Tarsus Reports Third Quarter 2022 Financial Results and Recent Business Achievements

November 9, 2022

New Drug Application for TP-03 accepted; PDUFA target action date August 25, 2023

Launched disease education, field medical team and payor engagement in anticipation of TP-03 launch

Cash runway anticipated into at least 2026 for the planned commercial launch of TP-03 and continued pipeline development

IRVINE, Calif., Nov. 09, 2022 (GLOBE NEWSWIRE) -- Tarsus Pharmaceuticals, Inc. (NASDAQ: TARS), whose mission is to address patient needs, starting with eye care, through the application of proven science and new technology, today announced financial results for the third quarter ended September 30, 2022, and recent business achievements.

“During 2022, we moved significantly closer to delivering a new potential drug to millions of patients suffering from one of the most common eye diseases, *Demodex* blepharitis. The NDA acceptance for TP-03 is a critical milestone for Tarsus, patients and the eye care professionals who treat them as we move closer toward potential commercialization. In parallel, we initiated a robust disease education program and launched our field medical team to continue to drive awareness and encourage eye care professionals to diagnose this highly prevalent disease,” said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. “We also advanced our pipeline with the start of an exploratory Phase 2a study in MGD and are on-track to initiate a Phase 2a study in Lyme disease prevention this quarter. As we look to 2023 and beyond, we are well capitalized with the financial resources we need to continue investing in our priorities to deliver innovative drugs to patients and further drive shareholder value and growth.”

Recent Business Highlights and Corporate Update

- New Drug Application (NDA) for TP-03 for the treatment of *Demodex* blepharitis accepted by U.S. Food and Drug Administration (FDA); Prescription Drug User Fee Act (PDUFA) target action date of August 25, 2023
- Increased Eye Care Professional (ECP) engagement and education to identify and diagnose *Demodex* blepharitis
  - “Look at the Lids” disease education campaign has generated > 26K unique website visits and nearly 500K digital/media impressions
- Launched first all optometrist Medical Science Liaison (MSL) team
  - Focused on disease prevalence, diagnosis and impact
  - MSL team deeply versed in medical care / blepharitis and serving all ECPs
- Launched national payor accounts team
  - Actively engaging with all top commercial and Medicare accounts
  - Each team member has ~20 years of diverse experience including innovative product launches and leadership positions with key payors and other channel partners
- Presented additional data from Saturn-1 and Saturn-2 at key medical meetings further demonstrating TP-03 as the potential definitive standard of care for *Demodex* blepharitis
- Data from the Callisto Phase 1b trial of TP-05, a novel, oral, non-vaccine potential therapeutic for the prevention of Lyme disease, expected by year-end
- Board of Directors updates
  - Appointed Scott Morrison to the Board and as Audit Committee Chair
  - Michael Ackermann, Ph.D, Co-founder and Chairman planning to transition off the Board by year-end 2022; Wendy Yarno expected to become Lead Independent Director and Bobak Azamian, M.D., Ph.D, Chief Executive Officer, expected to be appointed as Chairman of the Board following Dr. Ackermann’s transition
- Cash runway anticipated into at least 2026
  - $227 million of cash, cash equivalents and marketable securities as of September 30, 2022
  - $30 million in expected milestones through 2024 from China out-license with $10 million in December 2022 and $5 million in 1Q 2023

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 Acceptance	*Demodex* blepharitis		✓
TP-03	Initiate Phase 3 (Libra) in China with LianBio	*Demodex* blepharitis		✓
TP-04	Initiate Phase 2 (Galatea)[1]	Rosacea		
TP-05	Topline Phase 1b Data (Callisto)[2]	Lyme disease prevention		

