

**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 11, 2022

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) 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 11, 2022, Tarsus Pharmaceuticals, Inc. (the “Company”) issued a press release, which, among other matters, sets forth the Company’s results of operations for the three and six months ended June 30, 2022. 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 August 11, 2022
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 11, 2022

/s/ Leonard M. Greenstein

Leonard M. Greenstein

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)



Tarsus Reports Second Quarter 2022 Financial Results and Recent Business Achievements

TP-03 for the treatment of Demodex blepharitis met all endpoints in the Saturn-2 Phase 3 trial; NDA submission expected this year

Initiated Ersa Phase 2a trial evaluating TP-03 for the treatment of Meibomian Gland Disease

Cash runway anticipated into at least 2026 for the commercial launch of TP-03 and continued pipeline development

IRVINE, Calif., August 11, 2022 (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 eye diseases, today announced financial results for the second quarter ended June 30, 2022, and recent business achievements.

“We continued to execute on our top priority of advancing TP-03 for the treatment of Demodex blepharitis, including preparing for NDA submission this year. We are also expanding the commercial team and seeing growing disease awareness as we generate momentum towards a potential commercial launch next year,” said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. “Simultaneously, we’ve taken positive steps to advance our pipeline, including initiating our clinical program for MGD, and preparing for the start of two additional Phase 2 studies in Lyme disease prevention and Rosacea. These milestones, along with our strengthened balance sheet, are important steps toward our goal of becoming a leading eye pharmaceutical company.”

Recent Business Highlights and Corporate Update

- NDA submission of TP-03 for *Demodex* blepharitis (DB) expected this year
- TP-03 met the primary and all secondary endpoints, resolved DB and was safe and well-tolerated in Saturn-2 Phase 3, the second and final pivotal trial
- Initiated Ersa Phase 2a trial evaluating TP-03 for the treatment of Meibomian Gland Disease, another highly prevalent eyelid margin disease
- Data from the Callisto Phase 1b trial of TP-05, a novel, oral, non-vaccine potential therapeutic for the prevention of Lyme disease, expected this year
- Cash runway anticipated into at least 2026
 - \$245 million of cash as of June 30, 2022, including Q2 2022 net proceeds of \$74 million from follow-on equity raise and a \$15 million milestone from China out-license
 - \$30 million in expected milestones through 2024 from China out-license with \$15 million in H2 2022

2022 Milestones

Program	Milestone	Anticipated Indication	H1 2022	H2 2022
TP-03	Topline Pivotal Data (Saturn-2)	<i>Demodex</i> blepharitis	✓	
TP-03	Initiate Phase 2 (Ersa)	Meibomian Gland Disease		✓
TP-05	Initiate Ph2a (Carpo)	Lyme disease prevention		●
TP-03	NDA Submission	<i>Demodex</i> blepharitis		●
TP-04	Initiate Phase 2 (Galatea)	Rosacea		●
TP-05	Phase 1b Data (Callisto)	Lyme disease prevention		●
TP-03	Initiate Phase 3 trial in China (with LianBio)	<i>Demodex</i> blepharitis		●

Second Quarter 2022 Financial Results

- Second quarter net loss for 2022 was \$5.7 million, compared to net income of \$6.3 million for the same period in 2021

- Second quarter 2022 license fee and collaboration revenue, as part of the strategic partnership with LianBio, was \$15.3 million, compared to \$22.0 million for the same period in 2021
- Second quarter research and development expenses for 2022 were \$9.6 million (inclusive of stock-based compensation of \$1.0 million), compared to \$7.2 million for the same period in 2021
- Second quarter general and administrative expenses for 2022 were \$10.4 million (inclusive of stock-based compensation of \$2.5 million), compared to \$6.8 million for the same period in 2021
- As of June 30, 2022, cash and cash equivalents were \$245.4 million

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. Tarsus is studying two investigational medicines in clinical trials. Its lead product candidate, TP-03, is a novel therapeutic which has demonstrated positive results in two pivotal trials for the treatment of *Demodex* blepharitis. TP-03 is also being developed for the treatment of Meibomian Gland Disease. In addition, Tarsus is developing TP-05, an oral, non-vaccine therapeutic for the prevention of Lyme disease, which is currently being studied in a Phase 1b clinical trial.

