

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 8, 2024

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 8, 2024, 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, 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 May 8, 2024.
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 8, 2024

/s/ Jeffrey Farrow

Jeffrey Farrow

Chief Financial Officer and Chief Strategy Officer

(Principal Financial Officer and Principal Accounting Officer)



Tarsus Reports First Quarter 2024 Financial Results and Recent Business Achievements

Generated \$24.7 million in net product sales of XDEMVIY[®], an 89% increase over Q4 2023, and delivered approximately 26,000 bottles of XDEMVIY to patients

Secured multiple commercial payer contracts and remain on-track for broad commercial coverage by the end of 2024 and Medicare coverage beginning in 2025

Expanded sales force on-track to be in the field by the end of the third quarter 2024

*Strengthened financial position with an approximately \$108 million public equity offering and \$200 million financing commitment
Management to host conference call today, May 8, 2024, at 1:30 p.m. P.T. / 4:30 p.m. E.T.*

IRVINE, Calif., May 8, 2024 (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, 2024.

“This was another tremendous quarter for Tarsus as we continued building a new category in eye care to serve millions of *Demodex* blepharitis patients with XDEMVIY,” said Bobak Azamian, M.D., Ph.D., Chief Executive Officer and Chairman of Tarsus. “Our team continues to grow eye care provider adoption at an encouraging rate and enable patient access through payer contracting, and our strong balance sheet enables us to expand our sales force and continue accelerating our launch trajectory. We look forward to continuing to demonstrate our executional strength as we deliver on our mission of creating new categories in eye care and beyond.”

Recent Business Highlights

- The Company continues to execute on the commercial launch of XDEMVIY in the first quarter
 - Generated \$24.7 million in XDEMVIY net product sales, an 89% increase over Q4 2023
 - Delivered approximately 26,000 bottles of XDEMVIY to patients, an increase of 65% over Q4 2023
 - More than 8,000 ECPs, as of May 3, 2024, have started patients on XDEMVIY since launch with more than 50% of ECPs prescribing XDEMVIY to multiple patients
 - As expected, gross-to-net discounts remained consistent at approximately 55% given the impact of typical first quarter dynamics on net sales
- Launched the "Mite Party" campaign, a dynamic, multi-channel consumer marketing campaign for XDEMVIY designed to elevate consumer awareness of *Demodex* blepharitis through relatable messaging and compelling visuals
- Continued to expand payer coverage of XDEMVIY
 - Secured several contracts, including two major commercial plans with approximately 18 million covered lives that placed XDEMVIY on preferred status, and expect to begin recognizing the benefits of these contracts in Q2 2024

- Remain on-track for expected broad commercial coverage by the end of 2024 and Medicare coverage beginning in 2025
- On-track with plans to deploy approximately 50 additional sales force representatives and leaders by the end of Q3 2024
- Two additional independent meta-analyses of randomized controlled trials (Akhtar et al. and Talha et al.), now four in total, demonstrating the efficacy of XDEMZY were published in peer-reviewed journals
- Continuing to advance the pipeline and on-track with plans to engage with the FDA on TP-03 (Meibomian Gland Disease), TP-04 (Papulopustular Rosacea) and TP-05 (Lyme disease prevention) by year end 2024
- Secured \$200 million non-dilutive credit facility in April 2024
 - Elected to draw \$75 million at the close, providing approximately \$40 million net after the repayment of the previous facility

