

**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): February 25, 2025

TARSUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

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 (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 February 25, 2025, 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, 2024. 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 February 25, 2025
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: February 25, 2025 By: /s/ Jeffrey S. Farrow
Jeffrey S. Farrow
Chief Financial Officer and Chief Strategy Officer
(Principal Financial Officer and Principal Accounting Officer)



Tarsus Reports Strong Fourth Quarter and Full-Year 2024 Financial Results and Recent Business Achievements

Generated fourth quarter and full-year 2024 net product sales of XDEMVY® of \$66.4 million and \$180.1 million, respectively, during the first full year of launch

Presented groundbreaking XDEMVY data; first pharmacologic treatment to demonstrate functional improvements in Meibomian Gland Disease and patient symptoms in Demodex blepharitis patients

Continued advancing TP-04 (lotilaner ophthalmic gel) for the potential treatment of Ocular Rosacea, the next category-creating opportunity in eye care

Management to host conference call today, February 25, 2025, at 5 a.m. PT / 8 a.m. ET

IRVINE, Calif., February 25, 2025 (GLOBE NEWSWIRE) -- Tarsus Pharmaceuticals, Inc. (NASDAQ: TARS), today announced financial results for the fourth quarter and full-year ended December 31, 2024, and recent business achievements.

“Tarsus’ demonstrated category-creating blueprint has established XDEMVY as one of the most successful eye care launches to date,” said Bobak Azamian, M.D., Ph.D., Chief Executive Officer and Chairman of Tarsus. “We believe we are only beginning to unlock our full potential as the next leader in eye care and have so much to look forward to, including, potentially serving the millions of patients impacted by *Demodex* blepharitis, continuing to uncover new therapeutic indications and deepening our impact across eye care.”

Recent Business Highlights and Corporate Update

- XDEMVY continued to be one of the fastest growing therapeutics in eye care.
 - Generated \$66.4 million and \$180.1 million in XDEMVY net product sales for the fourth quarter and full-year 2024, respectively.
 - Dispensed more than 58,500 and 163,000 bottles to patients in the fourth quarter and full-year 2024, respectively.
- Established broad Eye Care Professional (ECP) utilization across more than 15,000 target ECPs.
- The expanded sales force deployed in the third quarter started to deliver meaningfully to the increased ECP utilization and prescription volumes reported for the fourth quarter of 2024.
- Broad commercial, Medicare and Medicaid reimbursement of XDEMVY now extends to more than 90% of covered lives, as of February 25, 2025.
 - Recognized a gross-to-net discount of approximately 45% in the fourth quarter and full-year 2024.
- Activated a memorable and action-oriented Direct-To-Consumer (DTC) campaign on streaming platforms in the fourth quarter of 2024, and initiated a trial-run on network television in January 2025, including spots on the Golden Globes, the GRAMMYs and the National Football League playoffs.

- The initial patient response from this campaign has been positive across multiple leading indicators, including the downloading of materials, taking the *Demodex* blepharitis (DB) quiz and utilizing the “find an eye doctor” tool on the XDEM VY website.
- DTC to continue on streaming platforms and meaningfully expand into a network television campaign beginning in the first quarter of 2025.
- Presented seminal data from the Ersu and Rhea clinical trials in DB patients with Meibomian Gland Disease (MGD) that underscore the benefit of XDEM VY broadly across multiple patient types, including functional improvements in:
 - Objective measures of MGD and the most common and impactful patient outcomes, including fluctuating vision.
- Continued to advance a robust pipeline.
 - Pursuing the next potentially transformative category in eye care – Ocular Rosacea a highly prevalent and underserved eye disease with no FDA-approved therapy.
 - TP-04 is an investigational topical sterile ophthalmic gel formulation of lotilaner specifically designed for application across the eyelid and surrounding tissue.
 - Based on positive FDA feedback, the Company established a clear regulatory path forward for TP-04 and plans to initiate a Phase 2 study in the second half of 2025.
 - Planning to advance TP-05 for the potential prevention of Lyme disease.
 - TP-05 is an investigational oral tablet designed to kill ticks and potentially prevent Lyme disease transmission.
 - Based on positive engagements with the FDA, the Company has confirmed the planned regulatory path forward, which currently includes a Phase 2 study in hundreds of patients and a Phase 3 prevention study in thousands of patients.
- Expanded and strengthened Tarsus’ eye care leadership with two key appointments to the executive team and Board of Directors, respectively.
 - Elizabeth Yeu, M.D., was appointed Chief Medical Officer. Dr. Yeu is a distinguished ophthalmologist with more than two decades of experience, who transitioned from her previous role as Chief Medical Advisor and Board Member of Tarsus.
 - Katherine H. (Kate) Goodrich, M.D., MHS, joined the Company’s Board of Directors. Dr. Goodrich is currently the Chief Medical Officer for Humana Inc., and brings decades of experience driving innovative and value-based initiatives designed to improve patient outcomes.

