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 4, 2021

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 4, 2021, 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, 2021. 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 4, 2021
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 4, 2021

/s/ Leo M. Greenstein

Leo M. Greenstein

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

Tarsus Pharmaceuticals, Inc. Reports Second Quarter 2021 Financial Results and Provides Business and Clinical Updates

Announced positive results of the Saturn-1 pivotal trial evaluating TP-03 for the treatment of Demodex blepharitis; results presented at the 2021 American Society of Cataract and Refractive Surgery (ASCRS) conference

Initiated Saturn-2, second pivotal Phase 3 trial evaluating the safety and efficacy of TP-03 for the treatment of Demodex blepharitis; Saturn-2 trial design similar to Saturn-1, topline data expected in Q1 2022

Initiated the Phase 1 Callisto trial evaluating TP-05, a novel, oral, non-vaccine therapeutic, for the prevention of Lyme disease

Cash and equivalents of $177 million, plus TP-03 license receivables of $20 million as of June 30, 2021

IRVINE, Calif., August 4, 2021 (GLOBE NEWSWIRE) -- Tarsus Pharmaceuticals, Inc. (NASDAQ: TARS), a late clinical-stage biopharmaceutical company 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 and provided business and clinical updates for the quarter ended June 30, 2021.

“We have achieved significant milestones on our lead product and pipeline so far in 2021 with the positive read-out of the Saturn-1 data for TP-03 in Demodex blepharitis, the initiation of Saturn-2, and the initiation of the Callisto trial of TP-05 for the prevention of Lyme disease,” said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. “Interest from the physician community also continues to build, as new Saturn-1 data presented at the ASCRS 2021 Annual Meeting reinforced the strong potential clinical utility of TP-03 with a broad range of patients showing a substantial response. Additionally, results from the Titan and Atlas studies reinforce the prevalence and burden of Demodex blepharitis, suggesting that this disease could affect as many as 25 million Americans, with 80% of patients reporting a negative impact on daily life. We believe this data supports both the need and opportunity for an FDA-approved therapeutic treatment option.”

Recent Business Highlights and Corporate Update:

- Announced positive results of the Phase 2b/3 Saturn-1 pivotal trial studying TP-03 (lotilaner ophthalmic solution, 0.25%) in patients with Demodex blepharitis. All pre-specified primary and secondary endpoints were met, and complete resolution of Demodex blepharitis signs was demonstrated in many patients treated with TP-03 (lotilaner ophthalmic solution, 0.25%).

    - 81% of patients on TP-03 achieved a clinically meaningful collarette cure, defined as 0-10 collarettes per lid at day 43 compared to 23% of those on vehicle ($p<0.0001$).
    - 44% of patients on TP-03 achieved the primary endpoint of complete collarette cure, defined as 0-2 collarettes per lid at day 43, compared to 7% on vehicle ($p<0.0001$).
    - 68% of patients on TP-03 achieved mite eradication defined as 0 mites per lash at day 43, compared to 18% on vehicle ($p<0.0001$).
    - Additionally, significant efficacy in lid erythema (redness) was demonstrated across multiple measures including complete and clinically meaningful composite cures, and in erythema alone. Results showed 45% of patients improved erythema by one (1) grade or more (compared to 28% of patients on vehicle, $p=0.0002$) and 19% of patients on TP-03 achieved a complete erythema cure (compared to 7% of patients on vehicle, $p<0.0001$).
    - TP-03 was well tolerated with a safety profile similar to the vehicle group. Additionally, the vast majority of TP-03 patients (92%) reported that the drop comfort was neutral to very comfortable. There were no serious treatment-related adverse events nor any treatment-related adverse events leading to treatment discontinuation.

- Released new data from the Saturn-1 Phase 2b/3 pivotal trial at the ASCRS 2021 Annual Meeting. The new Saturn-1 data reinforces the strong potential clinical utility of TP-03 for the treatment of Demodex blepharitis, with a broad range of patients showing a substantial response.

