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): June 21, 2021

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) **(Zip Code)**

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

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:

☐ 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, $0.0001 par value 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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 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 8.01. Other Events.

On June 21, 2021, Tarsus Pharmaceuticals, Inc. (the "Company") issued a press release announcing positive results of the Company's Saturn-1 pivotal trial evaluating TP-03 for the treatment of Demodex blepharitis. All pre-specified primary and secondary endpoints were met for the Saturn-1 trial. The Saturn-1 trial met the primary endpoint by demonstrating a statistically significant complete collarette cure at day 43 in patients with Demodex blepharitis treated with TP-03 compared to vehicle ($p<0.0001$; primary endpoint). The Saturn-1 trial also met the secondary endpoints of mite eradication ($p<0.0001$) and composite cure at day 43 based on complete collarette and erythema cures at day 43 ($p<0.0001$). In addition, significant, clinically meaningful improvements were observed within two weeks across multiple endpoints. TP-03 was well tolerated with a safety profile similar to vehicle, and there were no treatment-related discontinuations.

On June 21, 2021, the Company presented a corporate presentation relating to its positive results of the Saturn-1 pivotal 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 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in the corporate presentation is summary information that is intended to be considered in the context of the more complete information included in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such update may be made through the filing of other reports or documents with the SEC.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Tarsus Pharmaceuticals, Inc. Press Release Issued June 21, 2021.
99.2	Tarsus Pharmaceuticals, Inc. Corporate Presentation.
104	Cover Page Interactive Data File (embedded within XBRL document)

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.

Tarsus Pharmaceuticals, Inc.

DATE: June 21, 2021

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

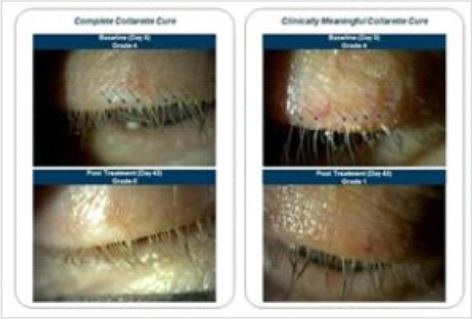
Tarsus Pharmaceuticals, Inc. Announces Positive Results of Saturn-1 Pivotal Trial Evaluating TP-03 for the Treatment of Demodex Blepharitis

Saturn-1 Phase 2b/3 trial met all primary and secondary endpoints, and demonstrated significant, clinically meaningful outcomes with no serious treatment-related adverse events and no treatment-related discontinuations, demonstrating the potential of TP-03 to treat Demodex blepharitis, a disease with no FDA-approved therapies

As many as 25 million Americans may have Demodex blepharitis, an ocular disease that can have a significant clinical burden and negatively impact patients' daily lives

Conference call and webcast scheduled for today at 8:00 a.m. ET to review detailed topline Saturn-1 data

Saturn-1 patients' collarettes at baseline and post treatment



Saturn-1 patients' collarettes at baseline (Day 0, Grade 4) and post treatment (Day 43, Grade 0, left) and (Day 43, Grade 1, right). Images demonstrate results which we believe are representative of favorable treatment with TP-03 for patients participating in the Saturn-1 trial. Other patients may experience different or less favorable results.

IRVINE, Calif., June 21, 2021 (GLOBE NEWSWIRE) — Tarsus Pharmaceuticals, Inc. (NASDAQ: TARS), a late clinical-stage biopharmaceutical company whose mission is to focus on unmet needs and apply proven science and new technology to revolutionize treatment for patients, starting with eye care, today announced that all pre-specified primary and secondary endpoints were met for its pivotal Phase 2b/3 Saturn-1 trial evaluating the company's novel investigational therapeutic, TP-03 (lotilaner ophthalmic solution, 0.25%), in patients with Demodex blepharitis. Results demonstrated a statistically significant complete collarette cure at day 43 in patients with Demodex blepharitis treated with TP-03 compared to vehicle (p<0.0001; primary endpoint). The Saturn-1 trial also met the secondary endpoints of mite eradication at day 43 (p<0.0001) and composite cure based on complete collarette and erythema cures at day 43 (p<0.0001). In addition, significant, clinically meaningful improvements were observed within two weeks across multiple endpoints. TP-03 was well tolerated with a safety profile similar to vehicle, and there were no treatment-related discontinuations.

"Millions of people are living with Demodex blepharitis, and we know from recent research that these patients are suffering daily. With no U.S. Food and Drug Administration (FDA)-approved therapies, both patients and eye care professionals need a solution to eradicate the mites that cause the disease," said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. "We believe the results from our Saturn-1 trial mark an important moment in Demodex blepharitis research, showing the potential of TP-03 to target the underlying cause of this disease and potentially become the standard of care for patients and clinicians. We expect to provide topline results for our second pivotal trial for TP-03, Saturn-2, in Q1 of 2022. If Saturn-2 trial data is positive, similar to the positive Saturn-1 results, we expect both Saturn-1 and Saturn-2 trials to support our submission of a New Drug Application (NDA) for TP-03 for the treatment of Demodex blepharitis in 2022."

Demodex blepharitis is a highly prevalent ocular disease, affecting as many as 25 million Americans, that can have a significant clinical burden and negatively impact patients' daily lives. The disease is caused by an infestation of Demodex mites, the most common ectoparasite found on humans, that live on the skin of the face and eyelids. Demodex blepharitis is characterized by inflammation of the eyelid margin, redness and ocular irritation. TP-03 has the potential to be the first FDA-approved therapeutic for Demodex blepharitis and targets the underlying cause of disease – Demodex mite infestation. The Saturn-1 trial is the first large-scale trial to show positive, clinically meaningful results for a therapeutic specifically designed to treat Demodex blepharitis.

Saturn-1 Phase 2b/3 Results

Results demonstrated 81% of patients achieved a significant, clinically meaningful collarette cure defined by a collarette grade of zero (0) or one (1) at day 43 compared to 23% of those on vehicle (p<0.0001). Additionally, a significant, clinically meaningful collarette cure was seen in 23% of patients on TP-03 compared to 11% on vehicle as early as day 8 (p=0.0003). Saturn-1 data also showed that 43% of patients on TP-03 achieved the primary endpoint of complete collarette cure (grade 0) at day 43, defined as zero to two (0-2) collarettes per lid compared to 7% on vehicle (p<0.0001). Collarettes, a pathognomonic sign of Demodex infestation, are composed of partially digested epithelial cells, mite waste products and eggs and are most easily observed at the base of the upper eyelashes when the patient looks down during a standard eye examination.

The secondary endpoint of complete mite eradication achieved statistically significant results by day 15, and 68% of patients on TP-03 achieved mite eradication compared to 18% on vehicle (p<0.0001) at day 43. Mite eradication is defined as a mite density of zero (0) mites per lash.