First Quarter 2024 Financial Results

- First quarter revenues were \$27.6 million, driven primarily by \$24.7 million in net product sales, and \$2.9 million in license fees and collaboration revenue.
- Cost of sales were \$1.7 million, due to manufacturing costs incurred after the approval of XDEMZY, the royalty we pay on net product sales and the amortization of the \$4.0 million approval milestone we paid to our licensor and are amortizing over a 10-year period.
- Research and development (R&D) expenses were \$12.1 million for the first quarter of 2024 compared to \$12.4 million for the same period in 2023. The decrease was due to \$1.6 million less program spend for TP-05 and \$1.0 million less in Elanco milestone expenses, partially offset by \$1.5 million of payroll expense (including non-cash stock-based compensation). Total R&D non-cash stock compensation expense incurred in the first quarter of 2024, was \$1.5 million, compared with \$1.2 million in the same period in 2023.
- Selling, general and administrative (SG&A) expenses were \$51.6 million for the first quarter of 2024 compared to \$15.1 million for the same period in 2023. The increase was due primarily to \$11.3 million of payroll and personnel-related expense (including non-cash stock-based compensation) and \$12.2 million of commercial and market research costs related to our commercial launch of XDEMZY, \$12.7 million of increased IT applications, legal, professional and other corporate expenses. Total SG&A non-cash stock compensation expense incurred in the first quarter of 2024, was \$3.9 million, compared with \$2.7 million in the same period in 2023.
- Net loss for the first quarter of 2024 was \$35.7 million, compared to a net loss of \$23.4 million for the same period in 2023. Basic and diluted net loss per share for the quarter ended March 31, 2024 was \$(1.01), compared with \$(0.88) for the same period in 2023.
- As of March 31, 2024, cash, cash equivalents and marketable securities were \$298.5 million, which includes the receipt of approximately \$108 million of net proceeds received from our follow-on offering completed in March 2024.

Conference Call and Webcast

Tarsus will host a conference call and webcast to discuss its first quarter 2024 financial results and business highlights today, May 8, 2024, 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 and is being evaluated as an investigational therapy for the treatment of Meibomian Gland Disease (MGD) in patients with *Demodex* mites. 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 aqueous gel formulation of lotilaner, a well-characterized anti-parasitic agent that paralyzes and kills ticks by selectively inhibiting parasite-specific GABA-Cl channels. Tarsus is studying TP-04 for the treatment of papulopustular rosacea (PPR).

About TP-05

TP-05 is an 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-03 as an investigational therapy for the treatment of Meibomian Gland Disease, TP-04 for the treatment of 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 our sales force expansion; our ability to achieve 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, the timing, objectives, and results of the clinical trials including the complete clinical results of the Ersa, Carpo, and Galatea trials, anticipated regulatory and development milestones, 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 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 XDEM VY and Tarsus' product candidates, particularly TP-03 for the treatment of 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 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, 2023 filed on February 27, 2024 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 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,	
	2024	2023
Revenues:		
Product sales, net	\$ 24,720	\$ —
License fees and collaboration revenue	2,894	2,500
Total revenues	27,614	2,500
Operating expenses:		
Cost of sales	1,654	—
Research and development	12,066	12,356
Selling, general and administrative	51,578	15,096
Total operating expenses	65,298	27,452
Loss from operations before other income (expense)	(37,684)	(24,952)
Other income (expense):		
Interest income	3,117	2,293
Interest expense	(983)	(684)
Other income, net	605	6
Unrealized loss on equity investments	(585)	(65)
Change in fair value of equity warrants issued by licensee	(201)	(17)
Total other income, net	1,953	1,533
Net loss	\$ (35,731)	\$ (23,419)
Other comprehensive loss:		
Unrealized (loss) gain on marketable securities and cash equivalents	(61)	4
Comprehensive loss	\$ (35,792)	\$ (23,415)
Net loss per share, basic and diluted	\$ (1.01)	\$ (0.88)
Weighted-average shares outstanding, basic and diluted	35,300,655	26,742,023

TARSUS PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(In thousands, except share and par value amounts)

	March 31, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 193,705	\$ 224,947
Marketable securities	104,819	2,495
Accounts receivable, net	29,885	16,621
Inventory	4,036	3,107
Other receivables	1,476	1,093
Prepaid expenses	6,803	7,868
Total current assets	340,724	256,131
Property and equipment, net	1,338	1,468
Intangible assets, net	3,767	3,867
Operating lease right-of-use assets	2,132	1,880
Long-term investments	—	631
Other assets	1,317	1,514
Total assets	\$ 349,278	\$ 265,491
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 36,570	\$ 23,691
Accrued payroll and benefits	5,958	13,245
Total current liabilities	42,528	36,936
Term loan, net	29,933	29,819
Other long-term liabilities	1,606	1,748
Total liabilities	74,067	68,503
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; 37,749,468 shares issued and outstanding at March 31, 2024 (unaudited); 34,211,190 shares issued and outstanding at December 31, 2023	6	5
Additional paid-in capital	555,655	441,641
Accumulated other comprehensive loss	(63)	(2)
Accumulated deficit	(280,387)	(244,656)
Total stockholders' equity	275,211	196,988
Total liabilities and stockholders' equity	\$ 349,278	\$ 265,491