    - 95% of TP-03 patients showed a significant improvement in mite count, achieving ≤0.5 mites per lash at day 43 from an average baseline of 3.2 mites per lash, compared to 36% of those on vehicle ($p<0.0001$).
    - 93% of TP-03 patients improved by at least one collarette grade or approximately 50 collarettes per lid by day 43, from an average baseline of grade 2.8 or approximately 100 collarettes per lid, compared to 50% of those on vehicle ($p<0.0001$).
    - An additional Saturn-1 safety analysis also revealed that TP-03 had no clinically significant effect on multiple safety measures including Corrected Distance Visual Acuity (CDVA), corneal staining, and intraocular pressure (IOP), and no significant findings from slit lamp biomicroscopy or fundus exam. In addition, no impact to endothelial cell density (ECD) was seen in a subset of 21 patients. ECD will be further evaluated as part of the Saturn-2 trial plan.

- Presented data from the Titan real world prevalence study at the ASCRS meeting. The Titan study is an IRB-approved, retrospective chart review of 1,032 patients across six U.S.-based ophthalmology and optometry practices, designed to better understand the

prevalence of collarettes in U.S. eye care clinics. Collarettes, or cylindrical dandruff, are a pathognomonic sign of Demodex blepharitis and are an accumulation of mite waste product and eggs that form at the base of the eyelashes. In data presented at ASCRS, the Titan study revealed the presence of collarettes in 58% (n=595) of patients. When projected across the U.S. population, these results suggest that Demodex blepharitis could affect as many as 25 million Americans. The study also revealed that the prevalence of Demodex blepharitis is similar to that of dry eye (58%, n=593).

- Commenced enrollment in Saturn-2, the second pivotal trial evaluating TP-03 for the treatment of Demodex blepharitis. Saturn-2 is a randomized, controlled, multicenter, double-masked trial studying the safety and efficacy of TP-03. The trial is expected to enroll 418 participants and has a similar design to Saturn-1. Saturn-2's primary endpoint is the proportion of patients achieving collarette cure, defined as 0 to 2 collarettes per lid. Secondary endpoints include the eradication of Demodex mites and the proportion of patients achieving a cure based on a composite of collarette cure and erythema cure (eyelid redness). Topline results for the study are anticipated in Q1 of 2022.

- Initiated the Phase 1 Callisto trial of TP-05, a novel, oral, non-vaccine therapeutic, for the prevention of Lyme disease and malaria. The Phase 1 Callisto trial is a single ascending dose and multiple ascending dose trial designed to evaluate the safety, tolerability, and pharmacokinetics (PK) of TP-05 in healthy volunteers. There are currently no U.S. Food and Drug Administration (FDA)-approved pharmacological prophylactic options for Lyme disease, which is the most common vector-borne disease in the United States, transmitted to humans through the infection of the bacterium Borrelia burgdorferi following the bite of a tick vector.

- Presented data from the Atlas study at the virtual Association for Research in Vision and Ophthalmology (ARVO) 2021 Annual Meeting. The Atlas study is believed to be the first multi-center observational study to evaluate the functional and psychosocial impact of Demodex blepharitis, along with clinical manifestations, in adult patients. Overall, the study showed that Demodex blepharitis is associated with a significant symptomatic and psychosocial burden, negatively affecting daily life in the majority (80%) of patients with the disease.

- Received $35 million in proceeds as part of the partnership with LianBio; an additional $20 million is expected in Q3 2021 for clinical milestones achieved in June 2021.

Second Quarter 2021 Financial Results

- Second quarter net income for 2021 was $6.3 million, compared to a net loss of $(3.3) million for the same period in 2020.
- Second quarter 2021 license fee and collaboration revenue, as part of strategic partnership with LianBio, was $22.0 million; and $0.7 million in associated expense in proportion to this revenue.
- Second quarter research and development expenses for 2021 were $7.2 million (inclusive of stock-based compensation of $0.4 million), compared to $1.7 million for the same period in 2020.

