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 9, 2023

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)**	**(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 Stock 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 2.02 Results of Operations and Financial Condition.

On May 9, 2023, Tarsus Pharmaceuticals, Inc. (the "Company") issued a press release, which, among other matters, sets forth the Company's results of operations for the three months ended March 31, 2023. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The foregoing information, including Exhibit 99.1, is being furnished under Item 2.02 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated May 9, 2023
104	Cover Page Interactive Data File (embedded within XBRL document)

SIGNATURES

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

TARSUS PHARMACEUTICALS, INC.

Date: May 9, 2023

/s/ Jeffrey Farrow

Jeffrey Farrow
Chief Financial Officer and Chief Strategy Officer
(Principal Financial Officer and Principal Accounting Officer)

Tarsus Reports First Quarter 2023 Financial Results and Recent Business Achievements

Continuing to build market awareness through disease education and deploying commercial leadership in anticipation of TP-03 August 25, 2023 PDUFA

Presented health economics data suggesting a costly and substantial burden of illness in patients with Demodex blepharitis

Tarsus to host investor webcast highlighting planned commercialization strategy and opportunity for TP-03 in Demodex blepharitis on Thursday, June 15, 2023

IRVINE, Calif., May 9, 2023 (GLOBE NEWSWIRE) -- Tarsus Pharmaceuticals, Inc. (NASDAQ: TARS), 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 financial results for the first quarter ended March 31, 2023, and recent business achievements.

"We are off to a tremendous start this year highlighted by the progress and execution of our commercial strategy as we prepare for the potential launch of TP-03 in the fall," said Bobak Azamian, M.D., Ph.D., Chief Executive Officer and Chairman of Tarsus. "TP-03 has the potential, if approved, to be the first FDA-approved treatment and standard of care for *Demodex* blepharitis, a prevalent eyelid condition that affects approximately 25 million patients in the United States. We look forward to providing an update on our expected commercial launch plans during our virtual event in June. In tandem, we have continued to advance our broad pipeline into proof-of-concept studies. Enrollment is ongoing in our Phase 2a rosacea trial of TP-04, and we remain on-track to provide readouts from our Phase 2a trials in Lyme disease prevention and Meibomian Gland Disease."

Recent Business Highlights and Corporate Update

- *Demodex* Expert Panel on Treatment and Eyelid Health (DEPTH) published two papers on the importance of diagnosis and management of *Demodex* blepharitis (DB) Eye; https://doi.org/10.1038/s41433-023-02500-4
    - Clinical diagnosis and management of DB: established consensus about the disease, including signs, symptoms and diagnosis
    - DEPTH consensus regarding current clinical practice management options for DB: collarettes are pathognomonic, patients with >10 collarettes should be treated even in the absence of symptoms; efficacy can be tracked by collarette resolution
    - DEPTH panel consensus was obtained by using the Delphi methodology, an approach that allows experts to achieve consensus by performing qualitative and quantitative analyses and utilizing sequential surveys

- Presented health economics data (Academy of Managed Care Pharmacy 2023) that suggests a costly, substantial burden of illness in patients with DB and the need for a safe, effective, FDA-approved treatment
    - Ongoing disease impact and additional office visits are potentially driving up healthcare resource utilization
    - Patients reported having delayed diagnosis, multiple office visits, unresolved DB and high costs of disease management

- Current non-FDA approved therapies to manage DB do not address the root problem or provide satisfactory relief for most patients

- Awareness, Trial and Usage (ATU) market research survey of ~250 optometrists and ophthalmologists to capture and analyze awareness and likelihood to prescribe a potential prescription therapeutic for DB
  - Growing confidence in making a diagnosis with 68% believing collarettes are pathognomonic to DB and 66% recognizing the importance of screening patients for the presence of collarettes during eye exams
  - 93% indicated they would prescribe an FDA-approved therapeutic for DB

- Disease education campaigns driving awareness on the prevalence and impact of DB
  - "Look at the Lids" disease education campaign has generated nearly 200K unique website visits, up from 125K last quarter and more than 2.3M digital/media impressions, an increase of 300K impressions since last quarter
  - Launched "*Don't Freak Out. Get Checked Out.*", a disease education campaign designed to encourage patients who may have DB to visit their eye care provider for an eyelid check

- Continuing to engage with top commercial and Medicare accounts, educating on *Demodex* blepharitis, prevalence and potential health economic value

- Salesforce infrastructure in place: VP of Sales, two regional directors and 11 district managers
  - Focused sales force targeting ~15K optometrists and ophthalmologists, which represents >80% of the market; planned to activate upon potential FDA approval of TP-03

- Appointed Jeff Farrow as Chief Financial Officer and Chief Strategy Officer

Anticipated 2023 Milestones

Program	Milestone	Anticipated Indication	H1 2023	H2 2023
TP-04	Initiated Phase 2a (Galatea)	Rosacea	✓	
TP-03	Approval and Launch	*Demodex* blepharitis		●
TP-03	Topline Phase 2a (Ersa)	Meibomian Gland Disease		●
TP-05	Topline Phase 2a Data (Carpo)	Lyme disease prevention		●
TP-05	Initiate Phase 2b	Lyme disease prevention		●

