

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 1, 2025

TARSUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-39614
(Commission File Number)

81-4717861
(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) 418-1801

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 1, 2025, 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, 2025. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 1, 2025.
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 1, 2025

/s/ Jeffrey Farrow

Jeffrey Farrow

Chief Financial Officer and Chief Strategy Officer

(Principal Financial Officer and Principal Accounting Officer)



Tarsus Reports First Quarter 2025 Financial Results and Recent Business Achievements

Generated \$78.3 million in net product sales of XDEMVY[®], an increase of 217% year over year and 18% over Q4 2024, and dispensed approximately 72,000 bottles to patients

Strengthened financial position with approximately \$135 million raised in public equity offering; cash, cash equivalents and marketable securities of approximately \$408 million as of March 31, 2025

On-track to initiate a Phase 2 trial of TP-04 (lotilaner ophthalmic gel) for the potential treatment of Ocular Rosacea in H2 2025

Management to host conference call today, May 1, 2025, at 1:30 p.m. P.T. / 4:30 p.m. E.T.

IRVINE, Calif., May 1, 2025 (GLOBE NEWSWIRE) -- Tarsus Pharmaceuticals, Inc. (NASDAQ: TARS), today announced financial results for the first quarter ended March 31, 2025.

“Tarsus has entered 2025 with incredible momentum, driven by strong execution of our category-creating strategic blueprint for success and a focused commitment to leadership in eye care. The XDEMVY launch is continuing to exceed our expectations and is on track to potentially become one of the best-selling anterior segment medicines,” said Bobak Azamian, M.D., Ph.D., Chief Executive Officer and Chairman of Tarsus. “Building on a foundation of strong commercial performance and the success of our recent equity offering, we believe we are well positioned to accelerate the growth of XDEMVY, create another new category in Ocular Rosacea and continue to advance our pipeline.”

Recent Business and Clinical Highlights

- XDEMVY is on track to potentially be one of the fastest growing and best-selling anterior segment medicines. In the first quarter, the Company:
 - Generated \$78.3 million in XDEMVY net product sales, an increase of 217% year over year and 18% over Q4 2024.
 - Dispensed approximately 72,000 bottles of XDEMVY to patients, an increase of 23% over Q4 2024.
- Broad commercial, Medicare and Medicaid reimbursement of XDEMVY now extends to more than 90% of covered lives.
 - Recognized a gross-to-net discount of approximately 47%.
- Substantially increased the depth of prescribing among our target Eye Care Professionals (ECPs).
 - At the end of Q1 2025, the number of ECPs writing more than one prescription per week increased by nearly 110% compared to Q3 2024.

- Direct-To-Consumer (DTC) advertising drove a 140% increase in the average weekly website visits in March 2025 compared to December 2024.
 - Ongoing investment expected to increase alongside leading indicators of utilization.
- Presented new data showing the global prevalence and real-world patient burden of *Demodex* blepharitis (DB).
 - The Elara study showed the high prevalence and significant impact of DB in Japan, consistent with the U.S.
 - Results of the Orion registry showed XDEMZY-treated patients experienced meaningful improvements in some of the most impactful symptoms of disease, including fluctuating vision, redness, itchy eyelids, burning or stinging, dryness and crusted eyes.
 - The combined data from the Ersa and Rhea studies in DB patients with Meibomian Gland Disease (MGD) showed statistically significant and clinically meaningful improvements of the meibomian glands, with at least three times more glands secreting normal or clear liquid in XDEMZY-treated patients compared to vehicle at day 43.
- Strengthened financial position with a \$134.8 million upsized public equity offering which will continue to fund the launch of XDEMZY and ongoing pipeline investment.
- Continued to advance a robust pipeline with multiple catalysts expected in 2025.
 - On-track to initiate a Phase 2 study of TP-04 (lotilaner ophthalmic gel) for Ocular Rosacea, a highly prevalent and underserved eye disease with no FDA-approved therapy, in H2 2025.
 - Anticipated to meet with regulatory authorities in Japan in H2 2025 to help determine a regulatory path forward for XDEMZY in Japan.
 - On-track for potential European regulatory approval in 2027 of a preservative-free formulation of XDEMZY.
 - On-track to initiate a Phase 2 study of TP-05 (an investigational oral tablet) for the potential prevention of Lyme disease in 2026.