For composite cure, 68% of patients experienced a significant, clinically meaningful cure of both a grade zero (0) or one (1) collarette and erythema score at day 43 compared to 20% on vehicle (p<0.0001), with significant improvements seen as early as day 8. Additionally, 13.4% of patients on TP-03 achieved a complete composite cure, which was another secondary endpoint, based on a composite of collarette cure and erythema cure compared to 1.0% on vehicle (p<0.0001) at day 43. Composite cure is defined as the presence of zero to two (0-2) collarettes on the upper eyelid and the absence of erythema (redness). Results for complete erythema cure (19% of patients on TP-03 compared to 7% of patients on vehicle, *p<0.0001)* and one (1) grade or more erythema improvement (45% of patients on TP-03 compared to 28% of patients on vehicle, *p=0.0002)* were also statistically significant.

Trial Safety Data

TP-03 is a well-characterized anti-parasitic agent that paralyzes and eradicates Demodex mites by selectively inhibiting parasite-specific GABA-Cl channels. Saturn-1 trial results demonstrated that TP-03 was well tolerated with a safety profile similar to the vehicle group. Additionally, most TP-03 patients (92%) reported that the drop comfort was neutral to very comfortable. There were no serious treatment-related adverse events nor any treatment-related adverse events leading to treatment discontinuation. All treatment-related ocular adverse events in the TP-03 group were mild with the most common being instillation site pain/burning/stinging (11.8%, n=25). Other adverse events occurring at a rate of ³1% in the TP-03 group included instillation site pruritis, reduced visual acuity, eye pain and eye discharge, each representing 1.4% (n=3) of patients.

Saturn-1 Phase 2b/3 Trial Design

Saturn-1 was a randomized, controlled, multicenter, double-masked trial evaluating the safety and efficacy of TP-03 in adults with Demodex blepharitis. The trial enrolled 421 adults aged 18 and over having more than 10 collarettes on the upper lid and at least mild erythema of the upper eyelid margin. Each patient had at least 1.5 mites per lash on the upper and lower eyelids combined. One drop of TP-03 was self-administered twice per day in each eye for six weeks and patients were instructed not to touch or rub their lid margin. Enrolled patients received no treatment for blepharitis symptoms (i.e., lid hygiene) during the trial or 14 days prior to enrollment.

“Demodex blepharitis is a widespread, yet frequently overlooked condition that can negatively impact the quality of life for many patients and lead to more serious health outcomes if left untreated,” said Elizabeth Yeu, M.D., Chief Medical Advisor for Tarsus. “I am highly encouraged by the results seen in the Saturn-1 trial and I’m hopeful that there may be a treatment option on the horizon that targets the underlying cause of this disease to help patients finally find relief.”

Tarsus is also evaluating TP-03 in its pivotal Saturn-2 (Phase 3) trial, which has the same endpoints as Saturn-1, and commenced patient enrollment in May of 2021. Tarsus expects topline results for the Saturn-2 trial in Q1 2022, and, if the results are similarly positive, Tarsus expects data from both the Saturn-1 and Saturn-2 trials to support submission of a New Drug Application (NDA) to the FDA for TP-03 for the treatment of Demodex blepharitis. TP-03 has the potential to help millions of patients and eye care professionals struggling to manage Demodex blepharitis.

Conference Call and Webcast Information

A detailed summary of the Saturn-1 findings will be presented on a conference call and live, listen-only webcast today at 8:00 a.m. ET. The dial-in numbers are (833) 540-1160 for domestic callers and (929) 517-0351 for international callers. The Conference ID is 3766845. The webcast of the conference call can be accessed at https://edge.media-server.com/mmc/p/uh6zebmu. After the live webcast, the event will remain archived on the Tarsus Pharmaceuticals website at https://ir.tarsusrx.com/ for 90 days.

About TP-03

TP-03 (lotilaner ophthalmic solution, 0.25%) is a novel, investigational therapeutic designed to target and eradicate Demodex mites. TP-03 is a topical ophthalmic formulation of lotilaner, which is a well-characterized anti-parasitic agent that paralyzes and eradicates Demodex mites by selectively inhibiting parasite-specific GABA-Cl channels. It is a potent, non-competitive antagonist of insect and arachnid GABA-Cl channels and a highly lipophilic molecule, which may promote its uptake in the oily sebum of the hair follicle where the mites reside. Tarsus has completed four Phase 2 clinical trials of TP-03 in Demodex blepharitis, all of which met their respective endpoints with no significant adverse events nor any events leading to treatment discontinuation. TP-03 was also evaluated in the pivotal Saturn-1 (Phase 2b/3) trial and met all primary and secondary endpoints with no serious treatment-related adverse events and no treatment-related discontinuations. It is currently being evaluated in the Saturn-2 (Phase 3) pivotal trial. If approved, TP-03 may offer treatment for millions of patients around the world with Demodex blepharitis.

About Demodex Blepharitis

Blepharitis is a common ocular condition that is characterized by inflammation of the eyelid margin, redness and ocular irritation. Demodex blepharitis is caused by infestation of Demodex mites, the most common ectoparasite found on humans. Demodex mites cause approximately 45% of blepharitis, or about 9 million cases in the U.S. and the number may be as high as approximately 25 million based on Tarsus’ internal research indicating about 58% of patients presenting to eye care clinics have collarettes, a pathognomonic sign of Demodex infestation, and a published study estimating that at least 45 million people annually visit an eye care clinic. Currently, there are no FDA-approved treatments for Demodex blepharitis.

About Tarsus Pharmaceuticals, Inc.