First Quarter 2023 Financial Results

- First quarter net loss for 2023 was $23.4 million, compared to net loss of $20.2 million for the same period in 2022
- First quarter 2023 license fee and collaboration revenue, as part of the strategic partnership with LianBio, was $2.5 million, compared to $0.5 million for the same period in 2022
- First quarter research and development expenses for 2023 were $12.4 million (inclusive of stock-based compensation of $1.2 million), compared to $12.1 million for the same period in 2022
- First quarter general and administrative expenses for 2023 were $15.1 million (inclusive of stock-based compensation of $2.7 million), compared to $7.9 million for the same period in 2022, which was primarily due to an increase of $3.7 million of payroll and personnel-related costs; and $2.9 million of commercial and market research costs as we continue to prepare for the potential launch of TP-03
- As of March 31, 2023, cash, cash equivalents and marketable securities were $201.2 million

About Tarsus Pharmaceuticals, Inc.

Tarsus Pharmaceuticals, Inc. applies proven science and new technology to revolutionize treatment for patients, starting with eye care. Tarsus 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. Tarsus is studying three investigational medicines in clinical trials. Its lead product candidate, TP-03, is a novel therapeutic which has demonstrated positive results in two pivotal trials for the treatment of *Demodex* blepharitis, and the New Drug Application for TP-03 has been accepted by the U.S. Food & Drug Administration (FDA) with a PDUFA target action date of August 25, 2023. TP-03 is also being developed for the potential treatment of Meibomian Gland Disease, and is currently being studied in a Phase 2a clinical trial. In addition, Tarsus is developing TP-04 for the treatment of Rosacea and TP-05, an oral tablet for the potential prevention of Lyme disease. TP-04 and TP-05 are both currently being studied in Phase 2a clinical trials to evaluate safety, tolerability, and proof-of-activity.

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 include statements regarding the potential approval and commercialization of TP-03, the market size for TP-03, TP-04, and TP-05, including our ability to educate the market about *Demodex* blepharitis, the timing, objectives, and results of the clinical trials, anticipated regulatory and development milestones, the initiation of Phase 2b studies for Lyme disease prevention, our ability to continue investing in our business, future events and Tarsus' plans for and the anticipated benefits of its product candidates including TP-03, TP-04 and TP-05, 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' ability to obtain regulatory approval for and successfully commercialize TP-03 for the treatment of *Demodex* blepharitis, 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-04, TP-05, or any other product candidate that Tarsus develops receives marketing approval, Tarsus may not be successful in educating healthcare professionals and the market about the need for treatments specifically for *Demodex* blepharitis, MGD, rosacea, Lyme disease prevention, 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, TP-04 for the treatment of Rosacea, as well as TP-05 for the prevention 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; 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; and if Tarsus is unable to access capital (including but not limited to cash, cash equivalents, and credit facilities) and/or loses capital, as a result of potential failure of any financial institutions that Tarsus does business with directly or indirectly. 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, 2022 filed on March 17, 2023 and the most recent Form 10-Q quarterly filing filed with the SEC, which Tarsus incorporates by reference

into this press release, 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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TARSUS PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Revenues:		
License fees and collaboration revenue	$ 2,500	$ 539
Operating expenses:		
Cost of license fees and collaboration revenue	—	33
Research and development	12,356	12,081
General and administrative	15,096	7,946
Total operating expenses	27,452	20,060
Loss from operations before other income (expense) and income taxes	(24,952)	(19,521)
Other income (expense):		
Interest income	2,293	—
Interest expense	(684)	(316)
Other income (expense), net	6	37
Unrealized loss on equity investments	(65)	(192)
Change in fair value of equity warrants issued by licensee	(17)	(245)
Total other income (expense), net	1,533	(716)
Provision for income taxes	—	(1)
Net loss	$ (23,419)	$ (20,238)
Other comprehensive loss:		
Unrealized gain on marketable securities and cash equivalents	4	—
Comprehensive loss	$ (23,415)	$ (20,238)
Net loss per share, basic	$ (0.88)	$ (0.98)
Net loss per share, diluted	$ (0.88)	$ (0.98)
Weighted-average shares outstanding, basic	26,742,023	20,710,224
Weighted-average shares outstanding, diluted	26,742,023	20,710,224

TARSUS PHARMACEUTICALS, INC.

BALANCE SHEETS
(In thousands, except share and par value amounts)

	March 31, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 65,997	$ 71,660
Marketable securities	135,222	145,366
Accounts receivable	2,500	—
Other receivables	418	3,582
Prepaid expenses	4,509	4,767
Total current assets	208,646	225,375
Property and equipment, net	1,193	957
Operating lease right-of-use assets	540	575
Long-term investments	306	371
Other assets	529	585
Total assets	$ 211,214	$ 227,863
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 9,049	$ 9,910
Accrued payroll and benefits	4,206	5,519
Total current liabilities	13,255	15,429
Term loan, net	24,515	19,434
Other long-term liabilities	40	100
Total liabilities	37,810	34,963
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 26,800,512 shares issued and outstanding at March 31, 2023 (unaudited); 26,727,458 shares issued and outstanding at December 31, 2022	5	5
Additional paid-in capital	305,651	301,732
Accumulated other comprehensive loss	(70)	(74)
Accumulated deficit	(132,182)	(108,763)
Total stockholders' equity	173,404	192,900
Total liabilities and stockholders' equity	$ 211,214	$ 227,863