#### **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM 8-K

#### CURRENT REPORT Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (date of earliest event reported): May 2, 2022

#### TARSUS PHARMACEUTICALS, INC. (Exact name of registrant as specified in charter)

Delaware (State or other jurisdi of incorporation) ctio

001-39614 (Commission File Number) 81-4717861 (I.R.S. Employer Identification No.)

15440 Laguna Canyon Road, Suite 160 Irvine, CA 92618 (Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (949) 409-9820

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

D Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

D Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	TARS	The Nasdaq Global Market LLC
		(Nasdag Global Select Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (CFR §240.12b-2).

Emerging growth company 🗵

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. 🗵

Item 7.01 Regulation FD Disclosure.

On May 2, 2022, Tarsus Pharmaceuticals, Inc. (the "Company") issued a press release announcing positive results of the Company's Saturn-2 pivotal Phase 3 trial evaluating TP-03 for the treatment of Demodex blepharitis.

Additionally, on May 2, 2022, the Company presented a corporate presentation relating to its positive results of the Saturn-2 pivotal Phase 3 trial evaluating TP-03 for the treatment of Demodex blepharitis and posted the corporate presentation to the investor section of the Company's website. A copy of this presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K (the "Report").

The information in this Report, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), or otherwise subject to the liabilities of that Section, and shall not be deemed incorporated by reference in any registration statement or other filing pursuant to the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise expressly stated in such filing.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.

Description

- 99.1 <u>Tarsus Pharmaceuticals, Inc. Corporate Presentation.</u>
- 104 Cover Page Interactive Data File (embedded within XBRL document)

#### SIGNATURES

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

Date: May 2, 2022

Tarsus Pharmaceuticals, Inc.

By: /s/ Leo M. Greenstein Leo M. Greenstein Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

# 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 on assurances of future performance. Instead, they are based on our current expectations about future events and financial rends that we believe may affect our financial condition, results of operations, business strategy, and financial needs. All statements of historical facts contained in this presentation, including comparisons between the market for treating by epidemical market opportunity and patient populations for our product conditions, results of operations, business strategy, and financial reads that including comparisons between the market for treating by epidemical market opportunity and patient populations for our product conditions or on the market for treating by epidemical market opportunity and patient populations for our product conditions or product conditions, our expectations, we represent to our convercial potential that are represented to convercialize to convercial potential to a results of our product conditates in the programs on dependent programs and dependent programs and dependent programs and dependent programs and dependent product conditates or the indications; our ability to develop additional product conditates in the presentation of unoread conditates represent





### 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



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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...

# ...dedicated to addressing important diseases with impactful therapeutics





# **TP-03**

Designed to provide complete resolution of Demodex blepharitis

2022

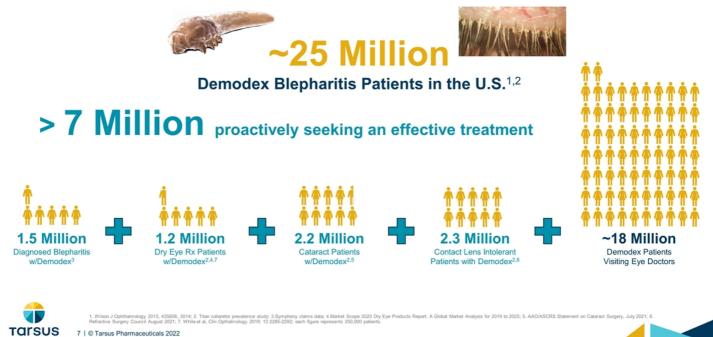
### **TP-03 for Demodex Blepharitis Standard of Care Potential**

#### 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 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



\*Tarsus Atlas Study – Yeu et al. Psychosocial Impact of Demodex Bilepharitis. Abstract presented at ARVO 2021, Abstract #3544846 8 | © Tarsus Pharmaceuticals 2022 Collarettes, the pathognomonic sign of *Demodex* blepharitis, are caused by an infestation of *Demodex* mites.