TP-05	Initiate Phase 2a (Carpo)[2]	Lyme disease prevention		

1. On-track to initiate in 2023. 2. On-track to complete by year-end 2022.

Third Quarter 2022 Financial Results

- Third quarter net loss for 2022 was $22.5 million, compared to net loss of $15.7 million for the same period in 2021
- Third quarter 2022 license fee and collaboration revenue, as part of the strategic partnership with LianBio, was $0, compared to $1.2 million for the same period in 2021
- Third quarter research and development expenses for 2022 were $10.9 million (inclusive of stock-based compensation of $1.0 million), compared to $10.2 million for the same period in 2021
- Third quarter general and administrative expenses for 2022 were $12.0 million (inclusive of stock-based compensation of $2.6 million), compared to $6.7 million for the same period in 2021
- As of September 30, 2022, cash, cash equivalents and marketable securities were $226.6 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, and the New Drug Application has been accepted by the U.S. Food & Drug Administration (FDA) with a PDUFA target action date of August 25, 2023. TP-03 is also being developed for the treatment of Meibomian Gland Disease, and currently being studied in a Phase 2a clinical trial. 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 potential approval and commercialization of TP-03, the initiation of Phase 2 studies for Lyme disease prevention and the treatment of rosacea, our cash runway expectations, our ability to continue investing in our business, the terms of the license agreement 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, the board transition matters 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-04, 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, MGD, rosacea, Lyme disease prevention, 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, TP-04 for the treatment of Rosacea, as well as TP-05 for the prevention 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.

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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,	
	2022	**2021**	**2022**	**2021**
Revenues:				
License fees	$ —	$ 708	$ 13,893	$ 53,067
Collaboration revenue	—	532	1,923	3,622
Total revenues	—	1,240	15,816	56,689
Operating expenses:				
Cost of license fees and collaboration revenue	—	65	555	2,099
Research and development	10,912	10,209	32,596	33,674
General and administrative	11,994	6,671	30,316	18,625
Total operating expenses	22,906	16,945	63,467	54,398
(Loss) income from operations before other income (expense) and income taxes	(22,906)	(15,705)	(47,651)	2,291
Other income (expense):				
Interest income	1,061	8	1,372	24
Interest expense	(633)	—	(1,507)	—
Other (expense) income, net	(7)	5	136	(68)
Unrealized loss on equity investments	(13)	—	(326)	—
Change in fair value of equity warrants issued by licensee	(18)	(346)	(520)	(1,222)
Total other income (expense), net	390	(333)	(845)	(1,266)
Benefit (provision) for income taxes	5	341	4	(1)
Net (loss) income	$ (22,511)	$ (15,697)	$ (48,492)	$ 1,024
Other comprehensive (loss) income:				
Unrealized loss on marketable securities and cash equivalents	(10)	—	(10)	—
Comprehensive (loss) income	$ (22,521)	$ (15,697)	$ (48,502)	$ 1,024
Net (loss) income per share, basic	$ (0.84)	$ (0.76)	$ (2.03)	$ 0.05
Net (loss) income per share, diluted	$ (0.84)	$ (0.76)	$ (2.03)	$ 0.05
Weighted-average shares outstanding, basic	26,662,374	20,641,285	23,923,512	20,511,973
Weighted-average shares outstanding, diluted	26,662,374	20,641,285	23,923,512	22,032,487

TARSUS PHARMACEUTICALS, INC.

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

	September 30, 2022	December 31, 2021
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 169,489	$ 171,332
Marketable securities	57,083	483

Accounts receivable	17	—
Other receivables	3,995	92
Prepaid expenses	3,494	4,045
Total current assets	234,078	175,952
Property and equipment, net	951	755
Operating lease right-of-use assets	696	1,074
Long-term investments	157	—
Other assets	583	1,126
Total assets	$ 236,465	$ 178,907
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 10,181	$ 8,680
Accrued payroll and benefits	4,092	2,798
Total current liabilities	14,273	11,478
Term loan, net	19,356	—
Other long-term liabilities	209	699
Total liabilities	33,838	12,177
Commitments and contingencies		
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; 26,671,812 shares issued and outstanding at September 30, 2022 (unaudited); 20,726,580 shares issued and 20,698,737 outstanding, which excludes 27,840 shares subject to repurchase at December 31, 2021	5	4
Additional paid-in capital	297,796	213,398
Accumulated other comprehensive loss	(10)	—
Accumulated deficit	(95,164)	(46,672)
Total stockholders' equity	202,627	166,730
Total liabilities and stockholders' equity	$ 236,465	$ 178,907