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): March 13, 2023

TARSUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39614**	**81-4717861**
(State or other jurisdiction of incorporation or organization)	**(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 (see General Instruction A.2. below):

☐ 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 (§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 March 13, 2023, Tarsus Pharmaceuticals, Inc. (the "Company") issued a press release, which, among other matters, sets forth the Company's results of operations for the year ended December 31, 2022. 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 March 13, 2023
104	Cover Page Interactive Data File (embedded within XBRL document)

SIGNATURE

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: March 13, 2023 By: /s/ Leonard M. Greenstein

Leonard M. Greenstein
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Tarsus Reports Full-Year 2022 Financial Results and Recent Business Achievements

Engaging with more than two-thirds of key optometrists and/or ophthalmologists, and top payers on Demodex blepharitis in anticipation of TP-03 August 25, 2023 PDUFA

Completed enrollment of Ersa, a Phase 2a trial evaluating TP-03 for MGD with topline data expected in 2H 2023 and initiated Galatea Phase 2a trial evaluating TP-04 for Rosacea

Cash runway anticipated into at least 2H 2026 to support planned TP-03 commercialization and continued pipeline development

IRVINE, Calif., March 13, 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 full-year ended December 31, 2022, and recent business achievements.

"In 2022 we had a clear vision to transform eyelid health, starting with the development of our novel investigational treatment for *Demodex* blepharitis, a disease that impacts millions of Americans. This year, we continue to focus on this unique opportunity, and we are actively educating the market on the disease as we move closer to our PDUFA target action date," said Bobak Azamian, M.D., Ph.D., Chief Executive Officer and Chairman of Tarsus. "Alongside our efforts in *Demodex* blepharitis, we're working to advance our pipeline, including the initiation of our Phase 2 trial in rosacea, and our planned Phase 2a data readouts from our Lyme disease prevention and MGD-related trials in the second half of 2023. We remain well capitalized and positioned to deliver on our commitment to uniquely change the landscape of eyelid health."

Recent Business Highlights and Corporate Update

- New Drug Application (NDA) for TP-03 for the treatment of *Demodex* blepharitis accepted by the U.S. Food and Drug Administration (FDA); Prescription Drug User Fee Act (PDUFA) target action date of August 25, 2023

- Launched an 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 *Demodex* blepharitis
    - More than 90% indicated they would prescribe an FDA approved therapeutic for *Demodex* blepharitis

- Engaged and educated more than two-thirds of target Eye Care Practitioners (ECPs) on the disease, identification and diagnosis of *Demodex* blepharitis
    - "Look at the Lids" disease education campaign has generated more than 125K unique website visits and nearly 2M digital/media impressions

- Actively engaging with top commercial and Medicare accounts, educating on the potential value of prescription therapies for *Demodex* blepharitis

- Completed enrollment of Ersa, a Phase 2a trial evaluating TP-03 for the potential treatment of Meibomian Gland Disease (MGD) with topline data expected in the second half of 2023

- Initiated Galatea, a Phase 2a trial evaluating TP-04, a novel gel formulation of lotilaner, for the potential treatment of rosacea
    - *Demodex* mites are highly prevalent in rosacea patients and may contribute to the pathology of disease
    - TP-04 is being developed to eradicate *Demodex* mites, a potential root cause of disease
    - Positive Phase 1 data shows TP-04 was well tolerated and safety data supports progression to Phase 2a

- Cash runway anticipated into at least the second half of 2026

Anticipated 2023 Clinical and Regulatory Milestones

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

Full-Year 2022 Financial Results

- Full year TP-03 out-license revenue for greater China territory was $25.8 million, compared to $57.0 million in 2021
- Full year net loss was $62.1 million, compared to $13.8 million in 2021
- Full year research and development expenses were $42.6 million, compared to $41.7 million in 2021
- Full year general and administrative expenses were $44.9 million, compared to $25.4 million in 2021
- As of December 31, 2022, cash, cash equivalents and marketable securities were $217.0 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 2 studies for Lyme disease prevention and the treatment of rosacea, our cash runway expectations, 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; 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, 2021 filed on March 14, 2022 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)

	Year Ended December 31,	
	2022	**2021**
Revenues:		
License fees	$ 23,893	$ 53,067
Collaboration revenue	1,923	3,960
Total revenues	25,816	57,027
Operating expenses:		
Cost of license fees and collaboration revenue	955	2,075
Research and development	42,624	41,712
General and administrative	44,949	25,397
Total operating expenses	88,528	69,184
Loss from operations before other income (expense) and income taxes	(62,712)	(12,157)
Other income (expense):		
Interest income	3,499	36
Interest expense	(2,199)	—
Other income (expense), net	86	(73)
Unrealized loss on equity investments	(268)	(591)
Change in fair value of equity warrants issued by licensee	(501)	(987)
Total other income (expense), net	617	(1,615)
Loss from operations before income taxes	(62,095)	(13,772)
Benefit (provision) for income taxes	4	(55)
Net loss	$ (62,091)	$ (13,827)
Other comprehensive loss:		
Unrealized loss on marketable securities and cash equivalents	(74)	—
Comprehensive loss	$ (62,165)	$ (13,827)
Net loss per share, basic and diluted	$ (2.52)	$ (0.67)
Weighted-average shares outstanding, basic and diluted	24,619,700	20,554,086

TARSUS PHARMACEUTICALS, INC.

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

	December 31,	
	2022	**2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 71,660	$ 171,332
Marketable securities	145,366	483
Other receivables	3,582	92
Prepaid expenses	4,767	4,045
Total current assets	225,375	175,952
Property and equipment, net	957	755
Operating lease right-of-use assets	575	1,074
Long-term investments	371	—
Other assets	585	1,126
Total assets	$ 227,863	$ 178,907
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 9,910	$ 8,680
Accrued payroll and benefits	5,519	2,798
Total current liabilities	15,429	11,478
Term loan, net	19,434	—
Other long-term liabilities	100	699
Total liabilities	34,963	12,177
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 26,727,458 shares issued and outstanding at December 31, 2022; 20,726,580 shares issued and 20,698,737 outstanding, which excludes 27,840 shares subject to repurchase at December 31, 2021	5	4
Additional paid-in capital	301,732	213,398
Accumulated other comprehensive loss	(74)	—
Accumulated deficit	(108,763)	(46,672)
Total stockholders' equity	192,900	166,730
Total liabilities and stockholders' equity	$ 227,863	$ 178,907