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) November 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 November 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 September 30, 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 November 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: November 9, 2023

/s/ Jeffrey Farrow

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

Tarsus Reports Third Quarter 2023 Financial Results and Recent Business Achievements

Launched XDEMVY® (lotilaner ophthalmic solution) 0.25%, for the treatment of Demodex blepharitis

Achieved $1.7 million in net product sales with more than 1,700 dispensed bottles

Strengthened balance sheet with an approximately $100 million public equity offering

Management to host conference call today, November 9, 2023, at 1:30 p.m. P.T. / 4:30 p.m. E.T.

IRVINE, Calif., November 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 third quarter ended September 30, 2023, and recent business achievements.

"We are proud to be able to bring XDEMVY to the millions of people suffering from *Demodex* blepharitis, who, until recently, have been living without an effective, FDA-approved treatment option," said Bobak Azamian, M.D., Ph.D., Chief Executive Officer and Chairman of Tarsus. "The XDEMVY launch is off to a strong start and we are encouraged by the early momentum among eye care providers and patients we have generated in just the first few weeks of availability."

Recent Business Highlights

- On July 24, XDEMVY® was approved by the U.S. Food and Drug Administration (FDA) as the first and only therapeutic for *Demodex* blepharitis (DB), a highly prevalent eyelid disease that impacts approximately 25 million eye care patients in the U.S. It was approved a month prior to the PDUFA date and launched on August 24.
    - XDEMVY targets the root cause of DB and in pivotal trials demonstrated significant improvement in eyelids (reduction of collarettes, the pathognomonic sign of the disease, to no more than 2 collarettes per upper lid), mite eradication (mite density of 0 mites per lash) and erythema cure (Grade 0).
- Saturn-2 data were delivered as encore presentations at the American Academy of Optometry and American Academy of Ophthalmology conferences.
- XDEMVY was added to the American Academy of Ophthalmology's Preferred Practice Pattern (PPP) guidelines as the first and only FDA-approved therapeutic for the treatment of *Demodex* blepharitis.
- In the third quarter of 2023:
    - XDEMVY generated $1.7 million in net product sales
    - ~1,700 bottles of XDEMVY were delivered to patients
    - Recognized a better than anticipated gross-to-net discount of 73%.
- The Company's expansive disease education efforts continue to drive awareness among eye care providers (ECPs) and action in proactively diagnosing DB.
- Contract discussions with key commercial and Medicare accounts remain ongoing
    - Expect to secure broad commercial coverage sequentially throughout 2024 and Medicare coverage in 2025

Achieved and Anticipated 2023 and 2024 Milestones

Program	Milestone	Anticipated Indication	H2 2023	Q1 2024
XDEMVY	FDA Approval	*Demodex* blepharitis	X	
TP-03	Topline Phase 2a (Ersa)	Meibomian Gland Disease	●	
TP-04	Topline Phase 2a (Galatea)	Rosacea		●
TP-05	Topline Phase 2a (Carpo)	Lyme Disease Prevention		●

Third Quarter 2023 Financial Results

- Total revenues were $1.9 million, driven primarily by $1.7 million in net product sales, representing five weeks of sales following the launch of XDEMVY in late August.
- Cost of sales were $0.4 million, due to manufacturing costs incurred after the approval of XDEMVY, period costs associated with launching one month earlier than expected, 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 third quarter of 2023 compared to $10.9 million for the same period in 2022. The increase was due to $2.8 million of payroll expense (including non-cash stock-based compensation), partially offset by $1.9 million of program spend for TP-03. Total R&D non-cash stock compensation expense incurred in the third quarter of 2023, was $1.7 million, compared with $1.0 million in the same period in 2022.
- Selling, general and administrative (SG&A) expenses were $30.3 million for the third quarter of 2023 compared to $12.0 million for the same period in 2022. The increase was due primarily to $7.9 million of payroll expense and $8.1 million of commercial and market research costs related to our commercial launch of XDEMVY. Total SG&A non-cash stock compensation expense incurred in the third quarter of 2023, was $3.6 million, compared with $2.6 million in the same period in 2022.
- Net loss for the third quarter of 2023 was $39.1 million, compared to a net loss of $22.5 million for the same period in 2022. Basic and diluted net loss per share for the quarter ended September 30, 2023 was $(1.28), compared with $(0.84) for the same period in 2022.
- As of September 30, 2023, cash, cash equivalents and marketable securities were $246.9 million, which includes the receipt of $99.4 million of net proceeds received from our follow-on offering completed in August 2023.

