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	001-39614	81-4717861
(State or other jurisdiction of incorporation)	(Commission File Number)	(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)

☐ 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.

Risk Factor Update

Tarsus Pharmaceuticals, Inc. (the "Company") has updated the risk factor set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, "*Risks Related to Development and Commercialization of Our Product Candidates - Clinical drug development is a lengthy, expensive and risky process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results. If clinical trials of our product candidates, particularly TP-03 for the treatment of Demodex blepharitis, do not meet safety or efficacy endpoints or are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all*", as follows.

Risks Related to Development and Commercialization of Our Product Candidates

Clinical drug development is a lengthy, expensive and risky process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results. If clinical trials of our product candidates, particularly TP-03 for the treatment of Demodex blepharitis, do not meet safety or efficacy endpoints or are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. The research and development of drugs is an extremely risky industry. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Failure or delay can occur at any time during the clinical trial process. To date, we have focused substantially all of our efforts and financial resources on identifying, acquiring, and developing our product candidates, including conducting preclinical studies and clinical trials. Clinical testing is expensive and can take many years to complete, and we cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials. Our inability to successfully complete preclinical and clinical development could result in additional costs to us and negatively impact our ability to generate revenue. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize product candidates. We currently generate no revenues from sales of any products, and we may never be able to develop or commercialize a marketable product.

We have not yet completed any Phase 3 trials for any product candidate. The results of preclinical and early clinical trials of our product candidates and other products with the same mechanism of action may not be predictive of the results of later-stage clinical trials. For example, we may not be able to replicate the safety and efficacy results of our Phase 2 clinical trials for Demodex blepharitis in our Phase 3 trial, Saturn-2. Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria, relatively smaller sample size in earlier trials, and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval. Furthermore, as more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. For example, our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. The failure of any of our product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates or cause regulatory authorities to require additional testing before approving any of our product candidates.

We currently have two product candidates in clinical development and their risk of failure is high. For example, use of TP-03 requires the patient to follow a prescribed technique to administer the eye drops. Failure to properly administer the eye drops by the patient or inappropriate technique demonstration by the eye care practitioners, may adversely affect the outcome of TP-03 in demonstrating efficacy in one or more clinical trials. We are unable to predict if this product candidate or any of our future product candidates that advance into clinical trials will prove safe or effective in humans or will obtain marketing approval. If we are unable to complete preclinical or clinical trials of current or future product candidates, due to safety concerns, or if the results of these trials are not satisfactory to convince regulatory authorities of their safety or efficacy, we will not be able to obtain marketing approval for commercialization. Even if we are able to obtain marketing approvals for any of our product candidates, those approvals may be for indications that are not as broad as desired or may contain other limitations that would adversely affect our ability to generate revenue from sales of those products. Moreover, if we are not able to differentiate our product against other approved products within the same class of drugs, or if any of the other circumstances described above occur, our business would be materially harmed and our ability to generate revenue from that class of drugs would be severely impaired.

Each of our product candidates will require additional clinical development, management of clinical, preclinical (for some of our product candidates) and manufacturing activities, regulatory approval in multiple jurisdictions, achieving and maintaining commercial-scale supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We may experience delays in our ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. For example, the FDA had initially recommended that for TP-03 we conduct carcinogenicity testing and has subsequently agreed in Type C meeting minutes that we can submit a carcinogenicity waiver, and if not granted, the carcinogenicity testing could be conducted and submitted as a post-marketing requirement. Furthermore, the FDA recommended that we conduct embryofetal development studies in a second species, which have been completed. Any further recommendations by the FDA could cause delay of any regulatory approval by the FDA and cause our expenses to increase. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize TP-03, our other product candidates, or any other product candidates that we may develop, including:

- we may experience delays in or failure to reach agreement on acceptable terms with prospective CROs, vendors and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, vendors and trial sites;
- we may fail to obtain sufficient enrollment in our clinical trials, our enrollment needs may grow larger than we anticipate, or participants may fail to complete our clinical trials at a higher rate than we anticipate;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may decide, or regulators or institutional review boards or ethics committees may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards or ethics committees may not authorize us or our investigators to commence a clinical trial at a prospective clinical trial site or at all or may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate, and we may need to delay or suspend one or more trials until we complete additional financing transactions or otherwise receive adequate funding;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or may be delayed;

- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards or ethics committees to suspend or terminate trials;
- regulatory authorities may determine that the planned design of our clinical trials is flawed or inadequate;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution;
- we may not be able to timely or at all obtain INDs for a product candidate;
- we may modify a preclinical study or clinical trial protocol;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may be unable to establish clinical endpoints that applicable regulatory authorities consider clinically meaningful, or, if we seek accelerated approval, biomarker efficacy endpoints that applicable regulatory authorities consider likely to predict clinical benefit;
- we may experience delays due to the ongoing COVID-19 pandemic, including with respect to the conduct of ongoing clinical trials, receipt of product candidates or other materials, submission of New Drug Applications ("NDAs"), filing of INDs, and starting any clinical trials for other indications or programs; and
- we may experience manufacturing delays due to the recent COVID-19 pandemic in our supply chain caused by a shortage of raw materials, a lack of employees on site at our suppliers due to illness, or a lack of productivity at our suppliers due to local or national government quarantine restrictions on coming to the workplace.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive, if there are safety concerns or if we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

We cannot be certain whether any of our planned clinical trials will begin on schedule or any preclinical studies we plan to initiate will begin on our intended schedule, or whether any such studies or clinical trials will need to be restructured or will be completed on schedule, or at all. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, or are unable to achieve clinical endpoints due to unforeseen events, such as the COVID-19 pandemic, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that involve risks and uncertainties, including, without limitation, statements regarding expectations relating to the Company's plans relating to the clinical development of its current and future product candidates. Words such as "may," "will," "should," "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon the Company's current expectations. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties detailed in the Company's filings with the SEC. For a discussion of these and other factors, please refer to the Company's annual report on Form 10-K for the year ended December 31, 2021 as well as the Company's other filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this report.

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)