Collarettes are translucent, waxy coatings found at the base of the eyelash and are composed of mite waste and eggs.



### 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

<ul><li>arachnid GABA-CI o</li><li>Highly lipophilic mol</li></ul>		
Product Form	Multi-dose eye drop solution bottle	
S Targeted Use	Treatment of Demodex blepharitis	
MOA	Paralysis and death of Demodex mites	
Oiagnosis	Collarettes identified in standard eye examination	
Dosing	BID* for 6 weeks	
Efficacy	Collarette cure rate, mite eradication, lid erythema (redness) cure TP-03	
Consistency	85% of patients show meaningful collarette response, 50% cured	
Safety	Well-tolerated safety profile	



1P:03 Product profile based on Saturn-1 and Saturn-2 results. 1. The platents and patent applications owned by or licensed to us whothaded includes approximately 40 issued platents and approximately 38 pending patent applications. The lincides approximately 38 patent applications include composition includes composition includes approximately 38 pending patent applications. The lincides approximately 38 pending platent applications, the issued platents and at least to us whothaded includes approximately 40 issued platents and approximately 38 pending platent applications. The lincides approximately 38 pending platent applications, the issued platents and at least to us whothaded includes approximately 30 pending platent applications. The lincides approximately 38 pending platent applications include composition of matter claims. 9 | © Tarsus Pharmacouticals 2022 "BID means twice per day



# 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

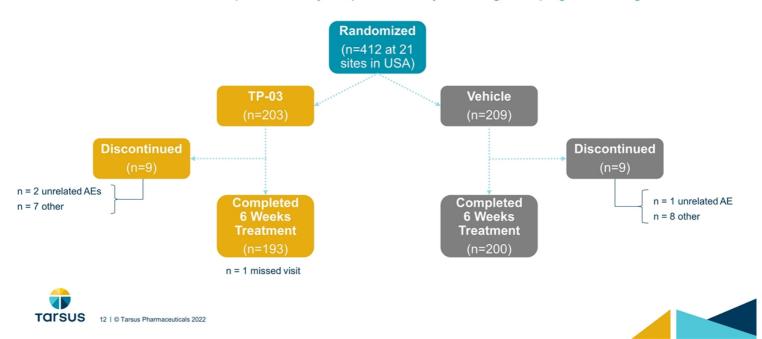
- Efficacy: Met all pre-specified primary and secondary endpoints
  - Primary Endpoint: Complete Collarette Cure p < 0.0001</p>
  - Secondary Endpoint: Mite Eradication p < 0.0001
  - Secondary Endpoint: Erythema Cure p < 0.0001
  - Secondary Endpoint: Erythema/Collarette Composite Cure p < 0.0001
- Safety: Generally safe and well tolerated, similar to Saturn-1
  - Solution Low rates of TP-03 related AE's, vast majority were mild
  - $\leq$  91% of patients reported the drop to be neutral to very comfortable





### **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



- >2/3 of lashes on lid with collarettes



- Between 1/3-2/3 of lashes on lid with collarettes •
- Approximately 150 collarettes/lid
   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



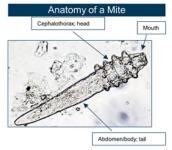
- Lashes with collarettes, if present, should be selected
- Occasionally, tails of mites can be observed in slit lamp examination



- 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



3 (Severe)\*

2 (Moderate)

1 (Mild)

0 (None)

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argin vascularity, Drug Design, Development and Thera



\*Image reproduced with permission from Jiang et al. Efficacy of intra-meibonian gland injection of the anti-VEGF agent bevacizumab for the treatment of meibo 2018-12 1289-1279, © Dove Medical Press Limited. Grades 0, 1, and 2 images are from patients in Saturn-1.
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### 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