First Quarter 2025 Financial Results

- **Product sales, net:** were \$78.3 million compared to \$24.7 million for the same period in 2024, driven by approximately 72,000 bottles of XDEMZY delivered to patients compared to approximately 26,000 bottles delivered in the prior year period.
- **Cost of sales:** were \$5.2 million compared to \$1.7 million for the same period in 2024, due to manufacturing costs incurred after the approval of XDEMZY, the royalty we pay on net product sales, and the amortization of the milestones paid to our licensor, which is being amortized over its remaining useful life of 8.4 years.
- **Research and development (R&D) expenses:** were \$14.4 million compared to \$12.1 million for the same period in 2024. The increase was primarily due to \$0.5 million of increased TP-04 program expenses, \$0.9 million of increased payroll and personnel-related costs, \$0.9 million of increased early-stage programs, and \$0.3 million of increased other indirect expenses. These increases were partially offset by \$0.4 million of decreased TP-03 program expenses. Total R&D non-cash stock compensation expense was \$1.5 million, which was consistent with \$1.5 million in the same period in 2024.
- **Selling, general and administrative (SG&A) expenses:** were \$85.0 million compared to \$51.6 million for the same period in 2024. The increase was due primarily to \$9.6 million of increased payroll and personnel-related costs (including non-cash stock-based compensation), and \$25.6 million of increased commercial and marketing costs, including direct-to-consumer advertising costs, as we continued our commercial expansion of XDEMZY. These increases were partially offset by \$1.9

million of decreased information technology applications, legal, professional and other corporate expenses. Total SG&A non-cash stock compensation expense was \$5.3 million, compared with \$3.9 million in the same period in 2024.

- **Net loss:** was \$25.1 million, compared to \$35.7 million for the same period in 2024. Basic and diluted net loss per share for the quarter ended March 31, 2025 was \$(0.64), compared with \$(1.01) for the same period in 2024.
- **Cash position:** As of March 31, 2025, cash, cash equivalents and marketable securities were \$407.9 million.

Conference Call and Webcast

Tarsus will host a conference call and webcast to discuss its first quarter 2025 financial results and business highlights today, May 1, 2025, at 1:30 p.m. P.T. / 4:30 p.m. ET. A live webcast will be available on the events section of the Tarsus website. A recorded version of the call will be available on the website shortly after the completion of the call and will be archived there for at least 90 days.

About XDEM VY®

XDEM VY (lotilaner ophthalmic solution) 0.25%, formerly known as TP-03, is a novel prescription eye drop designed to treat *Demodex* blepharitis by targeting and eradicating the root cause of the disease – *Demodex* mite infestation. XDEM VY was evaluated in two pivotal trials collectively involving more than 800 patients. Both trials met the primary endpoint and all secondary endpoints, with statistical significance and no serious treatment-related adverse events. Most patients found the XDEM VY eye drop to be neutral to very comfortable. The most common ocular adverse reactions observed in the studies were instillation site stinging and burning which was reported in 10% of patients. Other ocular adverse reactions reported by less than 2% of patients were chalazion/hordeolum (stye) and punctate keratitis.

XDEM VY Indication and Important Safety Information

INDICATIONS AND USAGE

XDEM VY is indicated for the treatment of *Demodex* blepharitis.

Most common side effects: The most common side effect in clinical trials was stinging and burning in 10% of patients. Other side effects in less than 2% of patients were chalazion/hordeolum and punctate keratitis.

For additional information, please see full prescribing information available at: <https://xdemvy.com/>.

About TP-03

TP-03 (lotilaner ophthalmic solution) 0.25% is a novel therapeutic designed to treat *Demodex* blepharitis by targeting and eradicating the root cause of disease – *Demodex* mite infestation. It was approved by the FDA in 2023 under the brand name XDEM VY® for the treatment of *Demodex* blepharitis. Lotilaner is a well-characterized anti-parasitic agent that paralyzes and eradicates *Demodex* mites by selectively inhibiting parasite-specific gamma-aminobutyric acid-gated chloride (GABA-Cl) channels. It is a highly lipophilic molecule, which may promote its uptake in the oily sebum of the eye lash follicles where the mites reside.

About TP-04

TP-04 is an investigational aqueous gel formulation of lotilaner, a well-characterized anti-parasitic agent that paralyzes and kills mites by selectively inhibiting parasite-specific GABA-Cl channels. Tarsus is studying TP-04 for the treatment of ocular rosacea (OR).

About TP-05

TP-05 is an investigational oral systemic formulation of lotilaner, a well-characterized anti-parasitic agent that selectively inhibits parasite-specific GABA-Cl channels. TP-05 is believed to be the only non-vaccine, drug-

based, preventative therapeutic in development designed to kill ticks to potentially prevent Lyme disease transmission.

