Tarsus Reports First Quarter 2022 Financial Results and Recent Business Achievements

May 10, 2022

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

Cash runway expected into at least 2026

IRVINE, Calif., May 10, 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 first quarter ended March 31, 2022, and recent business achievements.

"In the first quarter, we took important steps towards becoming a leading eye care pharmaceutical company. We reported strong and consistent Saturn-2 data, further validating the safety and efficacy of TP-03 and positioning it as the definitive standard of care for millions of patients who suffer from *Demodex* blepharitis," said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. "We also further strengthened our balance sheet by completing a $76 million public offering earlier this month. These proceeds, along with our other cash resources and expected commercialization of TP-03, are anticipated to bridge our company into profitability."

Recent Business Highlights and Corporate Update

- TP-03 met the primary and all secondary endpoints, resolved *Demodex* blepharitis (DB) and was safe and well-tolerated in Saturn-2 Phase 3, the second and final pivotal trial
  - Primary endpoint: *Demodex* complete collarette cure was achieved by 56% of patients on TP-03, compared to 13% on vehicle ($p<0.0001$) on day 43
    - Additionally, 89% of patients achieved a significant, clinically meaningful collarette cure compared to 33% of those on vehicle ($p<0.0001$)
  - Secondary endpoints:
    - Mite eradication was achieved by 52% of patients on TP-03, compared to 14% on vehicle ($p<0.0001$) on day 43
    - Complete lid erythema (redness) cure in 31.1% of patients on TP-03, compared to 9.0% of patients on vehicle ($p<0.0001$) on day 43
    - Complete composite cure in 19.2% of patients on TP-03, based on achieving both collarette cure and erythema cure, compared to 4.0% on vehicle ($p<0.0001$) on day 43
  - Safety Profile: TP-03 was well-tolerated with no serious treatment-related adverse events and a safety profile similar to Saturn-1
- Presented data from Atlas Continuation and Pandora studies at multiple medical meetings demonstrating the negative impact and clinical burden of DB on patients
  - Atlas Continuation Study: consistent results with original Atlas study showing nearly 80% of DB patients reporting a negative impact on daily life
  - Pandora preliminary findings show that DB patients have more bacterial strains on their eyelids which can lead to sub-optimal outcomes for surgical patients and contact lens users
- Advanced TP-05, a novel, oral, non-vaccine potential therapeutic for the prevention of Lyme disease, in 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
- Cash runway expected into at least 2026
  - $175 million of cash as of March 31, 2022, and $71 million net follow-on equity raise completed in May 2022
  - $30 million in expected milestones in 2022 and $15 million expected in 2024 from China out-license
  - $80 million of credit facility availability through the potential FDA approval of TP-03, $50 million upon achievement of certain quarterly revenue thresholds and $25 million available with lender approval

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-05	Initiate Ph2a	Lyme disease prevention	●	

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		●

First Quarter 2022 Financial Results

- First quarter net loss for 2022 was $20.2 million, compared to net income of $10.4 million for the same period in 2021
- First quarter 2022 license fee and collaboration revenue, as part of the strategic partnership with LianBio, was $0.5 million, compared to $33.4 million for the same period in 2021
- First quarter research and development expenses for 2022 were $12.1 million (inclusive of stock-based compensation of $0.7 million), compared to $16.3 million for the same period in 2021
- First quarter general and administrative expenses for 2022 were $7.9 million (inclusive of stock-based compensation of $2.0 million), compared to $5.2 million for the same period in 2021
- As of March 31, 2022, cash, cash equivalents and marketable securities were $175.3 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 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, 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.

Media Contact:
Adrienne Kemp
Sr. Director, Corporate Communications
(949) 922-0801
AKemp@tarsusrx.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 March 31,	
	2022	**2021**
Revenues:		
License fees	$ —	$ 33,311
Collaboration revenue	539	121
Total revenues	539	33,432
Operating expenses:		
Cost of license fees and collaboration revenue	33	1,297
Research and development	12,081	16,261
General and administrative	7,946	5,160
Total operating expenses	20,060	22,718
(Loss) income from operations before other (expense) income and income taxes	(19,521)	10,714
Other (expense) income:		
Interest (expense) income	(316)	9
Other income (expense), net	37	(34)
Unrealized loss on equity securities	(192)	—
Change in fair value of equity warrants	(245)	—
Total other expense, net	(716)	(25)
Provision (benefit) for income taxes	(1)	(313)
Net (loss) income and comprehensive (loss) income	$ (20,238)	$ 10,376
Net (loss) income per share, basic	$ (0.98)	$ (0.51)
Net (loss) income per share, diluted	$ (0.98)	$ 0.47
Weighted-average shares outstanding, basic	20,710,224	20,336,022
Weighted-average shares outstanding, diluted	20,710,224	21,824,574

TARSUS PHARMACEUTICALS, INC.

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

	March 31, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 175,010	$ 171,332
Marketable securities	291	483
Other receivables	306	92
Prepaid expenses and other current assets	3,131	4,045
Total current assets	178,755	175,952
Property and equipment, net	915	755
Operating lease right-of-use assets	926	1,074
Other assets	887	1,126
Total assets	$ 181,483	$ 178,907
LIABILITIES AND STOCKHOLDERS' EQUITY		

Current liabilities:		
Accounts payable and other accrued liabilities	$ 10,805	$ 8,680
Accrued payroll and benefits	1,805	2,798
Total current liabilities	12,610	11,478
Debt	19,180	—
Other long-term liabilities	496	699
Total liabilities	32,286	12,177
Commitments and contingencies (*Note 8*)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 authorized; no shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 20,731,062 shares issued and 20,718,528 outstanding, which excludes 12,534 shares subject to repurchase at March 31, 2022 (unaudited); 20,726,580 shares issued and 20,698,737 outstanding, which excludes 27,840 shares subject to repurchase at December 31, 2021	4	4
Additional paid-in capital	216,103	213,398
Accumulated deficit	(66,910)	(46,672)
Total stockholders' equity	149,197	166,730
Total liabilities and stockholders' equity	$ 181,483	$ 178,907