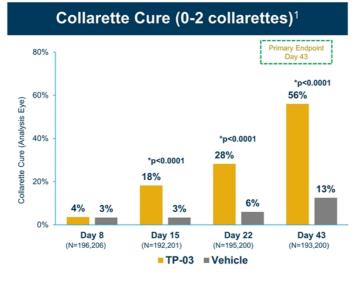






### Primary Endpoint of Complete Collarette Cure Achieved

Regulatory Endpoint of Complete Collarette Cure Observed by Week 2







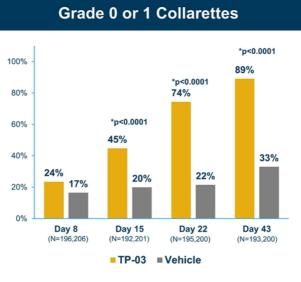


1. The primary efficacy endpoint was the proportion of patients achieving collarette cure (0-2 collarettes on the eyelid) as compared to the vehicle control, at day 43 17 | © Tarsus Pharmaceuticals 2022



### **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)









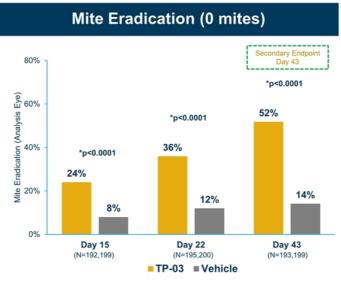




### Secondary Endpoint of Mite Eradication Achieved

#### Complete Mite Eradication Observed by Week 2

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



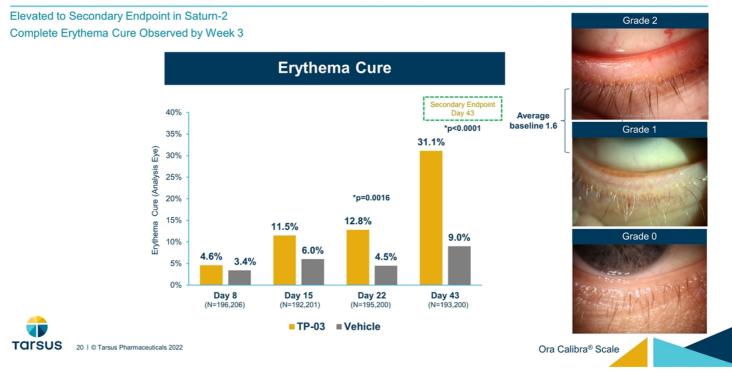






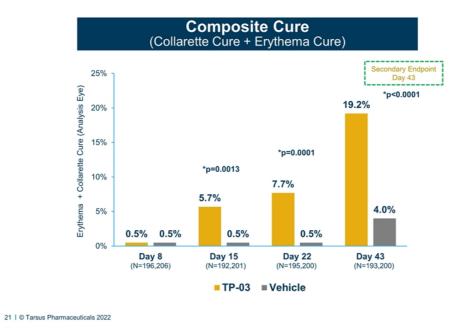


### Secondary Endpoint of Erythema Cure Achieved



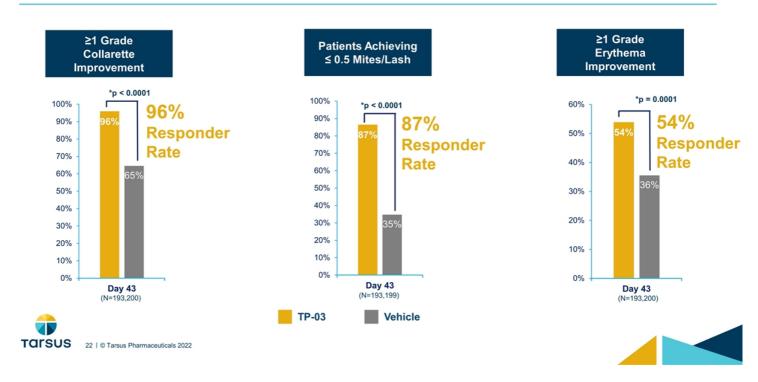
### Secondary Endpoint of Complete Composite Cure Achieved