Tarsus Pharmaceuticals, Inc. is a late clinical-stage biopharmaceutical company that applies proven science and new technology to revolutionize treatment for patients, starting with eye care. It is advancing its pipeline to address several diseases with high unmet need across a range of therapeutic categories, including eye care, dermatology, and infectious disease prevention. The company is studying two investigational medicines in clinical trials. Its lead product candidate, TP-03, is a novel therapeutic being studied in a second Phase 3 pivotal trial for the treatment of Demodex blepharitis. TP-03 is also being developed for the treatment of Meibomian Gland Disease. Tarsus is developing TP-05, an oral, non-vaccine therapeutic for the prevention of Lyme disease, which is currently being studied in a Phase 1 clinical trial.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute “forward-looking statements.” These statements includes statements regarding Tarsus’ plans for and the anticipating benefits of its product candidates, including TP-03, the timing, objectives and results of the clinical trials and anticipated regulatory and development milestones, including the timing of the Saturn-2 clinical trial and submission of an NDA, and the quotations of Tarsus’ management. The words, without limitation, “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would,” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these or similar identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Important factors that could cause actual results to differ materially from those in the forward-looking statements include: Tarsus has incurred significant losses and negative cash flows from operations since inception and anticipates that it will continue to incur significant expenses and losses for the foreseeable future; Tarsus may need to obtain additional funding to complete the development and any commercialization of its product candidates, if approved; Tarsus is heavily dependent on the success of its lead product candidate, TP-03 for the treatment of Demodex blepharitis; the COVID-19 pandemic may affect Tarsus’ ability to initiate and complete preclinical studies and clinical trials, disrupt regulatory activities, disrupt manufacturing and supply chain or have other adverse effects on Tarsus’ business and operations; even if TP-03, TP-05, or any other product candidate that Tarsus develops receives marketing approval, Tarsus may not be successful in educating eye care physicians and the market about the need for treatments specifically for Demodex blepharitis, Lyme disease, and/or other diseases or conditions targeted by Tarsus’ products; the development and commercialization of Tarsus products is dependent on intellectual property it licenses from Elanco Tiergesundheit AG; Tarsus will need to develop and expand the company and Tarsus may encounter difficulties in managing its growth, which could disrupt its operations; the sizes of the market opportunity for Tarsus’ product candidates, particularly TP-03 for the treatment of Demodex blepharitis and MGD, as well as TP-05 for the treatment of Lyme disease, have not been established with precision and may be smaller than estimated; the results of Tarsus’ earlier studies and trials may not be predictive of future results; any termination or suspension of, or delays in the commencement or completion of, Tarsus’ planned clinical trials could result in increased costs, delay or limit its ability to generate revenue and adversely affect its commercial prospects; and if Tarsus is unable to obtain and maintain sufficient intellectual property protection for its product candidates, or if the scope of the intellectual property protection is not sufficiently broad, Tarsus’ competitors could develop and commercialize products similar or identical to Tarsus’ products. Further, there are other risks and uncertainties that could cause actual results to differ from those set forth in the forward-looking statement and they are detailed from time to time in the reports Tarsus files with the Securities and Exchange Commission, including Tarsus’ Form 10-K for the year ended December 31, 2020 filed with the SEC on March 31, 2021 and Form 10-Q for the quarter ended March 31, 2021 filed with the SEC on May 11, 2021, which Tarsus incorporates by reference into this press release and copies of which are posted on its website and are available from Tarsus 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. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Any forward-looking statements contained in this press release are based on the current expectations of Tarsus’ management team and speak only as of the date hereof, and Tarsus specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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A photo accompanying this announcement is available at https://pr.globenewswire.com/FileDownloader/DownloadFile?source=pnr&fileGuid=d788bb0e-ef21-4338-aa1d-dc7612611b81

Exhibit 99.2

Saturn-1 Investor Presentation

Pivotal Trial Topline Data and Corporate Update

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 about future events 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 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 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; 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; the commercialization and market acceptance of our product candidates; and the implementation of our business model and strategic plans for our business and product candidates 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. Photos in this presentation relating specifically to the Saturn-1 trial will be explicitly denoted as such.

Participants on Today's Call

Bobby Azamian, M.D., Ph.D., President & CEO, Co-Founder
- Former CEO/CMO Metavention
- Extensive investment/entrepreneurial experience with Versant and Third Rock Ventures
- Medicine at Brigham, M.D., Harvard, Ph.D. Chemistry, Oxford

Metavention VERSANT THIRD ROCK

Leo Greenstein, J.D., CPA, Chief Financial Officer
- Former SVP, Finance & Corporate Controller of Spectrum Pharmaceuticals, Inc.
- 20+ years of finance leadership within publicly-traded companies
- Certified Public Accountant and Member of State Bar of California

SPECTRUM Endologix CLARIENT

Elizabeth Yeu, M.D., Chief Medical Advisor
- Nationally recognized leader in Ophthalmology
- Cornea, Cataract, Refractive and Ocular surface specialist
- Future President American Society of Cataract and Refractive Surgeons (ASCRS)

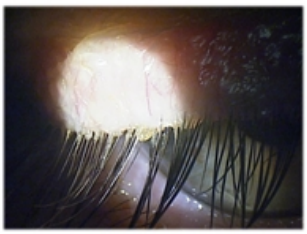
VIRGINIAeye consultants ASCRS

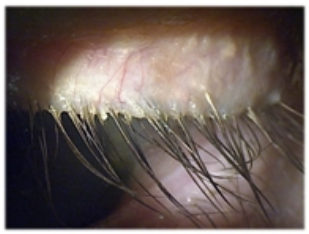
Aziz Mottiwala, MBA, Chief Commercial Officer
- Former CCO Opiant, and Head of Commercial at Avanir
- Former VP Marketing, Allergan Eye Care,(Restasis®, Lumigan®)
- 20+ years of Commercial experience, with 10+ years in eye care

opiant AVANIR Allergan

Demodex Blepharitis

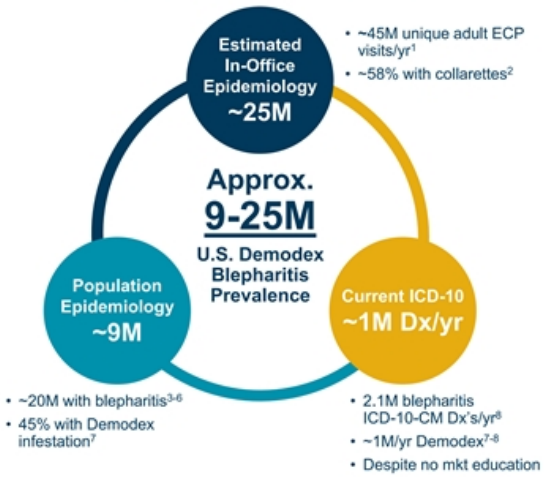
Example patient

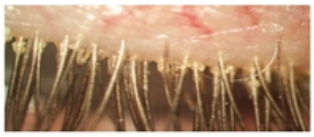




Blepharitis Is a Large and Underserved Market in Eye Care

Epidemiology of Demodex Blepharitis





Large Patient Population with Significant Disease Impact	**Titan** (collarette clinic prevalence) and **Atlas** (disease impact) studies demonstrate high prevalence of disease and significant burden on patients
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; 81% of patients currently seeking treatment[11]

1. Wilson J Ophthalmology 2015, 435606, 2014; 2. Titan 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 11.Atlas pre screening study

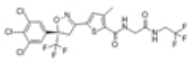
Agenda

- **Saturn-1 topline data presentation**
- **Saturn-2 update**
- **Tarsus corporate update**
  - Corporate vision
  - TP-03 market opportunity
  - Pipeline progress update
  - Upcoming catalysts

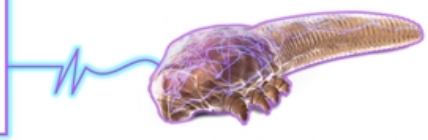
Saturn-1 Topline Data

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

Lotilaner



- Potent non-competitive antagonist of insect and arachnid GABA-Cl channels
- Highly lipophilic molecule
- **Projected Orange Book Exclusivity to at least 2038**



