2 Conclusions**

Saturn-2 Results Position TP-03 for Potential FDA Approval and Ultimate Commercial Success

- 56% of patients met primary endpoint of complete collarette cure
- Very high responder rate to TP-03
  - 96% of patients improved at least one collarette grade, 89% achieved a clinically meaningful cure
- Strong consistency across all endpoints compared with Saturn-1
- All primary and secondary endpoints met with high statistical significance
- Clinically and statistically significant effects seen within 2 weeks
- TP-03 was generally safe and well tolerated, similar to Saturn-1



## Two Successful Pivotal Trials with Consistency Across Endpoints

Consistency and High Statistical Significance Expected to Result in Definitive Standard of Care Therapy for Demodex Blepharitis

	Saturn-1 N=421 (Pivotal Phase 2b/3)	Saturn-2 N=412 (Pivotal Phase 3)	Combined N=833 Pivotal Data
Primary Endpoint: Complete Collarette Cure	<b>44%</b> vs. 7% (p<0.0001)	<b>56%</b> vs. 13% (p<0.0001)	<b>50%</b> vs. 10%
Clinically Meaningful Collarette Cure (Grade 0 or 1)	<b>81%</b> vs. 23% (p<0.0001)	<b>89%</b> vs. 33% (p<0.0001)	<b>85%</b> vs 28%
Mite Eradication	<b>68%</b> vs. 18% (p<0.0001)	<b>52%</b> vs 14% (p<0.0001)	<b>60%</b> vs 16%
Lid Erythema Cure	<b>19%</b> vs. 7% (p<0.0001)	<b>31%</b> vs. 9% (p<0.0001)	<b>25%</b> vs 8%
Safety	Generally safe and well tolerated	Generally safe and well tolerated	Generally safe and well tolerated

Anticipated NDA submission of TP-03 for Demodex blepharitis in H2 2022



# **Combined TP-03 Data Offers A Very Compelling Clinical Value Proposition**

## Complete Cure Rates: 50% or more of patients experienced a cure on key endpoints

	<b>Saturn-1</b> N=421 (Pivotal Phase 2b/3)	<b>Saturn-2</b> N=412 (Pivotal Phase 3)	Combined Data N=833
Primary Endpoint: Complete Collarette Cure	<b>44%</b> vs 7% (p<0.0001)	<b>56%</b> vs 13% (p<0.0001)	<b>50%</b> vs 10%
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Lid Erythema Cure	<b>19%</b> vs 7% (p<0.0001)	<b>31%</b> vs 9% (p<0.0001)	<b>25%</b> vs 8%

### Clinically Meaningful Response Rates: Approximately 90% of patients<sup>1</sup> experienced a clinically meaningful benefit

	<b>Saturn-1</b> (Pivotal Phase 2b/3)	<b>Saturn-2</b> (Pivotal Phase 3)	Combined Data
≤ 10 Collarettes (Grade 0 or 1)	<b>81%</b> vs 23% (p<0.0001)	<b>89%</b> vs 33% (p<0.0001)	<b>85%</b> vs 28%
≥ 1 Collarette Grade Improvement	<b>93%</b> vs 50% (p<0.0001)	<b>96%</b> vs 65% (p<0.0001)	<b>94%</b> vs 57%
≤ 0.5 Mites/Lash	<b>95%</b> vs 36% (p<0.0001)	<b>87%</b> vs 35% (p<0.0001)	<b>91%</b> vs 35%
≥ 1 Erythema Grade Improvement	<b>45%</b> vs 28% (p=0.0002)	<b>54%</b> vs 36% (p<0.0001)	<b>49%</b> vs 32%

## **Clinical Perspective**

Paul Karpecki OD

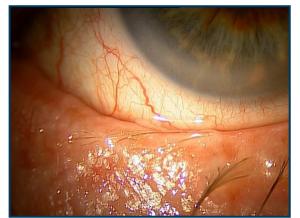


## Clinical Case Study of a Patient Significantly Impacted by Demodex Blepharitis

Initial presentation of 66-year-old male patient diagnosed via slit lamp exam

- Patient has been "dealing with this" for at least 3 years
  - Visited multiple doctors, multiple times before visiting my clinic
- Primary complaints of dryness, itching, redness and irritation
- Secondary complaint of eye watering in the mornings and when he goes outside
- Currently using gels and artificial tears
- Exam Notes:
  - Loss of lashes, thin lashes, scalloped eyelid margins, and meibomian gland loss
  - Significant redness/erythema and damage to external tissue
  - Some vision loss





# Lack of Effective Treatments Lead to Significant Patient Burden and Worsening of Disease

Six years later all management options have been exhausted with poor results

- Patient is now age 72 and has lid and lash damage from Demodex blepharitis
- Patient underwent the following additional treatments:
  - Lid scrubs, Tea Tree oil scrubs, high concentration in office tea tree oil and hypochlorous acid
  - Microblepharoexfoliation (2 times)
  - Steroid ointment, Combination steroid/antibiotic drops (3 types)
  - Oral Azithromycin and tetracycline