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. XDEM VY (lotilaner ophthalmic solution) 0.25% is FDA approved in the United States for the treatment of *Demodex* blepharitis. Tarsus is also developing TP-04 for the potential treatment of Ocular Rosacea and TP-05 as an oral tablet for the prevention of Lyme disease, all of which are in Phase 2.

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 commercial success and growth of XDEM VY in *Demodex* blepharitis, including market size, acceptance, demand, prescription fill rate and adoption rate for XDEM VY; our ability to successfully implement and continue our new direct-to-consumer campaign; our ability to achieve and maintain distribution and patient access for XDEM VY and timing and breadth of payer coverage; our ability to continue to educate the market about *Demodex* blepharitis; our ability to initiate planned clinical studies; anticipated regulatory and development milestones including potential Europe and Japan regulatory pathways and approval for XDEM VY; the results of our clinical studies; the test results of our pipeline formulations; our ability to continue investing in our business, 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 is heavily dependent on the successful commercialization of its lead product, XDEM VY for the treatment of *Demodex* blepharitis and the development and regulatory approval and commercialization of its current and future product candidates; Tarsus’ ability to obtain and maintain regulatory approval for and successfully commercialize its products, including XDEM VY for the treatment of *Demodex* blepharitis, and its product candidates to meet existing and future regulatory standards; 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’ capital requirements are difficult to predict and may change; Tarsus may need to obtain additional funding to achieve its goals and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force Tarsus to delay, reduce, or eliminate its product development programs, commercialization efforts or other operations; Tarsus may not be successful in educating healthcare professionals and the market about the need for treatments specifically for *Demodex* blepharitis and other diseases targeted by XDEM VY or our product candidates; the development and commercialization of Tarsus products is dependent on intellectual property it licenses from Elanco Tiergesundheits AG; Tarsus expects to expand its development, regulatory, operational, sales, and marketing capabilities and Tarsus may encounter difficulties in managing its growth, which could disrupt its operations; the sizes of the market opportunity for XDEM VY and Tarsus’ product candidates, particularly TP-04 for the treatment of Ocular 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 statements 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, 2024 filed on February 25, 2025 and the most recent Form 10-Q quarterly filing filed with the SEC on May 1, 2025, 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 earnings 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.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2025	2024
Revenues:		
Product sales, net	\$ 78,335	\$ 24,720
License fees and collaboration revenue	—	2,894
Total revenues	78,335	27,614
Operating expenses:		
Cost of sales	5,211	1,654
Research and development	14,409	12,066
Selling, general and administrative	84,995	51,578
Total operating expenses	104,615	65,298
Loss from operations before other income (expense)	(26,280)	(37,684)
Other income (expense):		
Interest income	3,454	3,117
Interest expense	(2,213)	(983)
Other income (expense), net	(81)	(181)
Total other income (expense), net	1,160	1,953
Net loss	\$ (25,120)	\$ (35,731)
Unrealized gain (loss) on marketable securities and cash equivalents	(94)	(61)
Comprehensive loss	\$ (25,214)	\$ (35,792)
Net loss per share, basic and diluted	\$ (0.64)	\$ (1.01)
Weighted-average shares outstanding, basic and diluted	39,345,359	35,300,655

TARSUS PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(In thousands, except share and par value amounts)

	March 31, 2025	December 31, 2024
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 175,787	\$ 94,819
Marketable securities	232,129	196,557
Accounts receivable, net	62,426	46,760
Inventory	2,705	2,620
Other receivables	1,727	1,299
Prepaid expenses	5,999	14,650
Total current assets	480,773	356,705
Restricted cash, non-current	2,563	2,562
Inventory, non-current	2,532	2,533
Property and equipment, net	2,787	2,314
Intangible assets, net	8,086	8,326
Operating lease right-of-use assets	393	552
Long-term investments	3,000	3,000
Other assets	616	999
Total assets	\$ 500,750	\$ 376,991
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 76,375	\$ 64,789
Accrued payroll and benefits	9,933	15,823
Total current liabilities	86,308	80,612
Long-term debt, net	71,984	71,845
Total liabilities	158,292	152,457
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; 41,995,537 shares issued and outstanding at March 31, 2025 (unaudited); 38,349,826 shares issued and outstanding at December 31, 2024	6	6
Additional paid-in capital	727,697	584,559
Accumulated other comprehensive income (loss)	85	179
Accumulated deficit	(385,330)	(360,210)
Total stockholders' equity	342,458	224,534
Total liabilities and stockholders' equity	\$ 500,750	\$ 376,991