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) August 10, 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 August 10, 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 June 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 August 10, 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: August 10, 2023

/s/ Jeffrey Farrow

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

Tarsus Reports Second Quarter 2023 Financial Results and Recent Business Achievements

XDEMVY™ (lotilaner ophthalmic solution) 0.25% received FDA approval for the treatment for Demodex blepharitis

On track to have XDEMVY and sales force in market by the end of August 2023

Completed enrollment of Galatea, a Phase 2a trial evaluating TP-04 for Rosacea, with topline data expected in 1H 2024

Strengthened balance sheet with $100 million public equity offering in August 2023

IRVINE, Calif., August 10, 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 second quarter ended June 30, 2023, and recent business achievements.

“The FDA approval of XDEMVY for the treatment of *Demodex* blepharitis is a seminal milestone for Tarsus, the eye care community and most importantly for patients, many of whom have struggled for years without an approved, effective treatment option,” said Bobak Azamian, MD, PhD, Chief Executive Officer and Chairman of Tarsus. “We are well-positioned and well-funded, expect to launch XDEMVY later this month to capture the potentially very significant patient demand, and anticipate rapid adoption among eye care providers and meaningful prescription volume in the early days following XDEMVY’s entrance into the market.”

Recent Business Highlights and Corporate Update

- On July 24, 2023, the FDA approved XDEMVY (lotilaner ophthalmic solution) 0.25% for the treatment of *Demodex* blepharitis (DB)
  - First and only approved therapeutic for DB, a highly prevalent eyelid disease that impacts approximately 25 million eye care patients in the U.S.
  - 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)

- Actively engaging in contracting discussions with all the top commercial and Medicare accounts and expect to secure commercial coverage sequentially throughout 2024 and Medicare coverage in 2025

- Completed recruitment of our 85-person sales force targeting ~15K optometrists and ophthalmologists, which represents >80% of the projected market; expect sales force to be deployed by the end of August when we anticipate product to be available

- Established unique distribution model leveraging high touch retail and digital pharmacies to offer broad patient access with a potential 2x fill rate compared to traditional approaches

- Active disease education continuing to drive awareness and encouraging eye care providers (ECPs) to proactively diagnose DB

- Consistently > 90% of ~250 optometrists and ophthalmologists surveyed indicated they would prescribe an FDA-approved therapeutic for DB
- "Look at the Lids" disease education campaign has generated nearly 300K unique website visits, up from 200K last quarter and nearly 3M digital/media impressions, an increase of 700K impressions since last quarter

- Saturn-2 pivotal trial results were published in the American Academy of Ophthalmology journal
  - XDEMVY met the primary, all secondary endpoints and was generally well tolerated

Achieved and Anticipated 2023 Milestones

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

Second Quarter 2023 Financial Results

- Second quarter net loss for 2023 was $31.4 million, compared to a net loss of $5.7 million for the same period in 2022, which was primarily due to: (i) a decrease of $15.3 million of license fee and collaboration revenue, (ii) an increase of $9.9 million of general and administrative expenses, and (iii) an increase of $2.9 million of research and development expenses
- Second quarter 2023 there were no amounts reported within license fee and collaboration revenue related to the strategic partnership with LianBio, compared to $15.3 million for the same period in 2022
- Second quarter research and development expenses for 2023 were $12.5 million (inclusive of stock-based compensation of $1.5 million), compared to $9.6 million for the same period in 2022
- Second quarter general and administrative expenses for 2023 were $20.3 million (inclusive of stock-based compensation of $3.7 million), compared to $10.4 million for the same period in 2022, which was primarily due to a $5.3 million increase of payroll and personnel-related costs; and a $3.5 million increase of commercial and market research costs related to our commercial expansion as we prepare to launch our recently approved product, XDEMVY
- As of June 30, 2023, cash, cash equivalents and marketable securities were $178.2 million, not including the recent equity public offering of $100 million in gross proceeds, completed in August 2023

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 current management tools, 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 timing and availability of XDEMVY for prescription, 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 sales force size and hiring plans; our ability to continue to educate the market about *Demodex* blepharitis, the market size for TP-03, TP-04, and TP-05, the timing, objectives, and results of the clinical trials, anticipated regulatory and development milestones, 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 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; 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 XDEMVY for the treatment of *Demodex* blepharitis, 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 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.

Media Contact:
Adrienne Kemp
Sr. Director, Corporate Communications
(949) 922-0801
AKemp@tarsusrx.com

Investor Contact:
David Nakasone
Head of Investor Relations
(949) 620-3223
DNakasone@tarsusrx.com

TARSUS PHARMACEUTICALS, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
License fees and collaboration revenue	$ —	$ 15,277	$ 2,500	$ 15,816
Operating expenses:				
Cost of license fees and collaboration revenue	—	522	—	555
Research and development	12,546	9,603	24,902	21,684
General and administrative	20,275	10,376	35,371	18,322
Total operating expenses	32,821	20,501	60,273	40,561
Loss from operations before other income (expense) and income taxes	(32,821)	(5,224)	(57,773)	(24,745)
Other income (expense):				
Interest income	2,226	297	4,519	311
Interest expense	(815)	(544)	(1,499)	(874)
Other (expense) income, net	(47)	106	(41)	143
Unrealized gain (loss) on equity investments	15	(121)	(50)	(313)
Change in fair value of equity warrants issued by licensee	18	(257)	1	(502)
Total other income (expense), net	1,397	(519)	2,930	(1,235)
Provision for income taxes	—	—	—	(1)
Net loss	$ (31,424)	$ (5,743)	$ (54,843)	$ (25,981)
Other comprehensive loss:				
Unrealized gain on marketable securities and cash equivalents	47	—	51	—
Comprehensive loss	$ (31,377)	$ (5,743)	$ (54,792)	$ (25,981)
Net loss per share, basic	$ (1.17)	$ (0.24)	$ (2.05)	$ (1.15)
Net loss per share, diluted	$ (1.17)	$ (0.24)	$ (2.05)	$ (1.15)
Weighted-average shares outstanding, basic	26,815,733	24,332,531	26,779,203	22,531,384
Weighted-average shares outstanding, diluted	26,815,733	24,332,531	26,779,203	22,531,384

TARSUS PHARMACEUTICALS, INC.

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

	June 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 106,773	$ 71,660
Marketable securities	71,455	145,366
Other receivables	246	3,582
Prepaid expenses	5,002	4,767
Total current assets	183,476	225,375
Property and equipment, net	1,541	957
Operating lease right-of-use assets	2,137	575
Long-term investments	322	371
Other assets	1,451	585
Total assets	$ 188,927	$ 227,863
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 9,459	$ 9,910
Accrued payroll and benefits	5,306	5,519
Total current liabilities	14,765	15,429
Term loan, net	24,607	19,434
Other long-term liabilities	1,826	100
Total liabilities	41,198	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; 26,899,572 shares issued and outstanding at June 30, 2023 (unaudited); 26,727,458 shares issued and outstanding at December 31, 2022	5	5
Additional paid-in capital	311,353	301,732
Accumulated other comprehensive loss	(23)	(74)
Accumulated deficit	(163,606)	(108,763)
Total stockholders' equity	147,729	192,900
Total liabilities and stockholders' equity	$ 188,927	$ 227,863