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): November 17, 2020

Tarsus Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39614**	**81-4717861**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

15440 Laguna Canyon Road, Suite 160
Irvine, California 92618
(Address of principal executive offices, including zip code)

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

N/A
(Former name or former address, if changed since last report)

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 (see General Instruction A.2):

☐ 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)

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

☐ 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, par value $0.0001 per share	**TARS**	**The Nasdaq Global Market LLC (Nasdaq 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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 November 17, 2020, Bobak Azamian, M.D., Ph.D., the Chief Executive Officer of Tarsus Pharmaceuticals, Inc. (the "Company") presented an overview of the Company at the Jefferies Virtual London Healthcare Conference (the "Investor Presentation"). Dr. Azamian presented on Tuesday, November 17, 2020 at 2:35 A.M. PST, the time of which was advanced from the time previously announced.

The Investor Presentation may be accessed under the "For Investors" tab on the Company's website at www.tarsusrx.com and will be available for replay for a period of 90 days. Additionally, a copy of the slides comprising the Investor Presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01, including Exhibit 99.1, 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 incorporated by reference into any registration statement or other document 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	Tarsus Pharmaceuticals, Inc. November 17, 2020 Investor Presentation.

SIGNATURES

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

Dated: November 17, 2020

Tarsus Pharmaceuticals, Inc.

By: /s/ Bobak Azamian
Bobak Azamian, M.D., Ph.D.
President and Chief Executive Officer

Tarsus Pharmaceuticals

Jefferies Virtual London Healthcare Conference
November 17, 2020

tarsus

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; 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.

Tarsus Board and Executive Team

Board of Directors

Andrew Goldberg — VIVO CAPITAL

Bhaskar Chaudhuri — FRAZIER HEALTHCARE PARTNERS

Bill Link — Flying-L-Partners

Jason Tester — HOROWITZ GROUP

Michael Ackermann, Chairman

Bobby Azamian, Chief Executive Officer

Executive and Management Team

Bobby Azamian
CEO

Michael Ackermann
Chairman

Sesha Neervannan
COO

Aziz Mottiwala
CCO

Leo Greenstein
CFO

Elizabeth Yeu
Chief Medical Advisor (Consultant)

Mark Holdbrook
VP, Clinical Affairs

Kim Norman
Sr. Director, Finance

Stephanie Baba
Director, Clinical Affairs

Shawn Hickok
Director, Pharmaceutical Scienc

Maáza Martin
Director, Marketing

Steven Reyes
Director, Project Management

tarsus

Corporate Highlights

Potential for first-ever FDA-approved therapeutic for Demodex blepharitis. Significant market opportunity with no approved therapies

Completed five clinical trials, including two Phase 2b randomized control trials. **Consistently met safety and efficacy endpoints**

Commenced Phase 2b/3 enrollment in September 2020 (Saturn-1 trial)

Demodex blepharitis is a significant market opportunity with estimated cases in the U.S. as high 25 million. We believe it parallels the dry eye market[1]

Pipeline with novel API advancing to Phase 2a proof of concept in MGD[2], and Phase 1/2 trials in rosacea[3], Lyme disease and malaria[4]

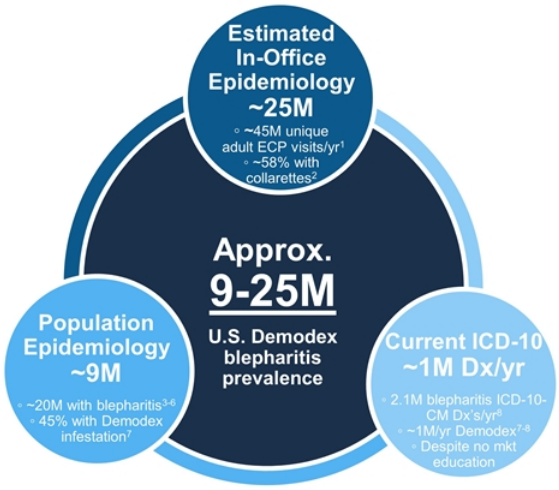
1 – The market for Demodex blepharitis may not be similar based on differences in the underlying disease, different ECP and patient attitudes, and treatment and/or key assumptions we have not taken into our analysis.
2 – We intend to rely on preclinical studies for Demodex blepharitis and clinical safety assessments from the Demodex blepharitis program in order to advance to Phase 2a for MGD. We have not conducted and we do not intend to conduct any preclinical studies with TP-03 for the treatment of MGD.
3 – We intend to leverage systemic preclinical data from our TP-03 program and augment with additional dermal preclinical studies to select formulation in order to advance to Phase 1/2. We have not conducted any preclinical studies in rosacea with TP-04 to date. See slide [24] (including the footnotes thereto) for more information.
4 –In relation to Lyme disease and malaria, we intend to leverage oral systemic preclinical data from our TP-03 program as well as third-party oral systemic preclinical studies for Lyme disease or community malaria reduction, respectively (and will not conduct our own preclinical studies for Lyme disease and malaria). See slide [24] (including the footnotes thereto for more information.

