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): March 14, 2022

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 March 14, 2022, Tarsus Pharmaceuticals, Inc. (the "Company") issued a press release, which, among other matters, sets forth the Company's results of operations for the year ended December 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 March 14, 2022
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: March 14, 2022 By: /s/ Leo M. Greenstein

Leo M. Greenstein
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Tarsus Pharmaceuticals, Inc. Reports Full-Year 2021 Financial Results and Recent Business Achievements

Expecting Saturn-2 Phase 3 topline data in April 2022, the second pivotal of TP-03 for the treatment of Demodex blepharitis, and NDA submission this year

Advancing pipeline this year with planned Phase 2 initiations of TP-03 for Meibomian Gland Disease and TP-04 for Rosacea, and TP-05 Phase 1b data for Lyme disease prevention

Anticipated cash runway into at least the second half of 2024, inclusive of $171 million of cash as of December 31, 2021, expected milestones from China out-license, and credit facility availability

IRVINE, Calif., March 14, 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 patients, starting with eye care, today announced financial results for the full-year ended December 31, 2021 and recent business achievements.

“During the last 12 months we made significant progress and built considerable momentum towards becoming a leading eye care pharmaceutical company. We completed enrollment in the Phase 3 Saturn-2 trial, the second pivotal trial of TP-03 and potentially first FDA approved therapy for Demodex blepharitis, a lid margin disease affecting approximately 25 million people in the U.S. The Saturn-2 trial is similar in size and design to our successful Saturn-1 trial that met all endpoints and demonstrated clinically meaningful outcomes in resolving Demodex blepharitis,” said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. “We enter 2022 well positioned to deliver Saturn-2 topline data in April, submit the NDA this year for TP-03, a potential blockbuster therapeutic. Our financial strength enables us to advance our pipeline and commercial capabilities to drive meaningful value for patients and our stockholders.”

Recent Business Highlights and Corporate Update

- Completed enrollment in the Saturn-2 Phase 3 trial, the second pivotal trial of TP-03, a potential pioneering therapeutic for Demodex blepharitis (DB)
    - Pivotal topline data expected in April 2022, which, if positive, is expected to be followed by an NDA submission later this year
    - The trial is designed to evaluate the same primary and secondary endpoints as the pivotal Saturn-1 trial in which TP-03 met all endpoints and was well-tolerated

- Reported positive pivotal Saturn-1 trial results emphasizing the potential of TP-03 to be the standard of care for DB patients
    - Met primary endpoint of collarette cure, additional endpoints of mite eradication and lid erythema (redness) cure, and demonstrated clinically meaningful outcomes in resolving DB
    - Well-tolerated with a safety profile similar to the vehicle group

- Expanded market awareness and increased physician focus on DB
    - Presented data from Titan and Atlas studies estimating there are approximately 25 million DB patients in the U.S. and DB negatively affecting daily life in 80% of patients
    - Growing physician awareness and focus of recent major medical meetings and educational programs
    - Published three peer reviewed papers in the second half of 2021 and expect at least four in the first half of 2022

- Advanced TP-05, a novel, oral, non-vaccine potential therapeutic for the prevention of Lyme disease, into the Callisto Phase 1b trial with data expected in the second half of 2022
    - Callisto is a single and multiple ascending dose trial to evaluate safety, tolerability and pharmacokinetics of TP-05 in healthy volunteers
    - There are approximately 80 million people in the U.S. at risk for Lyme disease exposure, more than 30 million of which are at moderate-to-high risk, which can result in severe neurological and other debilitating symptoms

- Expanded executive leadership team with the appointment of Jose Trevejo, M.D., Ph.D., as Chief Medical Officer
    - Dr. Trevejo has over 20 years of experience advancing the clinical development of novel therapeutics, in particular infectious diseases, which will be impactful in furthering our anti-parasitic platform across multiple indications, including Lyme disease prevention, community malaria reduction, rosacea and meibomian gland disease