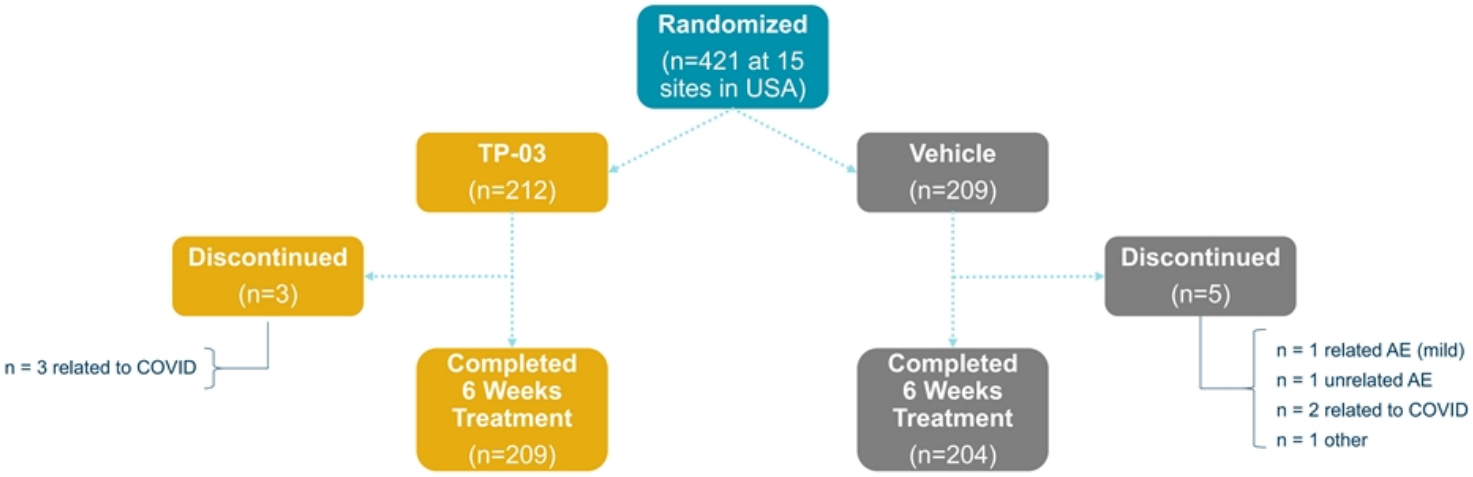
Product Form	Multi-dose eye drop solution bottle, preserved
Targeted Use	Treatment of Demodex blepharitis
MOA	Paralysis and death of Demodex mites
Diagnosis	Collarettes identified in standard eye examination
Dosing	BID* for 6 weeks
Efficacy Goal	1° collarette cure rate, 2° mite eradication, 2° redness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

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

*BID means twice per day

Saturn-1 Patient Enrollment and Follow-up

6 Week Treatment and Follow-up, twice a day drop without any touching or wiping of lid margin



Saturn-1: All Primary and Secondary Endpoints Met and Clinically Meaningful Effects Demonstrated with TP-03

- **Efficacy:** All pre-specified primary and secondary endpoints were met
  - ☑ Primary Endpoint: Complete Collarette Cure **p < 0.0001**
  - ☑ Clinically Meaningful Collarette Cure (Grade 0 or 1) **p < 0.0001**
  - ☑ Secondary Endpoint: Mite Eradication **p < 0.0001**
  - ☑ Secondary Endpoint: Composite Lid Erythema and Collarette Complete Cure **p < 0.0001**
  - ☑ Clinically Meaningful Composite Lid Erythema and Collarette Cure **p < 0.0001**
  - ☑ Erythema Cure **p = 0.0001** and Erythema Response **p = 0.0002**
  - ☑ Rapid Cures: Improvements Seen in 2 Weeks **p ≤ 0.0149 in Primary and Secondary Endpoints**

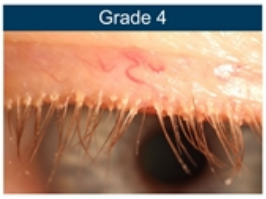
- **Safety:** TP-03 was well-tolerated, with safety profile similar to vehicle
  - ☑ All TP-03-related AE's were mild with no treatment related discontinuations
  - ☑ 92% of patients reported the drop to be neutral to very comfortable

Collarette Grading Scale Used in Saturn-1

Non-linear scale for counting collarettes performed by each site investigator

Average baseline

Grade 4

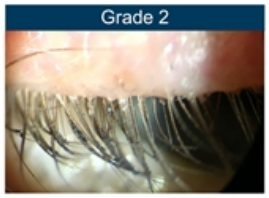


- **>2/3 of lashes** on lid with collarettes
- Approximately 150 collarettes/lid

Grade 3

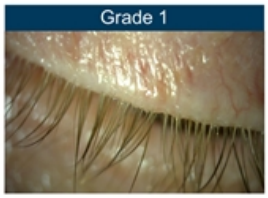
- **Between 1/3-2/3 of lashes** on lid with collarettes
- Approximately 100 collarettes/lid

Grade 2



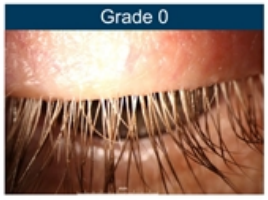
- **Between 10 collarettes to 1/3 of lashes** on lid with collarettes
- Approximately 50 collarettes/lid

Grade 1



- **3-10 collarettes** on the lashes

Grade 0



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

Photos are images taken of patients in Saturn-1 with the corresponding collarette grade.

Mite Density Determination Used in Saturn-1

Trained mite-counters (CRO) used for consistency across sites

Step 1

- **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

Step 2

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

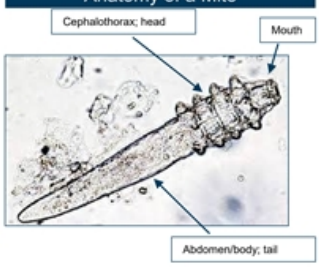
Step 3

- 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

Step 4

- 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

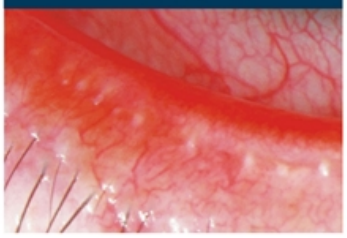
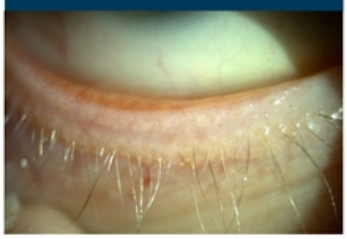
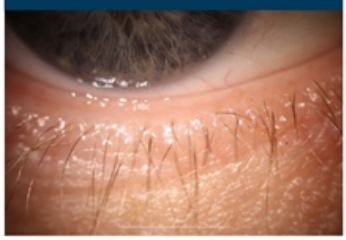
Anatomy of a Mite



Lid Margin Erythema Scale Used in Saturn-1

Established and validated scale used in blepharitis studies, performed by each investigator