## What's Ahead

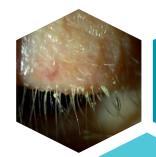
Aziz Mottiwala, MBA Bobak Azamian, MD, PhD



## **Demodex Blepharitis Market is Primed for Activation**

# ~25 Million Patients total addressable market in U.S.<sup>1,2</sup> >7M Patients/year visiting ECPs seeking an effective treatment

- Increasing market awareness & ECP focus on Demodex blepharitis
  - 87% of ECPs surveyed indicate they explicitly look for Demodex as part of blepharitis diagnosis<sup>3</sup>
  - Clear market segments for early use: Blepharitis, Dry Eye, Cataracts and Contact Lens intolerance
  - >7M Patients/year visiting ECPs seeking treatment account for +\$1Bn Market opportunity
- Compelling disease visuals allow for simple diagnosis and patient education
  - Collarettes can be seen during a standard eye exam by every Ophthalmologist and Optometrist
  - Patients are motivated by visuals of collarettes, mites and redness
- Positive initial feedback from payers may enable clear reimbursement pathway
  - Receptivity to targeted MOA
  - High cure and responder rates provide good value to payers
  - Lack of existing treatment alternatives



Clear early market segments

Simple and confident diagnosis





Clear reimbursement pathway



## **Tarsus Commercial Leadership Team Combines Eye Care and Product Launch Expertise**



#### Aziz Mottiwala, MBA, Chief Commercial Officer

- Former CCO Opiant, and Head of Commercial at Avanir
- Former VP Marketing, Allergan Eye Care (Restasis®, Lumigan®)
- 20+ years of Commercial experience, with 10+ years in eye care









#### Scott Youmans, Vice President, Sales

- Former Director of Sales, Allergan Eye Care
- Former marketing lead for Allergan's Dry Eye Franchise
- 20+ years of sales and marketing experience, with over 14 years in Eve Care







#### Arthur Chan, Ph.D., Vice President, Medical Affairs

- Former Head of Medical Affairs, Dry Eye at Novartis
- Previously led all Field Medical Efforts for Alcon
- 18+ years of experience in Ophthalmic Medical Affairs



Alcon



#### Neera Clase, Vice President, Market Access

- Former VP, Market Access, Acadia Pharmaceuticals
- Established market access team and strategy at Relypsa
- 20+ years of reimbursement experience spanning multiple product launches







**Abbott** 



#### Matt Rossen, Vice President, Marketing

- Former VP, Marketing at QED Therapeutics
- Former marketing head for Jazz Sleep and Hematology products
- 20+ years of marketing leadership with multiple product launches

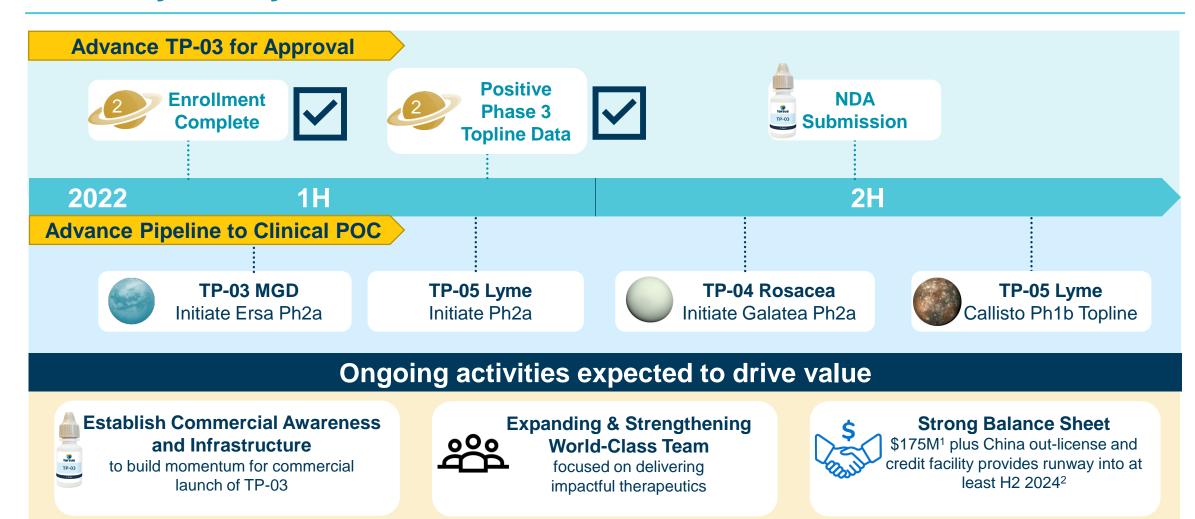








## **2022 Key Catalysts Position Tarsus for Growth**





# Revolutionizing Treatments for Eye Diseases, Starting with TP-03



## **US Market:**

~25M total addressable patients

## **Effective and Safe:**

Over 50% cures, and ~90% clinically meaningful outcomes Reimbursement:

Expected favorable outlook on pricing and coverage If NDA Approved:

Potential to become the definitive standard of care for Demodex blepharitis



Q&A