Our Mission

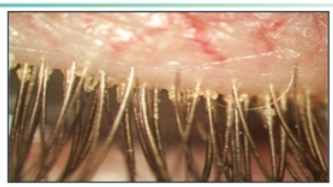
tarsus

Blepharitis is a Large and Underserved Market in Eye Care

Epidemiology of Demodex Blepharitis



1. Wilson J Ophthalmology 2015, 435606, 2014; 2. Tarsus collarette prevalence study; 3. MGD Report IOVS, Special Issue 2011, Vol. 52, N. 4; 4. American Optometric Association; 5.Cheng Cornea Sept 2020; 6. IOVS June 2020; 7. Zhao - Ophthalmic Epidemiology, 19(2), 95–102, 2012; 8. Symphony Claims Data Analysis; 9. Harmon, Market Scope Dry Eye Analyst Report, 2014 10. Tarkowski W, Moneta-Wielgoś J, Młocicki D. Demodex sp. as a Potential Cause of the Abandonment of Soft Contact Lenses by Their Existing Users. Biomed Res Int. 2015;2015:259109



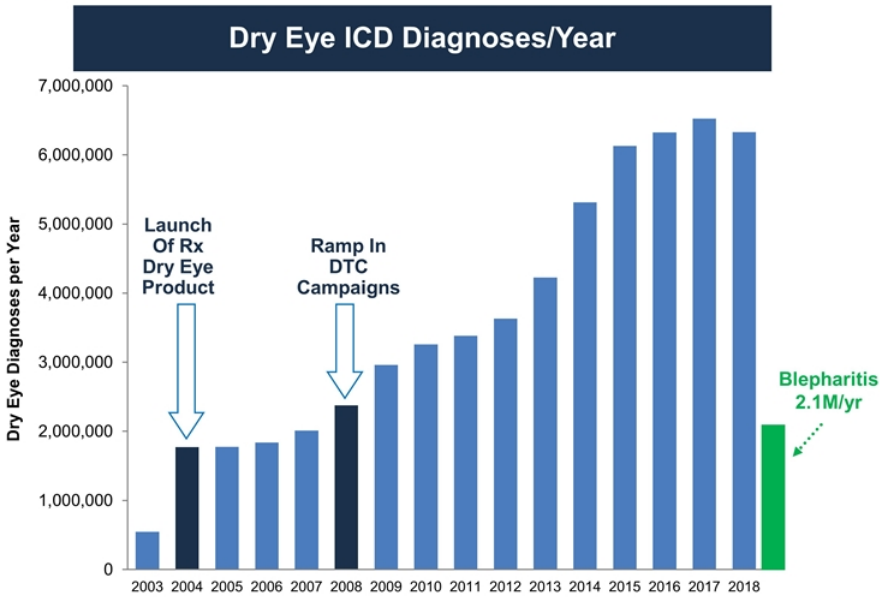
Largely Underdiagnosed, Education Needed	~ 58% of <u>all patients</u> in the eye clinic have collarettes[2] but current impression of only 10-15% of blepharitis cases
Significant head start on Diagnosis	2.1M ICD-10 **Blepharitis** Dx's/yr[8]
Blepharitis Routinely Causes	Eyelids to become red, irritated and itchy, with debris on the eyelashes.[9]
Blepharitis Can Lead To	Blurring of vision, missing or misdirected eyelashes, and inflammation of other eye tissue, particularly the cornea[4]
Concomitant Dry Eye	Significant overlap in **Dry Eye** patients. Demodex prevalent in ~69% of DE patients[5]
Blepharitis and Surgery	Important factor for maximizing surgical outcomes: 67% of **Cataract Patients** have Demodex blepharitis[6]
Contact Lens Drop-out	Studies have shown a direct correlation between Demodex blepharitis and **Contact Lens** intolerance[10]
Prescription Treatment	None