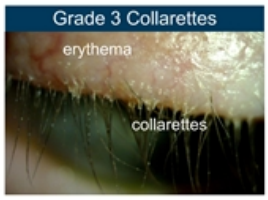
Average baseline 1.5

Grade 3	Grade 2	Grade 1	Grade 0
			
3 (Severe)*	**2 (Moderate)**	**1 (Mild)**	**0 (None)**

Hosseini K, Bourque LB, Hays RD. Development and evaluation of a measure of patient-reported symptoms of blepharitis. Health and Quality of Life Outcomes 2018;16:11 May 2018. Drug Design, Development and Therapy Volume 12:1269-1279

Saturn-1 Baseline Characteristics

	TP-03	Vehicle
Age	66.1	67.8
Female %	58	56
Collarette Score	2.8	2.8
Mite Density	3.2	3.2
Erythema Score	1.5	1.5

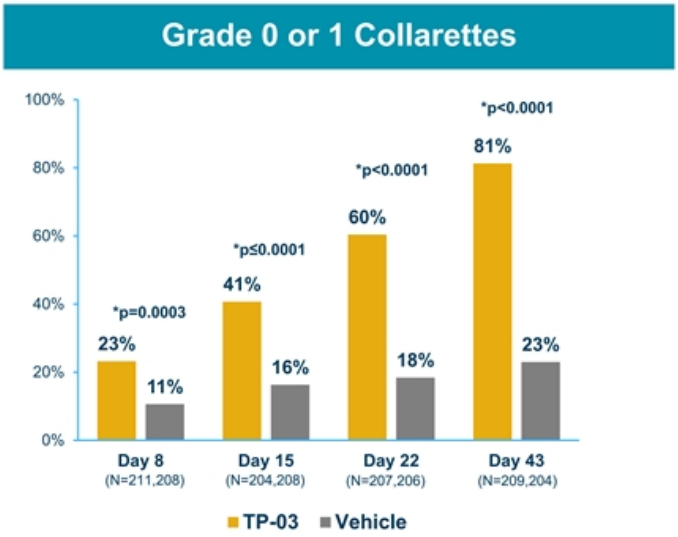


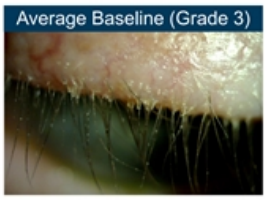
Photos are images taken of patients in Saturn-1

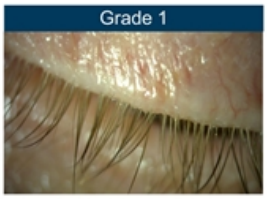
Clinically Meaningful Collarette Cure

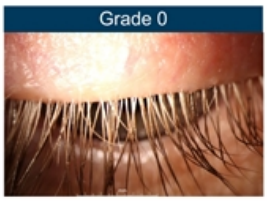
Clinically Meaningful Collarette Cure Observed by Week 1

Over 90% Avg. Reduction in Collarettes (Over 100 to Less than 10 per Lid)





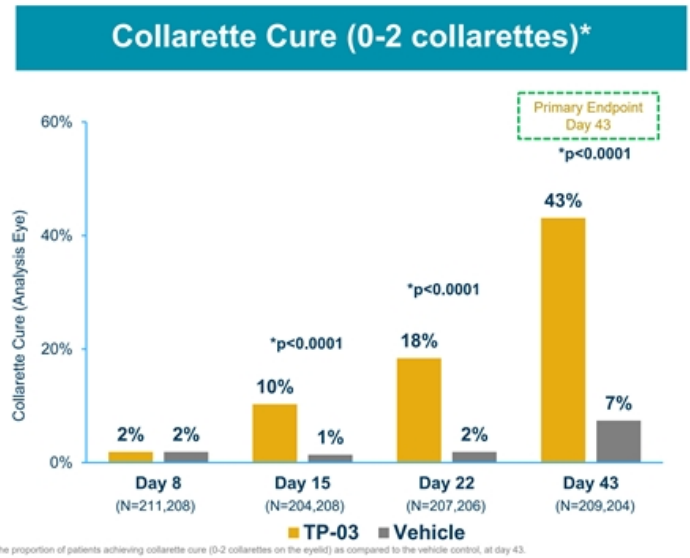


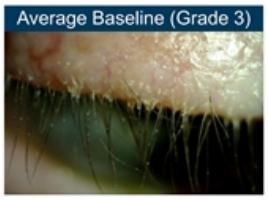


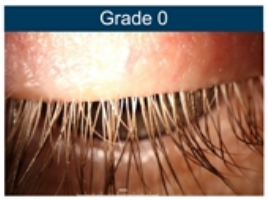
Photos are images taken of patients in Saturn-1 with the corresponding collarette grade.

Primary Endpoint of Complete Collarette Cure Achieved

Regulatory Endpoint of Complete Collarette Cure Observed by Week 2







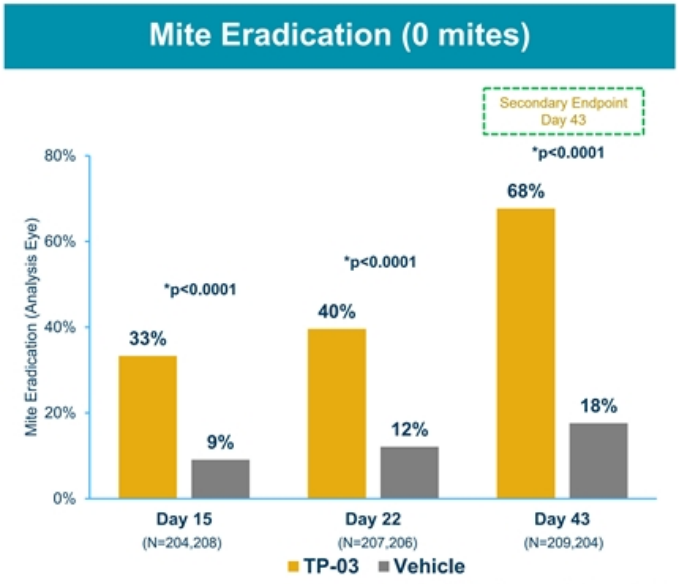
- The primary efficacy endpoint was the proportion of patients achieving collarette cure (0-2 collarettes on the eyelid) as compared to the vehicle control, at day 43.

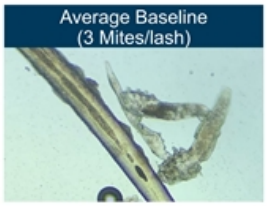
Photos are images taken of patients in Saturn-1 with the corresponding collarette grade.