Conference Call and Webcast
Tarsus will host a conference call and webcast to discuss its third quarter 2023 financial results and business highlights today, November 9, 2023, at 1:30p.m. P.T. / 4:30 p.m. ET. A live webcast will be available on the events section of the Tarsus website at www.tarsusrx.com. 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 *Demodex* Blepharitis
Blepharitis is a common lid margin disease that is characterized by eyelid margin inflammation, redness and ocular irritation. *Demodex* blepharitis is caused by an infestation of *Demodex* mites, the most common ectoparasite found on humans and accounts for over two-thirds of all blepharitis cases. *Demodex* blepharitis may affect as many as 25 million Americans based on an extrapolation from the Titan study indicating 58% of patients presenting to U.S. eye care clinics have collarettes, a pathognomonic sign of *Demodex* infestation, and that at least 45 million people annually visit an eye care clinic. *Demodex* blepharitis can have a significant clinical burden and negative impact on patients' daily lives. The Titan study also showed that management tools prior to the approval of XDEMVY, such as tea tree oil and lid wipes, are ineffective at targeting the root cause of *Demodex* blepharitis.

About XDEMVY®
XDEMVY (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. XDEMVY 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 XDEMVY 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.

XDEMVY Indication and Important Safety Information

INDICATIONS AND USAGE
XDEMVY 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: www.xdemvy.com.

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. XDEMVY (lotilaner ophthalmic solution) 0.25% is FDA approved in the United States for the treatment of *Demodex* blepharitis. Tarsus is also developing TP-03 for the treatment of Meibomian Gland Disease, which is currently being studied in a Phase 2a clinical trial. In addition, Tarsus is developing TP-04 for the potential treatment of Rosacea and TP-05, an oral tablet for the 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 market size, acceptance, demand, prescription fill rate and adoption rate for XDEMVY; our ability to achieve distribution and patient access for XDEMVY 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, 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’ ability to maintain regulatory approval for and successfully commercialize XDEMVY 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 commercialization of its product candidates, if approved; Tarsus is heavily dependent on the success of its lead product, XDEMVY for the treatment of *Demodex* blepharitis; 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 XDEMVY 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 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, the Form 10-Q for the quarter ended June 30, 2023 filed on August 10, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Product sales, net	$ 1,653	$ —	$ 1,653	$ —
License fees and collaboration revenue	218	—	2,718	15,816
Total revenues	1,871	—	4,371	15,816
Operating expenses:				
Cost of sales	377	—	377	—
Cost of license fees and collaboration revenue	—	—	—	555
Research and development	12,105	10,912	37,007	32,596
Selling, general and administrative	30,324	11,994	65,695	30,316
Total operating expenses	42,806	22,906	103,079	63,467
Loss from operations before other income (expense) and income taxes	(40,935)	(22,906)	(98,708)	(47,651)
Other income (expense):				
Interest income	2,840	1,061	7,359	1,372
Interest expense	(858)	(633)	(2,357)	(1,507)
Other (expense) income, net	(48)	(7)	(89)	136
Unrealized loss on equity investments	(111)	(13)	(161)	(326)
Change in fair value of equity warrants issued by licensee	(36)	(18)	(35)	(520)
Total other income (expense), net	1,787	390	4,717	(845)
Benefit from income taxes	—	5	—	4
Net loss	$ (39,148)	$ (22,511)	$ (93,991)	$ (48,492)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities and cash equivalents	15	(10)	66	(10)
Comprehensive loss	$ (39,133)	$ (22,521)	$ (93,925)	$ (48,502)
Net loss per share, basic and diluted	$ (1.28)	$ (0.84)	$ (3.35)	$ (2.03)
Weighted-average shares outstanding, basic and diluted	30,622,440	26,662,374	28,065,434	23,923,512

TARSUS PHARMACEUTICALS, INC.

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

	September 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 226,672	$ 71,660
Marketable securities	20,213	145,366
Accounts receivable, net	5,362	—
Inventory	15	—
Other receivables	1,008	3,582
Prepaid expenses	6,007	4,767
Total current assets	259,277	225,375
Property and equipment, net	1,614	957
Intangible assets, net	3,967	—
Operating lease right-of-use assets	2,011	575
Long-term investments	210	371
Other assets	1,253	585
Total assets	$ 268,332	$ 227,863
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 15,351	$ 9,910
Accrued payroll and benefits	7,898	5,519
Total current liabilities	23,249	15,429
Term loan, net	29,708	19,434
Other long-term liabilities	1,711	100
Total liabilities	54,668	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; 33,104,087 shares issued and outstanding at September 30, 2023 (unaudited); 26,727,458 shares issued and outstanding at December 31, 2022	5	5
Additional paid-in capital	416,421	301,732
Accumulated other comprehensive loss	(8)	(74)
Accumulated deficit	(202,754)	(108,763)
Total stockholders' equity	213,664	192,900
Total liabilities and stockholders' equity	$ 268,332	$ 227,863