- Second quarter general and administrative expenses for 2021 increased to $6.8 million (inclusive of stock-based compensation of $2.4 million), compared to $1.5 million for the same period in 2020.
- As of June 30, 2021, cash and cash equivalents were $176.7 million, and accounts receivable were $20 million for an achieved TP-03 clinical milestone.

About Tarsus Pharmaceuticals, Inc.
Tarsus Pharmaceuticals, Inc. is a late clinical-stage biopharmaceutical company that applies proven science and new technology to revolutionize treatment for patients, starting with eye care. It 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. The Company is studying two investigational medicines in clinical trials. Its lead product candidate, TP-03, is a novel therapeutic being studied in a second Phase 3 pivotal trial for the treatment of Demodex blepharitis. TP-03 is also being developed for the treatment of Meibomian Gland Disease. Tarsus is developing TP-05, an oral, non-vaccine therapeutic for the prevention of Lyme disease, which is currently being studied in a Phase 1 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 receipt by Tarsus of future payments and achievement and timing of milestones under the terms of the collaboration 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 and TP-05, the timing, objectives and results of the clinical studies, 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-05, or any other product candidate that Tarsus develops receives marketing approval, Tarsus may not be successful in educating eye care physicians and the market about the need for treatments specifically for Demodex blepharitis, Lyme disease, 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, as well as TP-05 for the treatment 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, 2020 filed with the SEC on March 31, 2021, and Form 10-Q for the quarter ended June 30, 2021 filed with the SEC on August 4, 2021, 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 INCOME (LOSS)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenues:				
License fees	$ 19,048	—	$ 52,359	—
Collaboration revenue	2,969	—	3,090	—
Total revenues	22,017	—	55,449	—
Operating expenses:				
Cost of license fees and collaboration revenue	737	—	2,034	—
Research and development	7,204	1,737	23,465	3,249
General and administrative	6,794	1,526	11,954	2,132
Total operating expenses	14,735	3,263	37,453	5,381
Income (loss) from operations before other (expense) income and income taxes	7,282	(3,263)	17,996	(5,381)
Other (expense) income:				
Interest income (expense), net	7	13	16	174
Other (expense) income, net	(39)	—	(73)	—
Change in fair value of equity warrant rights	(876)	—	(876)	—
Total other (expense) income	(908)	13	(933)	174
Provision for income taxes	(29)	—	(342)	—
Net income (loss) and comprehensive income (loss)	$ 6,345	$ (3,250)	$ 16,721	$ (5,207)
Net income (loss) per share				
Basic	$ 0.31	$ (1.23)	$ 0.81	$ (1.96)
Diluted	$ 0.29	$ (1.23)	$ 0.76	$ (1.96)
Weighted-average shares outstanding				
Basic	20,555,258	2,651,321	20,446,246	2,650,843
Diluted	21,966,599	2,651,321	21,895,304	2,650,843

TARSUS PHARMACEUTICALS, INC.

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

	June 30, 2021	December 31, 2020
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 176,735	$ 168,129
Restricted cash	—	20
Accounts receivable	20,000	—
Other receivables	157	20
Prepaid expenses and other current assets	4,012	2,486
Total current assets	200,904	170,655
Property and equipment, net of accumulated depreciation	481	548
Operating lease right-of-use asset	540	688
Other assets	1,525	81
Total assets	$ 203,450	$ 171,972
LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 8,985	$ 4,347
Accrued payroll and benefits	1,470	1,040
Total current liabilities	10,455	5,387
Other long-term liabilities	524	605
Total liabilities	10,979	5,992
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 authorized at June 30, 2021 and December 31, 2020; no shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 20,704,104 shares issued and 20,573,951 outstanding, which excludes 130,153 shares subject to repurchase at June 30, 2021 (unaudited); 20,502,576 shares issued and 20,323,301 outstanding, which excludes 179,375 shares subject to repurchase at December 31, 2020	4	4
Additional paid-in capital	208,591	198,821
Accumulated deficit	(16,124)	(32,845)
Total stockholders' equity	192,471	165,980
Total liabilities, preferred stock and stockholders' equity	$ 203,450	$ 171,972