Secondary Endpoint of Mite Eradication Rate Achieved

Complete Mite Eradication Observed by Week 2

68% of Patients Experienced Complete Eradication at Week 6 (Secondary Endpoint)



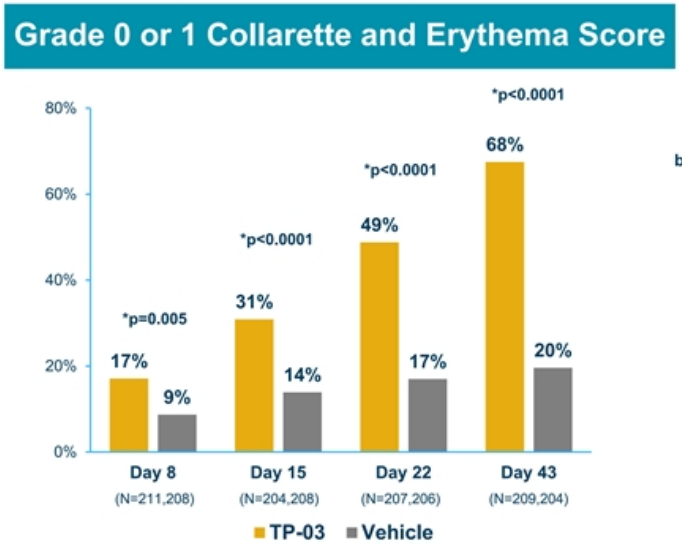


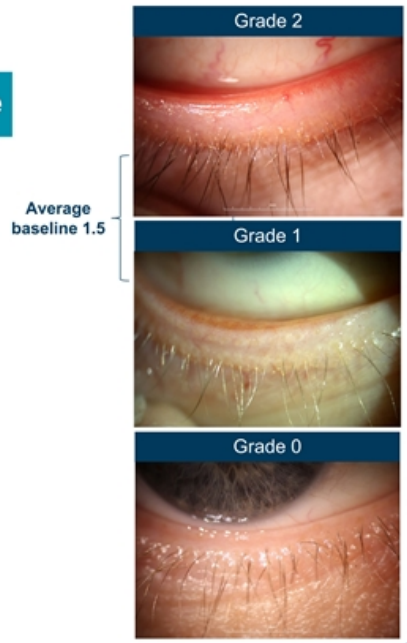
* Day 43 Vehicle results for secondary efficacy analysis with imputation is 17.3%

Clinically Meaningful Composite Cure

Clinically Meaningful Composite Cure Improvements Observed by Week 2

68% of Patients Experienced a Grade 0 or 1 Collarette and Erythema Score

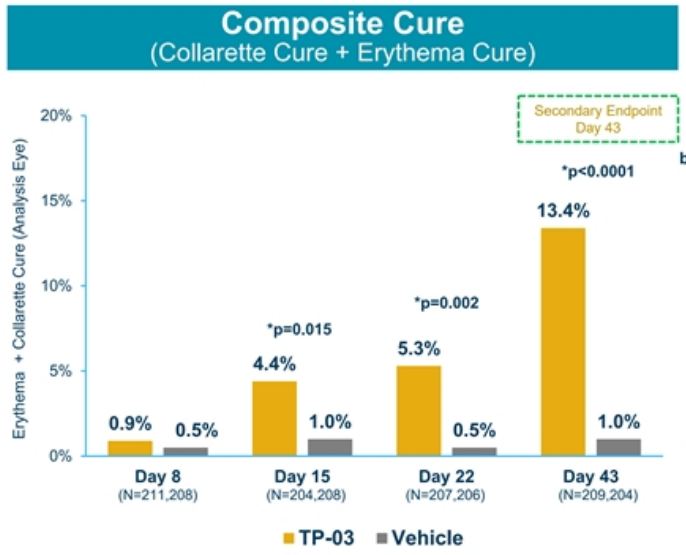


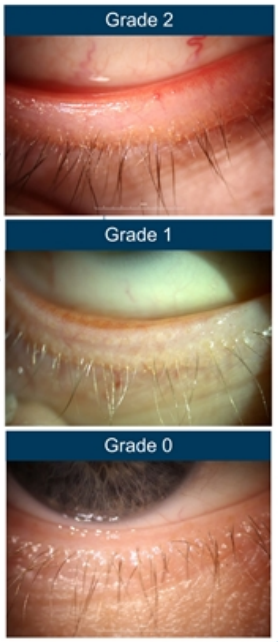


Photos are images taken of patients in Saturn-1.

Secondary Endpoint of Complete Composite Cure Achieved

Endpoint of Complete Composite Cure Observed by Week 2





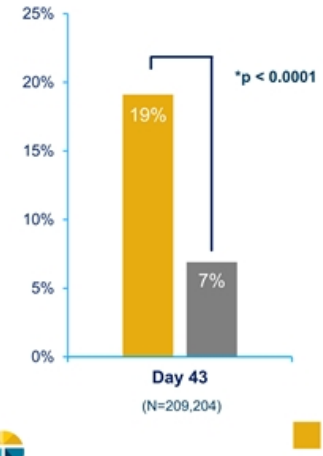
Photos are images taken of patients in Saturn-1.

Erythema Cure and Response

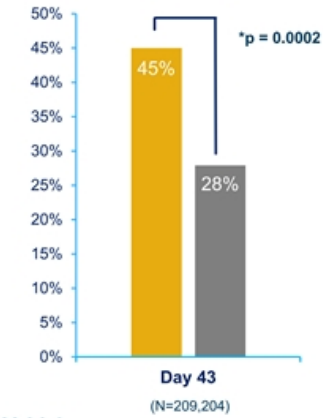
19% of Patients Experienced Complete Erythema Cure at Day 43