tarsus

Blepharitis has Potential Similarities to Dry Eye Market 15 Years Ago

Potential Large Latent Demand for a New Therapy

- Dry eye is a similar ocular surface disease to Blepharitis, that is likewise treated by ECPs*
- Large untapped patient population that was activated through education of ECPs and patients
- In 2003, no approved dry eye therapeutics
  - With approval of a prescription therapeutic and concurrent ECP and patient education, diagnosis rate increased 12 times
- Blepharitis already has 2.1 million diagnoses per year, despite no approved therapies
- Collarette prevalence study suggests Demodex blepharitis prevalence > 2 times dry eye prescriptions across MD and OD clinics

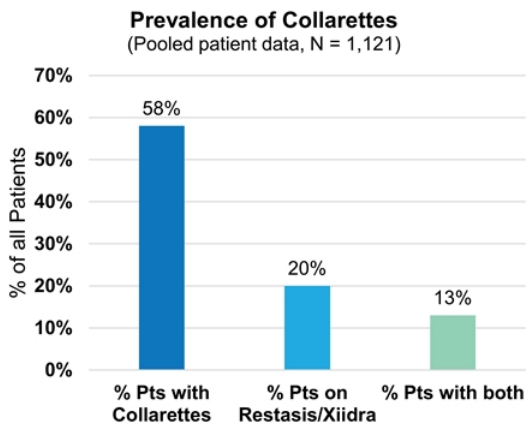


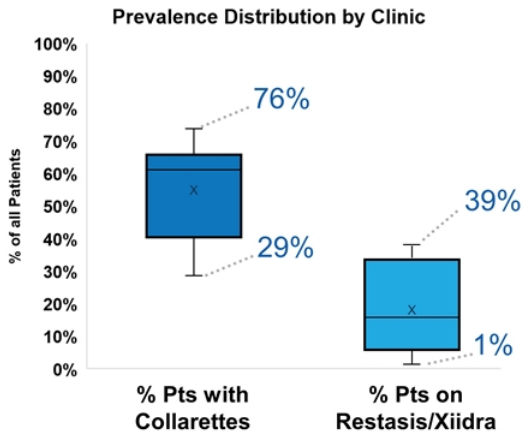
**The market for Demodex blepharitis may not be similar based on differences in the underlying disease, different ECP and patient attitudes, and treatment and/or key assumptions we have not taken into our analysis.*

tarsus

Half of All Patients Entering Clinic have Collarettes

- Since Demodex is newly appreciated as a cause of blepharitis, Tarsus performed the first-ever Demodex blepharitis in-clinic prevalence study
- Methods: every consecutive patient seen by the clinic is evaluated for
  1. Presence of collarettes (the pathognomonic sign and key diagnostic for Demodex blepharitis)
  2. Whether they have an active Rx for dry eye (Restasis® or Xiidra®)
- N = 1,121 consecutive patients, 8 clinics (MDs and ODs, geographically diverse)





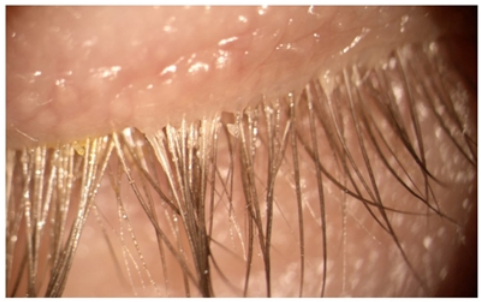
Note: Data from Tarsus Collarette Prevalence Study

tarsus

Collarettes Are Pathognomonic Sign of Demodex Infestation

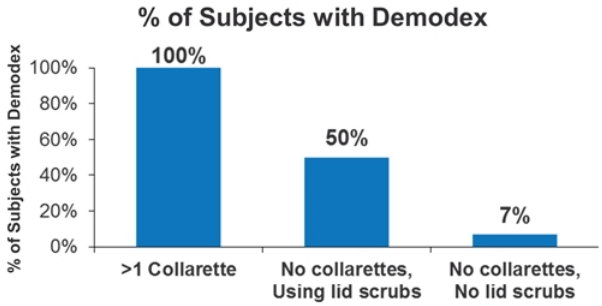
Collarettes Are Composed of Mite Waste Products and Eggs[1]

- Regurgitated undigested material combined with epithelial cells, keratin, and mite eggs
- Contain digestive enzymes, which cause irritation



