Tarsus Pharmaceuticals, Inc. Reports Third Quarter 2021 Financial Results and Recent Business Achievements

November 9, 2021

On track to complete enrollment in the fourth quarter of 2021 for the Saturn-2 Phase 3, the second pivotal trial of TP-03 for the treatment of Demodex blepharitis; topline data expected in the first quarter of 2022

Data from two pioneering studies on prevalence and impact of Demodex blepharitis were presented November 4th at the American Academy of Optometry 2021 Annual Meeting

Continued to advance the Callisto Phase 1 trial of TP-05, a novel, oral, non-vaccine therapeutic for the prevention of Lyme disease with data expected in the first half of 2022

Cash and equivalents of $184 million as of September 30, 2021, for expected runway into the second half of 2023

IRVINE, Calif., Nov. 09, 2021 (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, today announced financial results for the third quarter ended September 30, 2021 and recent business achievements.

“We are delighted with the progress we are making on our strategic objectives, including advancing our pipeline and commercial plan. We are on track to complete enrollment in Saturn-2, our second pivotal trial for TP-03, by year end. Additionally, our recently presented new data from Titan and Atlas further reinforces the large unmet market and impact Demodex blepharitis has on patients already seeing their eye doctor for common ocular conditions,” said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. “Looking ahead, we expect significant advancements in our pipeline, including initiating TP-03 for Meibomian Gland Disease and TP-04 for rosacea in the first half of 2022. Additionally, we expect to complete the Phase 1 trial of TP-05 for the prevention of Lyme disease and conduct further FDA discussions in the first half of 2022.”

Recent Business Highlights and Corporate Update:

- On track to complete enrollment by year end 2021 in Saturn-2, our second pivotal trial of TP-03, a potential pioneering therapeutic for Demodex blepharitis
    - Saturn-2 is expected to enroll 418 participants across 15-20 sites in the U.S.
    - The trial is designed to evaluate the same primary and secondary endpoints as the pivotal Saturn-1 trial in which TP-03 met the primary and secondary endpoints
    - Pivotal topline data continues to be expected in Q1 2022, which if positive, will be followed by a NDA submission in 2022

- Presented additional data from the Saturn-1 Phase 2b/3 pivotal trial at the American Society of Cataract and Refractive Surgery 2021 Annual Meeting demonstrating high treatment response rates reinforcing the potential of TP-03 to be the standard of care for Demodex blepharitis patients
    - 95% of TP-03 patients showed a significant improvement in mite count, achieving ≤0.5 mites per lash
    - 93% of TP-03 patients improved by at least one collarette grade

- Presented data from Titan and Atlas, two pioneering studies on the prevalence and impact of Demodex blepharitis respectively, at the American Academy of Optometry 2021 Annual Meeting
    - New Titan real-world prevalence data:
        - Demodex blepharitis accounts for over two-thirds of blepharitis cases and is also highly prevalent in many commonly seen patient groups, including dry eye, contact lens and cataracts
        - 75% of patients using tea tree oils and 57% of those using lid wipes were found to have a high prevalence of collarettes, indicating that current management tools for this disease are largely ineffective
    - The Atlas study, an observational study to evaluate the functional and psychosocial impact of Demodex blepharitis and clinical manifestations, showed that Demodex blepharitis is associated with a significant symptomatic and psychosocial burden, negatively affecting daily life in 80% of patients

- Continued to advance the Callisto Phase 1 trial evaluating TP-05, a novel, oral, non-vaccine therapeutic, for the prevention of Lyme disease with data expected in the first 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 of 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

- Appointed healthcare industry leader, Rosemary A. Crane, to our Board of Directors
    - Ms. Crane serves as the Chair of our newly created Science and Technology Committee, focused on external and internal innovation and pipeline opportunities
    - She has more than 30 years of extensive experience in the pharmaceutical industry, including executive leadership, board service, innovation, business development, operations, and global commercialization expertise

- Received $20 million in proceeds as part of the partnership with LianBio for clinical milestones achieved in June 2021, continue to expect to earn an additional $15 million in clinical milestones in the first half of 2022 (for a total of $70 million of proceeds since agreement execution in March 2021)

Third Quarter 2021 Financial Results

- Third quarter net loss for 2021 was $15.7 million, compared to a net loss of $10.1 million for the same period in 2020
- Third quarter 2021 license fee and collaboration revenue, as part of our strategic partnership with LianBio, was $1.2 million; and $0.1 million in associated expense in proportion to this revenue
- Third quarter research and development expenses for 2021 were $10.2 million (inclusive of stock-based compensation of $0.5 million), compared to $8.0 million for the same period in 2020
- Third quarter general and administrative expenses for 2021 increased to $6.7 million (inclusive of stock-based compensation of $1.6 million), compared to $2.2 million for the same period in 2020
- As of September 30, 2021, cash and cash equivalents were $183.8 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. 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, 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-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, 2020 filed on March 31, 2021 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:
SuJin Oh
Shop PR

(917) 841-5213
sujin@shop-pr.com

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

TARSUS PHARMACEUTICALS, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
License fees	$ 708	—	$ 53,067	—
Collaboration revenue	532	—	3,622	—
Total revenues	1,240	—	56,689	—
Operating expenses:				
Cost of license fees and collaboration revenue	65	—	2,099	—
Research and development	10,209	7,991	33,674	11,239
General and administrative	6,671	2,150	18,625	4,282
Total operating expenses	16,945	10,141	54,398	15,521
(Loss) income from operations before other income (expense) and income taxes	(15,705)	(10,141)	2,291	(15,521)
Other income (expense):				
Interest income, net	8	4	24	178
Other income (expense), net	5	—	(68)	—
Change in fair value of equity warrant rights	(346)	—	(1,222)	—
Total other (expense) income	(333)	4	(1,266)	178
Benefit (provision) for income taxes	341	(1)	(1)	(1)
Net (loss) income and comprehensive (loss) income	$ (15,697)	$ (10,138)	$ 1,024	$ (15,344)
Net (loss) income per share				
Basic	$ (0.76)	$ (3.71)	$ 0.05	$ (5.73)
Diluted	$ (0.76)	$ (3.71)	$ 0.05	$ (5.73)
Weighted-average shares outstanding				
Basic	20,641,285	2,729,685	20,511,973	2,677,315
Diluted	20,641,285	2,729,685	22,032,487	2,677,315

TARSUS PHARMACEUTICALS, INC.

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

	September 30, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 183,801	$ 168,129
Restricted cash	—	20
Other receivables	139	20
Prepaid expenses and other current assets	3,148	2,486
Total current assets	187,088	170,655
Property and equipment, net of accumulated depreciation	519	548
Operating lease right-of-use asset	1,190	688
Other assets	1,615	81

Total assets	$ 190,412	$ 171,972
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 8,119	$ 4,347
Accrued payroll and benefits	2,246	1,040
Total current liabilities	10,365	5,387
Other long-term liabilities	905	605
Total liabilities	11,270	5,992
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 authorized at September 30, 2021 and December 31, 2020; no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 20,714,228 shares issued and 20,671,079 outstanding, which excludes 43,149 shares subject to repurchase at September 30, 2021; 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	210,959	198,821
Accumulated deficit	(31,821)	(32,845)
Total stockholders' equity	179,142	165,980
Total liabilities and stockholders' equity	$ 190,412	$ 171,972