- Appointed two industry leaders to our Board of Directors
    - Elizabeth Yeu, M.D., a nationally recognized Ophthalmologist and Eye Care leader will continue to serve as Chief Medical Advisor and joined the Science and Technology Committee, focused on innovation and pipeline opportunities
    - Rosemary A. Crane, a healthcare leader with more than 30 years of pharmaceutical industry experience serves as the Chair of the Science and Technology Committee and the Audit Committee

- Secured $175 million non-dilutive credit facility providing significant financial optionality as we prepare for the expected NDA submission, commercial launch of TP-03, and advancement and expansion of our pipeline

- Received $55 million to date from our TP-03 out-license in Greater China and we expect to receive $30 million in milestones in 2022

Anticipated 2022 Milestones

Program	Milestone	Anticipated Indication	H1 2022	H2 2022
TP-03	Topline Pivotal Data (Saturn-2)	Demodex blepharitis	●	
TP-03	Initiate Phase 2 (Ersa)	Meibomian Gland Disease	●	
TP-03	NDA Submission	Demodex 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	Demodex blepharitis		●

Full-Year 2021 Financial Results

- Full year net loss was $13.8 million, compared to $26.8 million in 2020
- Full year research and development expenses were $41.7 million, compared to $18.8 million in 2020
- Full year general and administrative expenses were $25.4 million, compared to $8.2 million in 2020
- As of December 31, 2021, cash, cash equivalents and marketable securities were $171.8 million

About Tarsus Pharmaceuticals, Inc.

Tarsus Pharmaceuticals, Inc. 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. 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 Company’s estimates on its cash runway; the receipt by Tarsus of future payments and achievement and timing of milestones under the terms of the collaboration with LianBio, the potential 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 impact of recent new hires, the timing, objectives and results of the clinical trials including the potential clinical results of the Saturn-2 trial, 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 healthcare professionals 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, 2021 filed on March 14, 2022 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
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2021	**2020**
Revenues:		
License fees	$ 53,067	$ —
Collaboration revenue	3,960	—
Total revenues	57,027	—
Operating expenses:		
Cost of license fees and collaboration revenue	$ 2,075	$ —
Research and development	41,712	18,826
General and administrative	25,397	8,172
Total operating expenses	69,184	26,998
Loss from operations before other (expense) income and income taxes	(12,157)	(26,998)
Other (expense) income:		
Interest income	36	188
Other expense, net	(73)	—
Unrealized loss on equity securities	(591)	—
Change in fair value of equity warrants	(987)	—
Total other (expense) income, net	(1,615)	188
Loss from operations before income taxes	(13,772)	(26,810)
Provision for income taxes	(55)	(1)
Net loss and comprehensive loss	$ (13,827)	$ (26,811)
Net loss per share, basic and diluted	$ (0.67)	$ (4.32)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	20,554,086	6,207,367

TARSUS PHARMACEUTICALS, INC.

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

	December 31,	
	2021	**2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 171,332	$ 168,129
Marketable securities	483	—
Restricted cash	—	20
Other receivables	92	20
Prepaid expenses and other current assets	4,045	2,486
Total current assets	175,952	170,655
Property and equipment, net	755	548
Operating lease right-of-use assets	1,074	688
Other assets	1,126	81
Total assets	$ 178,907	$ 171,972
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 8,680	$ 4,347
Accrued payroll and benefits	2,798	1,040
Total current liabilities	11,478	5,387
Other long-term liabilities	699	605
Total liabilities	12,177	5,992
Commitments and contingencies (*Note 8*)		
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; 20,726,580 shares issued and 20,698,737 shares outstanding, which excludes 27,840 shares subject to repurchase at December 31, 2021; 20,502,576 shares issued and 20,323,201 outstanding, which excludes 179,375 shares subject to repurchase at December 31, 2020	4	4
Additional paid-in capital	213,398	198,821
Accumulated deficit	(46,672)	(32,845)
Total stockholders' equity	166,730	165,980
Total liabilities and stockholders' equity	$ 178,907	$ 171,972