Easily and Rapidly Diagnosed with Standard Eye Exam

- Demodex mites found on 100% of lashes with collarettes[2]
- Collarettes found in ~ 58% eye care patients[3]

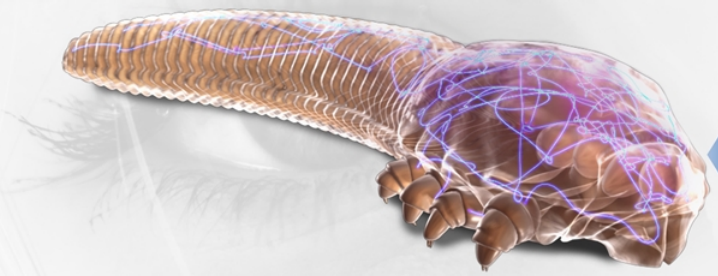


1. Fromstein 2018
2. Gao et al., Invst Ophth and Vis Sci, September 2005, Vol. 46, No. 3089-3094
3. Tarsus Collarette Prevalence Study

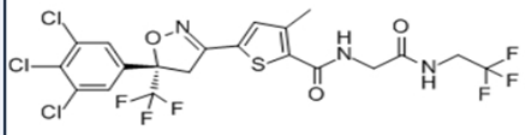
tarsus

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

TP-03 is designed to paralyze the mite nervous system through parasite-specific GABA inhibition



Lotilaner



- Potent non-competitive antagonist of insect and arachnid GABA-Cl channels
- Highly lipophilic molecule, which may promote its uptake in the oily sebum of the hair follicle, where the mites reside
- **Tarsus has licensed worldwide rights to Lotilaner for all human uses**

tarsus

TP-03 is a Novel Drug Designed to Treat Demodex Blepharitis by Eradicating Mites and Collarettes[1]

Product Form	Multi-dose eye drop solution bottle, preserved
Targeted Use	Treatment of Demodex blepharitis
MOA	Paralysis and death of Demodex mites
Diagnosis	Collarettes identified in standard eye examination
Dosing	BID* for 6 weeks
Efficacy Goal	1º collarette cure rate, 2º mite eradication, 2º redness + collarette cure rate
Safety Goal	Well-tolerated safety profile

*BID means twice per day

1. TP-03 Product profile based on Saturn-1 Trial Design

Extensive Clinical Trial Program for TP-03

Trial / Study	Design	Endpoints	Results Achieved		Status
PoC: Mercury	Ex-vivo mite testing on 80 mites	Ex-vivo mite death count	**100%** mites dead within 24 hours ($p < 0.001$)		✓
Clinical Trials			**Collarette Cure Rate****	**Mite Eradication Rate**	
P2a: Mars *	28-day BID dosing, single arm (n=15) Pilot formulation	Collarette grade Mite density Safety	**86%** at 28 days ($p < 0.05$)	**57%** at 28 days ($p < 0.05$)	✓
P2b: Jupiter *	28-day BID dosing, randomized 1:1 (n=60) Pilot formulation	1º – Mite density Safety 2º – Collarette grade	**88%** at 28 days ($p < 0.001$)	**67%** at 28 days ($p < 0.005$)	✓
P2a: Io **	42-day BID dosing, single arm (n=18) Current formulation	1º – Collarette cure rate 2º - Mite eradication Safety	**72%** at 42 days ($p < 0.05$)	**78%** at 42 days ($p < 0.05$)	✓
P2b: Europa **	42-day BID dosing, randomized 1:1 (n=54) Current formulation	1º – Collarette cure rate 2º – Mite eradication 2º – Redness Composite Safety	**80%** at 42 days ($p < 0.001$)	**73%** at 42 days ($p = 0.003$)	✓
P2b/3: Saturn-1 ** †	42-day BID dosing, randomized 1:1 (n≥350) Current formulation	1º – Collarette cure rate 2º – Mite eradication 2º – Redness Composite Safety	Trial initiated in September 2020		
P3: Saturn-2 ** ††	42-day BID dosing, randomized 1:1 (n=350) Current formulation	1º – Collarette cure rate 2º – Mite eradication 2º – Redness Composite Safety	Initiate trial in 2021		