Additional Potential Growth Drivers in 2025 and Beyond

- On-track for potential European regulatory approval of a preservative-free formulation of XDEM VY in 2027.
 - Initiated market development work, including Key Opinion Leader engagement, disease education and scientific presentations at major conferences.
- In Japan, the Company expects to share results from a DB prevalence study in the first half of 2025, and meet with Japanese regulatory authorities to help determine a regulatory path forward.
- The Chinese regulatory agency, National Medical Products Administration, accepted the New Drug Application (NDA) submitted by Tarsus’ partner, Grand Pharmaceutical Group Ltd., for TP-03 for DB.

Fourth Quarter 2024 Financial Results

- **Product sales, net:** were \$66.4 million compared to \$13.1 million for the same period in 2023, driven by approximately 58,500 bottles of XDEMVIY dispensed to patients compared to approximately 15,700 bottles dispensed in the prior year period.
- **Cost of sales:** were \$4.9 million compared to \$1.2 million for the same period in 2023, due to manufacturing costs incurred after the approval of XDEMVIY, the royalty we pay on net product sales and the amortization of the approval milestones we paid to our licensor and are amortizing over a remaining 8.7 years.
- **Research and development (R&D) expenses:** were \$16.9 million in the fourth quarter compared to \$13.3 million in the same period in 2023. The increase was primarily due to \$2.5 million more in milestone expenses, \$1.0 million of increased payroll and personnel-related costs (including non-cash stock-based compensation), and \$1.0 million of increased program spend for TP-03, partially offset by \$0.5 million less program spend on TP-05, \$0.2 million less program spend on TP-04, and \$0.2 million of decreased other indirect expenses. Total R&D non-cash stock-based compensation expense incurred was \$1.8 million in the fourth quarter, compared with \$1.5 million in the same period in 2023.
- **Selling, general and administrative (SG&A) expenses:** were \$69.0 million in the fourth quarter compared to \$43.0 million in the same period in 2023. The increase was due primarily to \$15.5 million of increased commercial and market research costs related to the commercial launch of XDEMVIY, \$7.8 million of increased payroll and personnel-related costs (including non-cash stock-based compensation), and \$2.7 million of increased information technology, legal, professional and other corporate infrastructure. Total SG&A non-cash stock-based compensation expense incurred was \$5.5 million in the fourth quarter, compared with \$3.8 million in the same period in 2023.
- **Net loss:** was \$23.1 million, compared to \$41.9 million for the same period in 2023. Basic and diluted net loss per share for the fourth quarter was \$(0.60), compared with \$(1.31) for the same period last year.
- **Cash position:** As of December 31, 2024, cash, cash equivalents and marketable securities were \$291.4 million.

Full-Year 2024 Financial Results

- **Product sales, net:** were \$180.1 million compared to \$14.7 million in the same period in 2023, driven by more than 163,000 bottles of XDEMVIY dispensed to patients.
- **Cost of sales:** were \$12.8 million compared to \$1.6 million for the same period in 2023, due to manufacturing costs incurred after the approval of XDEMVIY, the royalty we pay on net product sales and the amortization of the approval milestone we paid to our licensor and are amortizing over a remaining 8.7 years.
- **R&D expenses:** were \$53.4 million in 2024 compared to \$50.3 million in the same period in 2023. The increase was due to \$3.5 million of increased payroll and personnel-related costs (including non-cash stock-based compensation), \$1.5 million more in milestone expenses, \$1.2 million of increased program spend for TP-03, and \$0.7 million of increased other indirect expenses, partially offset by \$2.7 million less program spend on TP-05, and \$1.2 million less program spend on TP-04. Total R&D non-cash stock-based compensation expense incurred was \$6.8 million in 2024, compared with \$5.8 million in the same period in 2023.
- **SG&A expenses:** were \$237.3 million in 2024 compared to \$108.7 million in the same period in 2023. The increase was due primarily to \$52.0 million of increased commercial and marketing costs related to the commercial launch of XDEMVIY, \$39.7 million of increased payroll and personnel-related costs (including non-cash stock-based compensation), and \$36.8 million of increased information technology, legal,

professional and other corporate expenses. Total SG&A non-cash stock-based compensation expense incurred was \$20.4 million in 2024, compared with \$13.8 million in the same period in 2023.

- **Net loss:** was \$115.6 million, compared to \$135.9 million for the same period in 2023. Basic and diluted net loss per share for 2024 was \$(3.07), compared with \$(4.62) for 2023.