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 approval and commercialization of TP-03, the initiation of Phase 2 studies for Lyme disease prevention and the treatment of rosacea, cash runway expectations, the terms of the license agreement with LianBio, the ability of LianBio to commercialize TP-03 in the Greater China territory, the market size for TP-03 and TP-05, future events and Tarsus’ plans for and the anticipated benefits of its product candidates including TP-03, TP-04 and TP-05, the timing, objectives and results of the clinical trials, anticipated regulatory and development milestones 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 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 any commercialization of its product candidates, if approved; Tarsus is heavily dependent on the success of its lead product candidate, TP-03 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 TP-03 for the treatment of *Demodex* blepharitis and 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; and 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. 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, 2021 filed on March 14, 2022 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues:				
License fees	\$ 13,893	\$ 19,048	\$ 13,893	\$ 52,359
Collaboration revenue	1,384	2,969	1,923	3,090
Total revenues	15,277	22,017	15,816	55,449
Operating expenses:				
Cost of license fees and collaboration revenue	522	737	555	2,034
Research and development	9,603	7,204	21,684	23,465
General and administrative	10,376	6,794	18,322	11,954
Total operating expenses	20,501	14,735	40,561	37,453
(Loss) income from operations before other (expense) income and income taxes	(5,224)	7,282	(24,745)	17,996
Other (expense) income:				
Interest (expense) income, net	(247)	7	(563)	16
Other income (expense), net	106	(39)	143	(73)
Unrealized loss on equity investments	(121)	—	(313)	—
Change in fair value of equity warrants issued by licensee	(257)	(876)	(502)	(876)
Total other expense, net	(519)	(908)	(1,235)	(933)
Provision for income taxes	—	(29)	(1)	(342)
Net (loss) income and comprehensive (loss) income	\$ (5,743)	\$ 6,345	\$ (25,981)	\$ 16,721
Net (loss) income per share, basic	\$ (0.24)	\$ 0.31	\$ (1.15)	\$ 0.81
Net (loss) income per share, diluted	\$ (0.24)	\$ 0.29	\$ (1.15)	\$ 0.76
Weighted-average shares outstanding, basic	24,332,531	20,555,258	22,531,384	20,446,246
Weighted-average shares outstanding, diluted	24,332,531	21,966,599	22,531,384	21,895,304

TARSUS PHARMACEUTICALS, INC.

BALANCE SHEETS

(In thousands, except share and par value amounts)

	June 30, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 245,363	\$ 171,332
Marketable securities	—	483
Accounts receivable	17	—
Other receivables	603	92
Prepaid expenses and other current assets	4,300	4,045
Total current assets	250,283	175,952
Property and equipment, net	963	755
Operating lease right-of-use assets	813	1,074
Long-term investments	169	—
Other assets	600	1,126
Total assets	\$ 252,828	\$ 178,907
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 8,938	\$ 8,680
Accrued payroll and benefits	2,780	2,798
Total current liabilities	11,718	11,478
Term loan, net	19,262	—
Other long-term liabilities	343	699
Total liabilities	31,323	12,177
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; 26,650,078 shares issued and 26,644,252 outstanding, which excludes 5,826 shares subject to repurchase at June 30, 2022 (unaudited); 20,726,580 shares issued and 20,698,737 outstanding, which excludes 27,840 shares subject to repurchase at December 31, 2021	5	4
Additional paid-in capital	294,153	213,398
Accumulated deficit	(72,653)	(46,672)
Total stockholders' equity	221,505	166,730
Total liabilities and stockholders' equity	\$ 252,828	\$ 178,907