Two Pivotal Trials

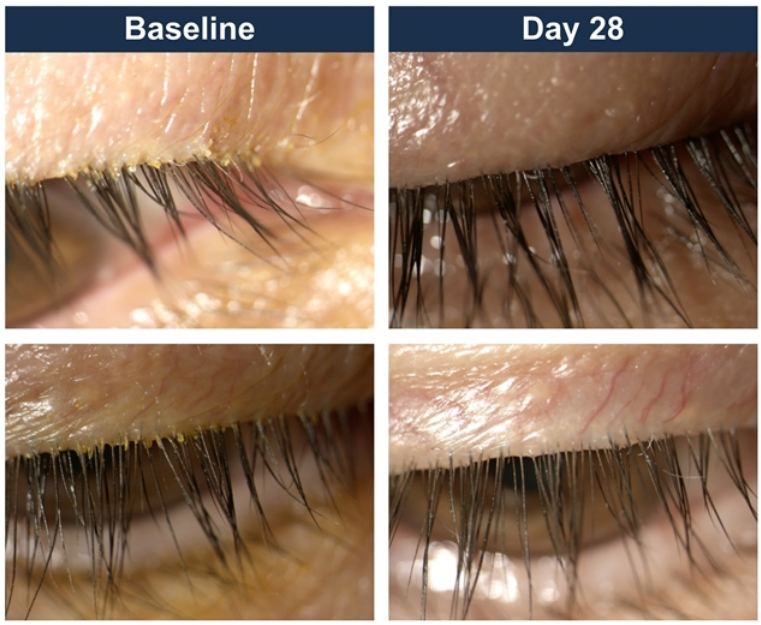
* The Mars and Jupiter trials used collarette grade as an endpoint, which has been translated into a collarette cure (defined as <10 collarettes). This is different from the collarette cure (defined as ≤2 collarettes) endpoint used in Io, Europa, Saturn-1 and the planned Saturn-2 trials. The Mars and Jupiter trials also used mite density as an endpoint, which is different from mite eradication. Mite density is translated into mite eradication, which is defined as zero mites per lash consistently throughout trials.
** Primary endpoint in Io, Europa, Saturn-1 and intended in Saturn-2 is collarette cure based on collarette grade.
† In connection with our IND application, a "no-objection" letter was received from the FDA regarding the trial design of the Saturn-1 trial.
††Saturn-2 design is highly comparable to that of Saturn-1 with respect to which the FDA raised no-objection and we expect to update the IND protocol prior to commencing Saturn-2.

Represents pivotal trial

Same formulation of TP-03 as expected in the Saturn trials

tarsus

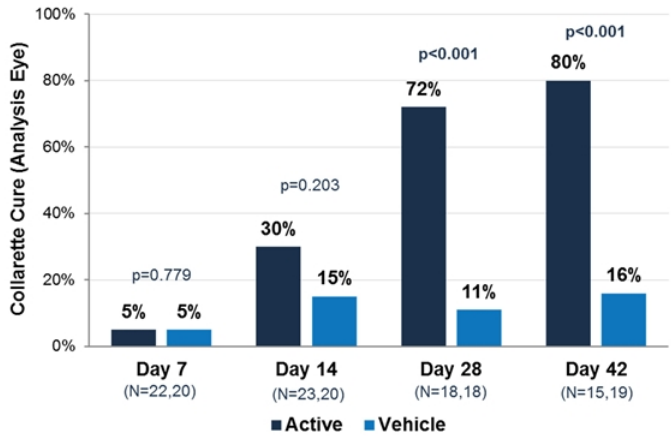
Cure of Collarettes with BID Use of TP-03



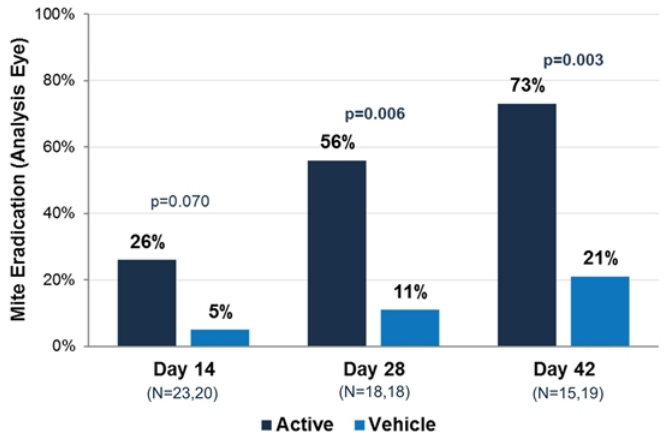
Europa Phase 2b: Results Consistent with Jupiter Trial

