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 11, 2021

TARSUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**012-3456**	**81-4717861**
(State or other jurisdiction of incorporation or organization)	**(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 (see General Instruction A.2. below):

☐ 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 Global 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 11, 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 months ended March 31, 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 May 11, 2021
104	Cover Page Interactive Data File (embedded within XBRL document)

SIGNATURE

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.

Date: May 11, 2021

By: /s/ Leo M. Greenstein

Leo M. Greenstein

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

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

Initiated Saturn-2, second pivotal Phase 3 trial evaluating the safety and efficacy of TP-03 for the treatment of Demodex blepharitis; topline data from Saturn-1 expected this July

Announced FDA acceptance of IND for TP-05, a novel candidate in development that aims to be first approved non-vaccine therapeutic for Lyme disease prevention

Presented results of pioneering Atlas study at ARVO 2021 Annual Meeting demonstrating the functional and psychosocial impact of Demodex blepharitis

Cash and cash equivalents of $156.2 million as of March 31, 2021; excludes Greater China out-license initial proceeds received in April and May 2021 of $25 million

IRVINE, Calif., May 11, 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 certain business and clinical updates for the quarter ended March 31, 2021.

“During the quarter, the company continued to execute on our pipeline goals for our most advanced program, TP-03 in Demodex blepharitis, as well as for our second asset, TP-05 for Lyme disease prevention,” said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. “Initiating the second pivotal Phase 3 trial for TP-03, Saturn-2, while planning for the topline data read-out from Saturn-1, now expected this July, moves us closer towards potential commercialization of a treatment for Demodex blepharitis. We have increased confidence in the market opportunity and need for a therapeutic option for the 25 million Americans that may be affected by this common ocular disease with no currently FDA-approved therapies.”

Recent Business Highlights and Corporate Update:

- Announced commencement of Saturn-2 enrollment, Tarsus’ second pivotal Phase 3 trial evaluating the company’s novel investigational treatment, TP-03, in patients with Demodex blepharitis. Up to 25 million Americans may be affected by Demodex blepharitis, which is caused by an infestation of Demodex mites. TP-03 is a topical ophthalmic formulation of lotilaner, a well-characterized anti-parasitic agent designed to

target and eradicate Demodex mites. Tarsus also recently completed enrollment for the Phase 2b/3 Saturn-1 pivotal trial, with 421 patients. Topline results of the trial are expected to be announced this July.

- Announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) application for TP-05, an oral, non-vaccine therapeutic for the prevention of Lyme disease. With this IND acceptance, Tarsus plans to initiate a Phase 1 single ascending dose and multiple ascending dose (SAD/MAD) study to evaluate the safety, tolerability, and pharmacokinetics (PK) of TP-05 in healthy volunteers. Study initiation is anticipated in July.

- Presented data from its Atlas study at the virtual Association for Research in Vision and Ophthalmology (ARVO) 2021 Annual Meeting. The Atlas study is 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.

- Also at ARVO, Tarsus presented the complete findings of the Europa study, a prospective, randomized, vehicle-controlled Phase 2b trial that evaluated the safety and efficacy of twice-daily TP-03, topical lotilaner ophthalmic solution 0.25%, in adult patients with Demodex blepharitis. In the trial, TP-03 demonstrated statistically significant results for the primary endpoint, collarette cure over vehicle, which was achieved in 80% of patients versus 16%, respectively, at 42 days ($p<0.001$) and the secondary endpoint of mite eradication, which was achieved in 73% of patients treated with TP-03 versus 21% of the vehicle group ($p=0.003$). There were no serious adverse events and no discontinuations due to adverse events.

- In March 2021, Tarsus announced its strategic partnership with LianBio Ophthalmology Limited (LianBio) to develop and commercialize TP-03 in Greater China (PRC, Hong Kong, Taiwan, and Macau) for the treatment of Demodex blepharitis and Meibomian Gland Disease (MGD), eye conditions with significant unmet treatment needs. In this arrangement, LianBio obtained exclusive TP-03 development and commercialization rights to Greater China for the treatment of Demodex blepharitis and MGD. As initial time-based consideration, LianBio paid Tarsus $15 million in April 2021 and $10 million in May 2021. LianBio remains contractually obligated to: (i) pay Tarsus up to $175 million in clinical, regulatory, and sales milestones upon achievement, (ii) pay Tarsus tiered low double-digit royalties on its sales of TP-03 in Greater China, and (iii) grant Tarsus equity warrants in LianBio, subject to vesting provisions. Assuming Tarsus achieves remaining U.S. clinical milestones for TP-03, as expected by March 2022, cumulative proceeds from LianBio will total $70 million within the first 12 months following agreement execution.

First Quarter 2021 Financial Results

- First quarter net income for 2021 was $10.4 million, compared to a net loss of $(2.0) million for the same period in 2020.
- First quarter 2021 license fee and collaboration revenue, as part of strategic partnership with LianBio, was $33.4 million; and $1.3 million in associated expense in proportion to this revenue.

- First quarter research and development expenses for 2021 were $16.3 million (inclusive of non-cash stock-based charges of $5.8 million), compared to $1.5 million for the same period in 2020.
- First quarter general and administrative expenses for 2021 increased to $5.2 million (inclusive of non-cash stock-based charges of $1.0 million), compared to $0.6 million for the same period in 2020.
- As of March 31, 2021, cash and cash equivalents were $156.2 million.

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. Its lead product candidate, TP-03, is a novel therapeutic being studied in two pivotal trials for the treatment of Demodex blepharitis. TP-03 is also being developed for the treatment of Meibomian Gland Disease.

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, 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 March 31,	
	2021	2020
Revenues:		
License fees	$ 33,311	$ —
Collaboration revenue	121	—
Total revenues	33,432	—
Operating expenses:		
Cost of license fees and collaboration revenue	1,297	—
Research and development	16,261	1,512
General and administrative	5,160	606
Total operating expenses	22,718	2,118
Income (loss) from operations before other (expense) income and income taxes	10,714	(2,118)
Other (expense) income:		
Interest income (expense), net	9	161
Other (expense) income, net	(34)	—
Total other (expense) income	(25)	161
Provision for income taxes	(313)	—
Net income (loss) and comprehensive income (loss)	$ 10,376	$ (1,957)
Net income (loss) per share		
Basic	$ 0.51	$ (0.74)
Diluted	$ 0.47	$ (0.74)
Weighted-average shares outstanding		
Basic	20,336,022	2,650,363
Diluted	21,824,574	2,650,363

TARSUS PHARMACEUTICALS, INC.

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

	March 31, 2021	December 31, 2020
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 156,179	$ 168,129
Restricted cash	20	20
Accounts receivable	25,000	—
Contract asset	7,199	—
Other receivables	247	20
Prepaid expenses and other current assets	2,806	2,486
Total current assets	191,451	170,655
Property and equipment, net of accumulated depreciation	589	548
Operating lease right-of-use asset	584	688
Other assets	1,330	81
Total assets	$ 193,954	$ 171,972
LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 9,433	$ 4,347
Accrued payroll and benefits	685	1,040
Total current liabilities	10,118	5,387
Other long-term liabilities	604	605
Total liabilities	10,722	5,992
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 authorized at March 31, 2021 and December 31, 2020; no shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 20,703,849 shares issued and 20,524,474 outstanding, which excludes 179,375 shares subject to repurchase at March 31, 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	205,697	198,821
Accumulated deficit	(22,469)	(32,845)
Total stockholders' equity	183,232	165,980
Total liabilities, preferred stock and stockholders' equity	$ 193,954	$ 171,972