45% of Patients Experienced Erythema Improvement at Day 43

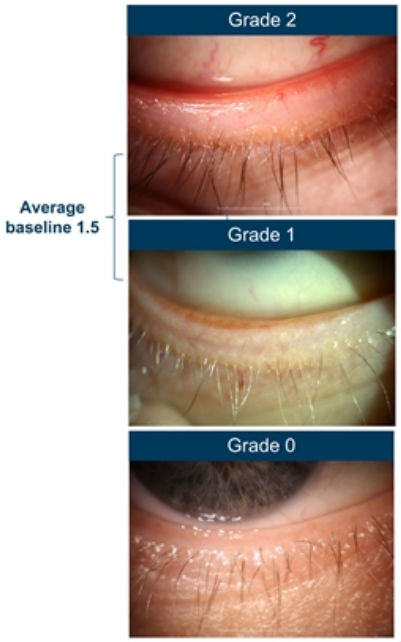
Grade 0 Erythema



1 Grade or More Erythema Improvement



TP-03 Vehicle



Ora Calibra® Scale

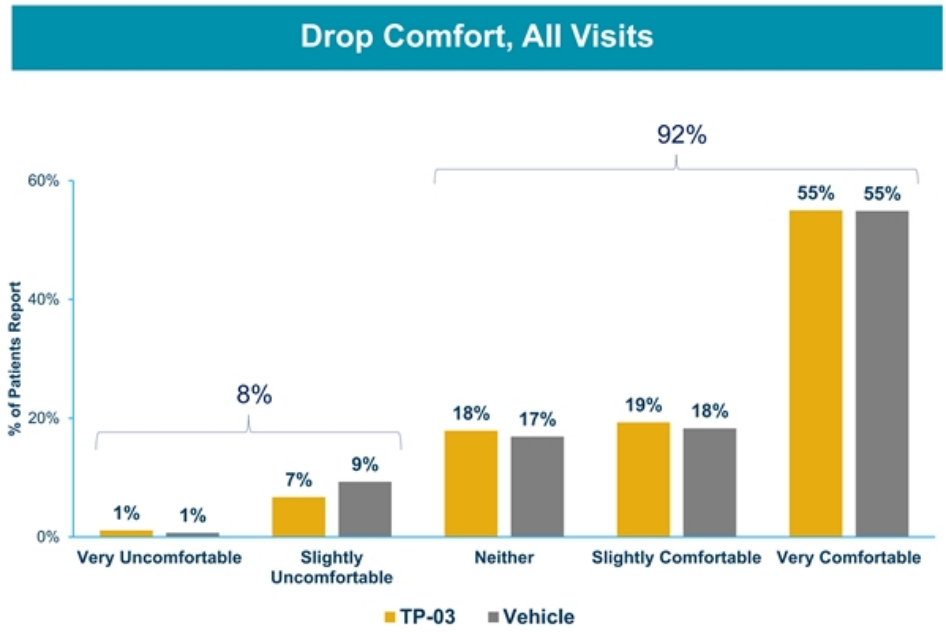
Photos are images taken of patients in Saturn-1.

Adverse Event Summary

- **Treatment related ocular AEs occurring at rate of ≥ 1% in active group**
  - Summary of Adverse Events occurring at any time during trial

	TP-03 (n=212)	Vehicle (n=209)
Instillation site pain/burning/stinging	25 (11.8%)	16 (7.7%)
Instillation site pruritis	3 (1.4%)	7 (3.3%)
Visual acuity reduced	3 (1.4%)	5 (2.4%)
Eye pain	3 (1.4%)	2 (1.0%)
Eye discharge	3 (1.4%)	1 (0.5%)
AE Severity	All Mild	One moderate AE All other AEs mild

TP-03 Was Well Tolerated With 92% of Patients Reporting TP-03 to Be Neutral to Very Comfortable

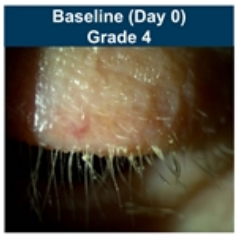


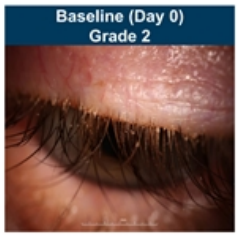
Improvements Seen Post Treatment Have Significant Clinical Impact

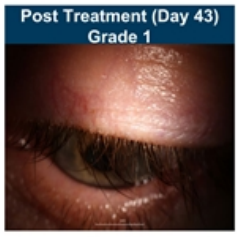
Cure rates and clinically meaningful effects validate the opportunity to benefit a large proportion of patients

Complete Collarette Cure

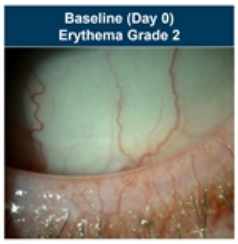
Clinically Meaningful Collarette Cure

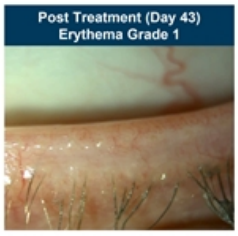






Erythema Response





Photos are images taken of patients in Saturn-1. Images demonstrate results which we believe are representative of favorable treatment with TP-03 for patients participating in the Saturn-1 trial. Other patients may experience different or less favorable results.

Conclusions

Saturn-1 results demonstrate a potentially powerful treatment for Demodex Blepharitis

- All primary and secondary endpoints met
- Clinically meaningful cures seen in 81% of patients
- All endpoints met with high statistical significance
- Erythema cure and improvements demonstrated
- Effects seen within 2 weeks across endpoints
- Positive safety profile
- Well tolerated

Saturn-2 Update

Saturn-2 Phase 3 Trial Design and Status

- Trial initiated in May 2021
- Substantively similar trial design to Saturn-1
- Expect top-line data to read out in 1Q2022

Tarsus Vision & Corporate Update

Our Vision

To become a leading eye care pharmaceutical company dedicated to meeting patient needs through boundless therapeutic ingenuity.

Major Accomplishments Since IPO That Have Advanced Our Growth Strategy

- Positive Saturn-1 Topline Data
- Saturn-2 Enrolling
- Titan Collarette Prevalence Study
- Atlas Disease Impact Study
- LianBio Partnership
- TP-05 IND Accepted
- Callisto TP-05 Phase 1 Trial Initiated
- Expanding Board with Biopharma Leadership
  Wendy Yarno

Titan Study Confirms Collarette Prevalence in ECP Clinic Patients and Key Patient Segments

Study Overview

IRB-APPROVED RETROSPECTIVE CHART REVIEW

Examined presence of collarettes and other characteristics

LARGE-SCALE ALL-COMERS (1,032 patients)

Consecutive patients with a wide variety of reasons for visit

DIVERSE ANTERIOR SEGMENT CLINICS

Geographically diverse (7 US sites) including both MD and OD clinics

25M

U.S. Demodex Blepharitis Patients

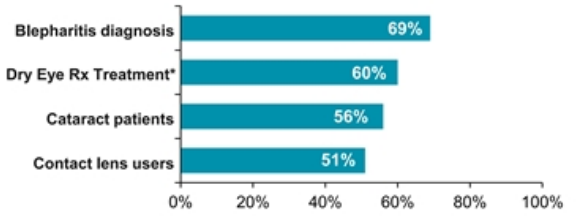
45M Unique Adults visiting an ECP per year; 58% of patients with collarettes

Key Findings

% of Overall Population

Key Patient Groups

% with collarettes within each group



* 22% of all study patients on Dry Eye Rx treatment

Additional Study at ARVO 2021 by Teo, Jacobson, Rosenberg showed (n=199):
55% prevalence of Mites,
62% overlap of Blepharitis
68% overlap with Dry Eye

Atlas Study Reveals Symptomatic and Psychosocial Burden of *Demodex* Blepharitis: 80% Report Negative Impact on Daily Life

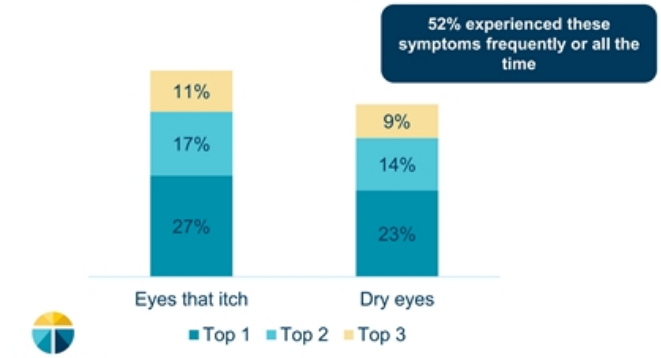
- Data presented at ARVO 2021
- Multicenter, observational study of patients pre-screened for the Saturn-1 pivotal trial
- Evaluated the clinical and patient reported impact of *Demodex* blepharitis (interim analysis of 311 patients)
  - Presence of *Demodex* mites (at least 1 mite per lash)
  - Presence of collarettes (> 10, upper lid)
  - At least mild erythema