Primary and secondary efficacy endpoints same as Saturn-1 trial

Collarette Cure (0-2 collarettes)*



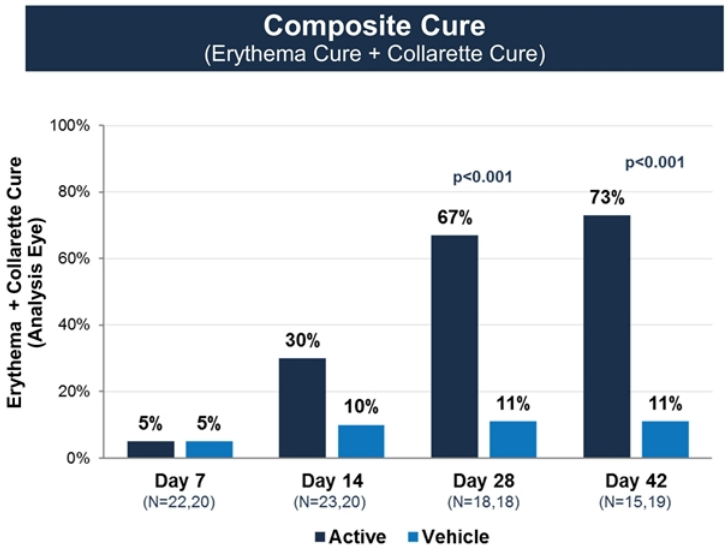
Mite Eradication (0 mites)



* The primary efficacy endpoint was the proportion of patients experiencing a cure based on collarette grade of two or fewer collarettes on the eyelid, or collarette cure, as compared to the vehicle control, at day 42.

Europa Phase 2b: Statistically Significant Composite Cure Rate

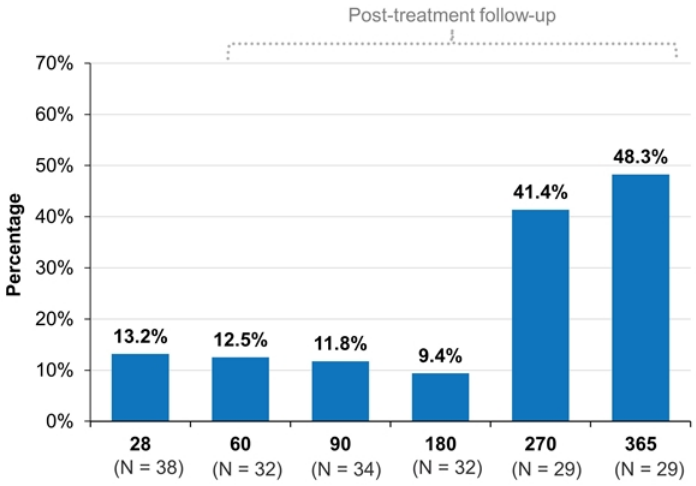
Lid erythema cure + collarette cure, FDA-requested additional secondary endpoint



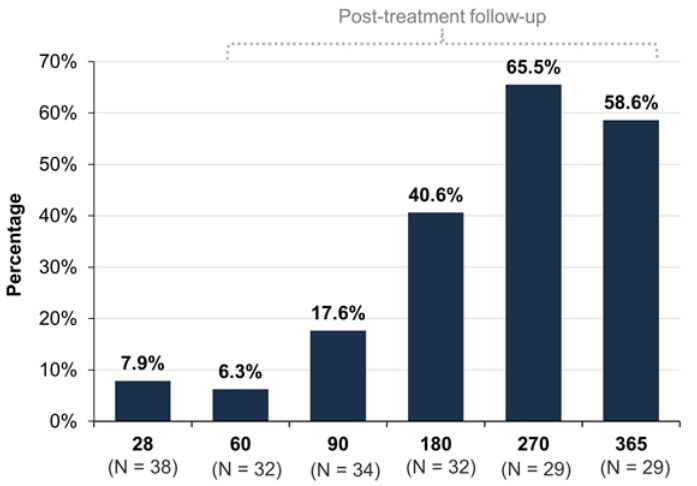
TP-03 Phase 2 Clinical Data Show Recurrence Rate of Clinical-Grade Demodex Blepharitis Post-Treatment

Post treatment data from Mars & Jupiter trials show recurrence of both collarettes & mite density