Conference Call and Webcast

Tarsus will host a conference call and webcast to discuss its fourth quarter and full-year 2024 financial results and business highlights today, February 25, 2025, at 5 a.m. PT / 8 a.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-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 potential treatment of Ocular Rosacea.

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 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 potential prevention of Lyme disease.

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, and adoption rate for XDEM VY; our ability to achieve and maintain

distribution and patient access for XDEMVY and timing and breadth of payer coverage; our ability to successfully implement our sales force expansion and new direct-to-consumer campaign including network television; our ability to continue to educate the market about *Demodex* blepharitis, the timing, objectives, and results of the clinical trials including planned initiation of Phase 2 trials for the potential treatment of Ocular Rosacea and the prevention of Lyme disease, the potential market size, opportunity, and ECP education for Ocular Rosacea and our other pipeline indications, anticipated regulatory and development milestones including the clarity of the regulatory path forward for TP-04 and TP-05 in the U.S., and potential Europe, Japan, and China regulatory pathways and approval for XDEMVY, the potential benefits of the new executive and board member, our ability to continue investing in our business and become an eye care leader, 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, XDEMVY 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 XDEMVY 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 XDEMVY or our product candidates; the development and commercialization of Tarsus products is dependent on intellectual property it licenses from Elanco Tiergesundheit AG; Tarsus expects to expand its development, regulatory, operational and 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 XDEMVY and Tarsus' product candidates, particularly TP-04 for the potential treatment of Ocular Rosacea, as well as TP-05 for the potential 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 planned to be filed on February 25, 2025, which Tarsus incorporates by reference into this press release, copies of which are or will be 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)

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Revenues:				
Product sales, net	\$ 66,408	\$ 13,076	\$ 180,059	\$ 14,729
License fees and collaboration revenue	—	—	2,894	2,718
Total revenues	66,408	13,076	182,953	17,447
Operating expenses:				
Cost of sales	4,926	1,216	12,826	1,593
Cost of license fees and collaboration revenue	—	—	—	—
Research and development	16,873	13,305	53,386	50,312
Selling, general and administrative	69,030	43,005	237,310	108,700
Total operating expenses	90,829	57,526	303,522	160,605
Loss from operations	(24,421)	(44,450)	(120,569)	(143,158)
Other income (expense):				
Interest income	3,647	2,978	15,014	10,337
Interest expense	(2,312)	(989)	(7,849)	(3,346)
Loss on debt extinguishment	—	—	(1,944)	—
Other income (expense), net	(27)	(13)	586	(102)
Realized/unrealized (loss) gain on equity investments	—	420	(591)	259
Change in fair value of equity warrants issued by licensee	—	152	(201)	117
Total other income, net	1,308	2,548	5,015	7,265
Net loss	\$ (23,113)	\$ (41,902)	\$ (115,554)	\$ (135,893)
Unrealized gain (loss) on marketable securities and cash equivalents	(167)	6	181	72
Comprehensive loss	\$ (23,280)	\$ (41,896)	\$ (115,373)	\$ (135,821)
Net loss per share, basic and diluted	\$ (0.60)	\$ (1.31)	\$ (3.07)	\$ (4.62)
Weighted-average shares outstanding, basic and diluted	38,560,907	31,944,237	37,604,538	29,383,276

TARSUS PHARMACEUTICALS, INC.
BALANCE SHEETS
(In thousands, except share and par value amounts)

	December 31,	
	2024	2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 94,819	\$ 224,947
Marketable securities	196,557	2,495
Accounts receivable, net	46,760	16,621
Inventory	2,620	3,107
Other receivables	1,299	1,093
Prepaid expenses	14,650	7,868
Total current assets	356,705	256,131
Restricted cash, non-current	2,562	—
Inventory, non-current	2,533	—
Property and equipment, net	2,314	1,468
Intangible assets, net	8,326	3,867
Operating lease right-of-use assets	552	1,880
Long-term investments	3,000	631
Other assets	999	1,514
Total assets	\$ 376,991	\$ 265,491
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 64,789	\$ 23,691
Accrued payroll and benefits	15,823	13,245
Total current liabilities	80,612	36,936
Long-term debt, net	71,845	29,819
Other long-term liabilities	—	1,748
Total liabilities	152,457	68,503
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; 38,349,826 shares issued and outstanding at December 31, 2024; 34,211,190 shares issued and outstanding at December 31, 2023	6	5
Additional paid-in capital	584,559	441,641
Accumulated other comprehensive income (loss)	179	(2)
Accumulated deficit	(360,210)	(244,656)
Total stockholders' equity	224,534	196,988
Total liabilities and stockholders' equity	\$ 376,991	\$ 265,491