Complete Composite Cure Observed by Week 2





### **Collarette, Mite & Erythema Improvement Responder Rates**



### **Adverse Event Summary**

#### Overall Low Rates of Ocular AEs

#### All AEs Were Mild or Moderate

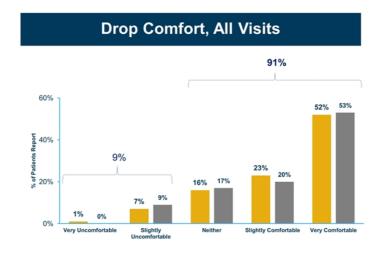
Treatment related ocular AE rates ≥ 1%			
	TP-03 (n=203)	Vehicle (n=209)	
Instillation site pain/burning/stinging	16 (7.9%)	14 (6.7%)	
Visual acuity reduced	1 (0.5%)	3 (1.4%)	
Dry eye	3 (1.5%)	1 (0.5%)	
AE Severity	Two moderate All others mild	One moderate All others mild	



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### **Drop Comfort Summary**



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

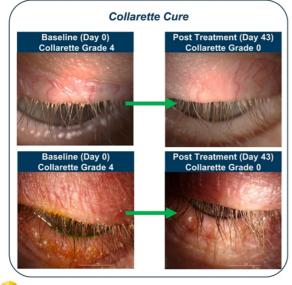


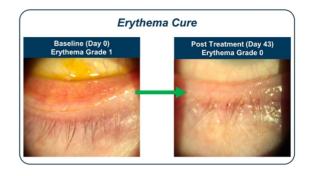
■ TP-03 ■ Vehicle



### Significant Clinical Impact Seen After Treatment

#### Consistent Collarette Cure and Erythema Cure Rates Observed





Photos are images taken of patients in Saturn-2. Images of patients may experience different or less favorable results TAISUS 25 | © Tarsus Pharmaceuticals 2022



#### 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

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### 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 <sup>N=421</sup> (Pivotal Phase 2b/3)	Saturn-2 <sup>N=412</sup> (Pivotal Phase 3)	Combined <sup>N=833</sup> 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 <sup>N=833</sup>
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%
1. With respect to collarettes, collaret 28   © Tarsus Pharmaceutic	e grade improvement, and mites per lash metrics in table als 2022		

# **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



1. Wilson J Ophthalmology 2015, 435606, 2014; 2. Titan collarette prevalence study; 3. Source: US HCP Quant Research (n=100 OPT and n= 100 OPH) Q4 2020(Q1 202 33 | © Tarsus Pharmaceuticals 2022



#### 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 Eye Care

**Allergan** Allergan K



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

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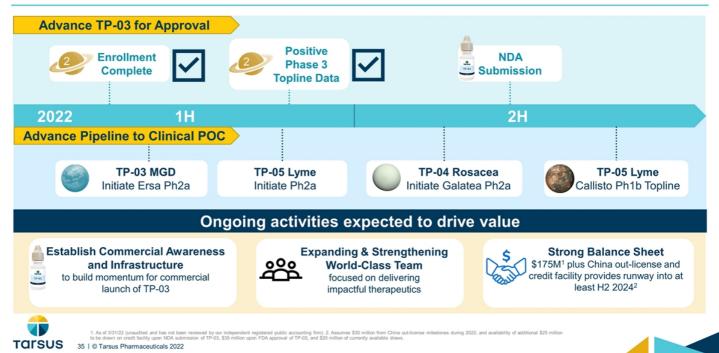
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### **2022 Key Catalysts Position Tarsus for Growth**



## 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:

Tarsus

Expected favorable outlook on pricing and coverage

### If NDA Approved:

Potential to become the definitive standard of care for Demodex blepharitis