>10 Collarettes on Lid



Mite Density of 1.0 or More



Data account for presence of collarettes or mites on either eye, (upper eyelid for collarette score)

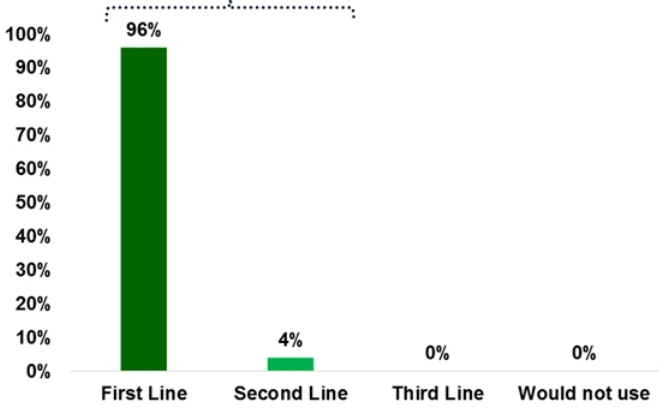
tarsus

Market Research Shows Positive Reaction from Providers and Patients

After exposure to information on collarettes, Demodex blepharitis and TP-03 Phase 2 data

Clinician Prescribing Intention

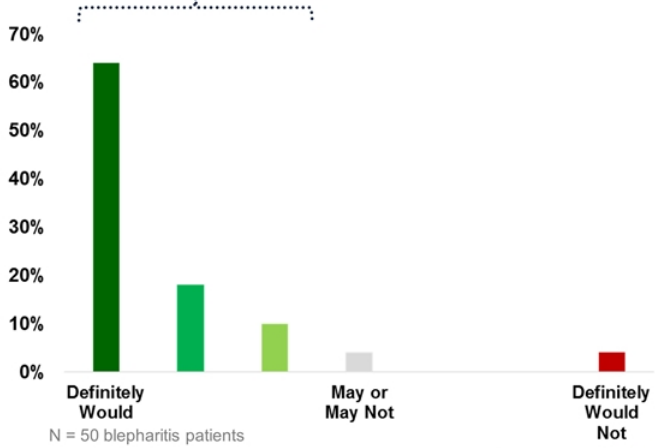
100% of ECPs indicated would prescribe 1L or 2L for Demodex blepharitis



N = 50 eye care providers (25 MDs, 25 ODs)
Market research sponsored by Tarsus

Patient Intention to Seek a Doctor

92% of blepharitis patients indicated would likely seek a doctor and ask about TP-03



N = 50 blepharitis patients

tarsus

TP-03 has Significant Market Potential in Demodex Blepharitis

Opportunity comparable to established ophthalmic therapeutics

Large addressable patient population

- High prevalence of an estimated 25 million patients and untapped educational opportunity similar to Dry Eye*
- 2.1 million current ICD-10 blepharitis diagnoses per year in U.S. (estimated 45% of these with Demodex infestation)
- Besides blepharitis, patients commonly present at ECPs with other conditions such as dry eye, cataracts, and contact lens discomfort

ECPs are generally believed to be comfortable treating ocular surface disease and respond to marketing education

- 25k active prescribers
- We have observed a significant willingness to prescribe by ECPs

Potential for favorable reimbursement

- Potential to be the first approved prescription treatment for Demodex blepharitis, strong and predictable outcomes drive value for payers
- We believe a novel treatment will drive compelling pricing and modest discounts