51% Experienced signs and symptoms > 4 yrs

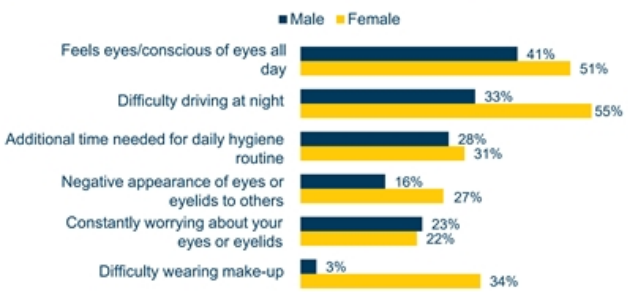
58% Never diagnosed with blepharitis

33% Made at least 2, and sometimes more than 6, visits to a doctor for this condition

Most Bothersome Symptoms



Functional and Psychosocial Impact

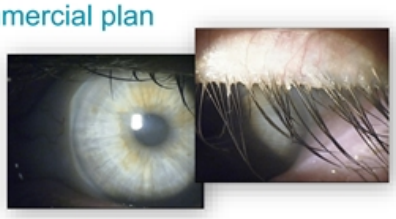


Commercial strategy will be focused on unique and innovative approaches to market education and patient engagement

Positive disruption of existing norms will be at the core of our commercial plan

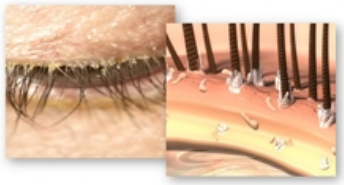
Elevate eyelid health as a foundation of ocular wellness

- Educate on the importance, prevalence and impact of Demodex blepharitis, and how disease management can be part of the overall practice routine
- Build a strong scientific platform through KOL engagement, evidence generation, and data dissemination
- Establish key patient segments: Diagnosed Blepharitis, Cataracts, Dry Eye, Contact Lens Intolerance



Transcend the annual visit cycle by leveraging compelling disease visuals and new technologies to drive patients into the ECP office

- Drive patients to seek optimal lid health outside the routine exam or contact lens refill
- Leverage social and other visual media to tell a motivating, visual disease story
- Explore telemedicine as a conduit to accelerate patient action and diagnosis



Offer a cure with no barriers to facilitate market building through a unique patient experience

- Rapid, complete, and durable cure without hassle or frustration
- Couple broad reimbursement strategy with streamlined patient resources, discounts, and fulfillment
- Ensure patient touchpoints drive successful outcomes, initially, and for retreatment

Pipeline with Different Formulations of Novel API

Current status and anticipated clinical trial events in our programs in the next 12 months

Candidate	Indication	Formulation	Preclinical / Phase 1 / Phase 2 / Phase 3	Status and Anticipated Future Milestones*	Worldwide Rights
TP-03	Demodex blepharitis (DB)	(Eye drop)	Phase 3	**2021**: Saturn-1 trial met primary and secondary endpoints; Saturn-2 Phase 3 trial initiated in May **Q1 2022**: Saturn-2 top-line data **2022:** NDA filing	Tarsus
	Meibomian Gland Disease (MGD)		Phase 2	**Q4 2021:** Initiate Phase 2a proof of concept**	
	Demodex blepharitis (Preservative–Free)		*Preservative-free formulation to be tested after NDA submission*	Bioequivalence studies (US) ***	(Greater China Rights)
	Demodex blepharitis and MGD in China		Phase 2	**2021:** Initiate pre-clinical work in China for DB and MGD **2022:** Initiate Phase 3 DB trial in China*	
TP-04	Rosacea	(Topical)	Phase 1	**Q4 2021:** Initiate Phase 1/2 trial †	Tarsus
TP-05	Lyme Disease	(Oral)	Phase 1	**2021**: IND Accepted Callisto Phase 1 trial initiated in June †† **1H 2022:** Callisto Phase 1 trial completion	Tarsus
	Malaria		Phase 1	**2021**: Callisto Phase 1 trial initiated in June †† **1H 2022:** Callisto Phase 1 trial completion	

* 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 prevention and community malaria reduction, 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 prevention or community malaria reduction, respectively (and will not conduct our own preclinical studies for Lyme disease prevention and community malaria reduction). 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. We have received FDA feedback from our pre-IND meeting and the FDA has accepted our IND application for Lyme disease prevention. We plan to commence a Phase 1 trial in 2021,and further intend to conduct additional trials based on these preclinical studies. In relation to community malaria reduction, we may conduct our trials outside the United States.

TP-05 Oral Tablet: Long-Acting Endectocide for Lyme Disease Prevention and Community Malaria Reduction

Lyme Disease Prevention Represents a Significant Unmet Need

Lyme Disease: Over 300k US cases/year

- Bacterial infection carried by ticks
- >30M people in US at risk of exposure
  - ~20M in high incidence geographies
- TP-05 is a non-vaccine based preventative therapeutic in development that targets ticks directly
  - Based on sustained PK levels in the blood, a more predictable approach compared to immunogenicity
  - Potential for >95% reduction in Lyme risk
    - Kills 70% of ticks within 4 hrs, 99% @ 8 hrs
    - Potential to prevent bacterial transmission (24-72 hrs)

TP-05 IND Accepted and Callisto Ph 1 Trial Initiated

IND accepted in May 2021

- Callisto trial will assess safety, PK, and tick kill objectives
  - To evaluate the safety and tolerability of TP-05 in healthy volunteers
  - To evaluate the pharmacokinetics (PK) of TP-05 in blood, skin, renal PK and food effect
  - To explore TP-05 treated blood for tick kill (ex-vivo) and human metabolites
- Callisto trial will also inform approach for community malaria reduction

Key Upcoming Catalysts to Advance our Growth

Saturn-2 Topline Results
1Q 2022

TP-03 NDA Filing
2022

TP-05 Callisto Phase 1 Trial Completion
1H 2022

TP-03 MGD Phase 2a Trial Initiation
4Q 2021

Topical Rosacea Phase 1/2 Trial Initiation
4Q 2021

Closing Remarks

- **Saturn-1 Phase 2b/3 pivotal trial results highly positive** and further supports TP-03 clinical and regulatory success
- TP-03 clinical outcomes and disease prevalence and impact studies validate attractive product profile for **potential first FDA-approved Demodex blepharitis therapeutic,** if approved
- Tarsus near-term clinical milestones, experienced executive team, and Board additions position company to become an **eye care pharmaceutical leader**
- Pipeline advancing with **TP-05 Callisto Phase 1 trial for Lyme disease prevention initiated** and key upcoming clinical milestones in next 12 months