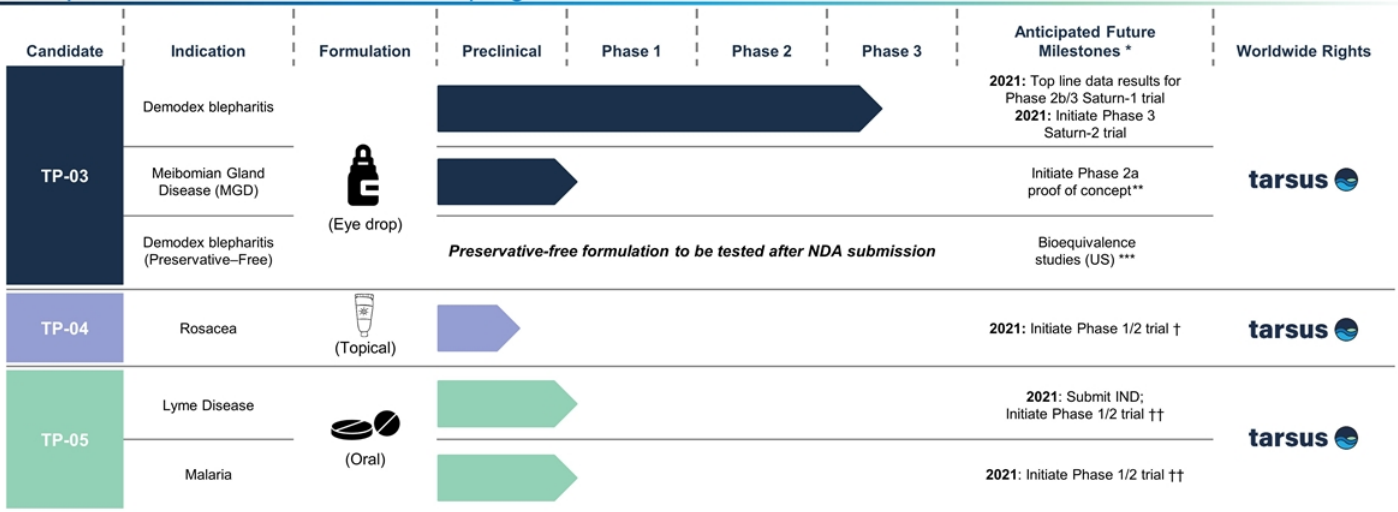
We Believe There are 3 Keys to Success

1. Educate ECPs about the prevalence of Demodex blepharitis and the safety and efficacy of our products
2. Highlight prevalence, impact, and simplicity of diagnosis of Demodex blepharitis
3. Patient focused education and marketing that increases awareness and patient identification

*The market for Demodex blepharitis may not be similar based on differences in the underlying disease, different ECP and patient attitudes, and treatment and/or key assumptions we have not taken into our analysis

Pipeline with Different Formulations of Novel API

Anticipated clinical trial events in our programs in 2021



* Anticipated milestones are subject to the impact of the ongoing COVID-19 pandemic on our business and those of our partners.

** We intend to rely on preclinical studies and clinical safety assessments from the Demodex blepharitis program. We have not conducted and do not intend to conduct any preclinical studies with TP-03 for the treatment of MGD in order to advance to Phase 2a.

*** We intend to leverage all preclinical, Phase 2 and Phase 3 data from the TP-03 Demodex blepharitis program. We intend to conduct *in vitro* or *in vivo* bioequivalence studies with our preservative-free formulation to compare it to the current preserved formulation of TP-03 in Demodex blepharitis after NDA submission and file a supplement.

† We intend to leverage systemic preclinical data from our TP-03 program and augment with additional dermal preclinical studies to select formulation in order to advance to Phase 1/2, which we intend to conduct outside the United States. We may need to address this approach with the FDA if we were to conduct a clinical trial in the United States. We have not conducted any preclinical studies in rosacea with TP-04 to date.

†† In relation to Lyme disease and malaria, we intend to leverage oral systemic preclinical data from our TP-03 program as well as third-party oral systemic preclinical studies for Lyme disease or community malaria reduction, respectively (and will not conduct our own preclinical studies for Lyme disease and malaria). The formulations used in preclinical studies use the common approach of a gavage that is scaled as appropriate for use in animals. However, human administration, while continuing to be oral, will take the form of a tablet or capsule. Subject to FDA feedback from our planned pre-IND meeting, we intend to conduct Phase 1/2 trials in these indications based on these preclinical studies. In relation to malaria, we may conduct our Phase 1/2 trial outside the United States. While we plan to discuss this approach for Lyme disease in a planned pre-IND meeting with the FDA, the FDA may reject our use of data from these preclinical studies and require us to conduct additional preclinical studies before advancing to clinical trials, which may delay our expected timelines for approval and increase costs.

tarsus

Tarsus Summary

- TP-03 is a novel therapeutic with potential to be the first FDA-approved therapeutic and the standard of care for the treatment of Demodex blepharitis
- Clinical efficacy and safety endpoints consistently achieved across multiple Phase 2 studies
- Phase 2b/3 Saturn-1 **currently enrolling and treating patients, topline expected in 2021**, followed by initiation of Phase 3 Saturn-2 trial in 2021[1]
- Clinical stage pipeline with potential applications to other indications in MGD, rosacea, Lyme disease, and malaria
- Multiple clinical events anticipated in 2021

1. Both subject to the impact of the ongoing COVID-19 pandemic