Tarsus Reports Second Quarter and Year-to-Date 2024 Financial Results and Recent Business Achievements

August 8, 2024

Generated $40.8 million in XDEMVY® net product sales in the second quarter and $65.5 million year-to-date

Delivered more than 37,000 bottles of XDEMVY to patients in the second quarter

Delivered an exceptional gross-to-net discount of 44% reflecting strong payer coverage including commercial and Medicare payers

Expanded sales force remains on-track to be fully deployed by the end of the third quarter 2024

Management to host conference call today, August 8, 2024, at 1:30 p.m. P.T. / 4:30 p.m. E.T.

IRVINE, Calif., Aug. 08, 2024 (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 second quarter and year-to-date period ended June 30, 2024.

“The XDEMVY launch continues building a strong foundation to serve patients and doctors with a high value new category of medicine, with impressive quarter-over-quarter growth and robust payer coverage, including additional Medicare coverage – making it one of the most successful eye care launches to date,” said Bobak Azamian, M.D., Ph.D., Chief Executive Officer and Chairman of Tarsus. “We believe we’re just scratching the surface of XDEMVY’s potential and expect the expansion of our sales force and a planned new direct-to-consumer campaign to continue accelerating our growth and the potential ability to reach millions of patients with *Demodex* blepharitis.”

Recent Business Highlights

- The commercial launch of XDEMVY continues to underscore the establishment of a new potential blockbuster category in eye care. In the second quarter, the Company:
  - Generated $40.8 million in XDEMVY net product sales, a 65% increase over Q1 2024
  - Substantially improved gross-to-net discount to 44% from 55% in Q1 2024
  - Delivered more than 37,000 bottles of XDEMVY to patients
  - Accelerated Eye Care Professional (ECP) adoption – approximately 11,000 ECPs, as of August 7, 2024, have started patients on XDEMVY launch-to-date with more than 60% prescribing XDEMVY to multiple patients

- Significantly expanded payer coverage of XDEMVY among commercial, and now Medicare payers
  - Secured several new contracts in the second quarter, including another major commercial plan with more than 20 million covered lives, and one major Medicare payer with more than 10 million covered lives, the benefits of which we expect to begin recognizing in Q3 2024
  - Remain well positioned for even broader coverage and a steady state gross-to-net discount percentage in the low 40’s in 2025

- On-track to deploy approximately 50 additional sales force representatives and leaders by the end of Q3 2024

- Continuing to advance the pipeline and remain on-track to engage with the FDA on TP-03 (Meibomian Gland Disease), TP-04 (Papulopustular Rosacea) and TP-05 (Lyme disease prevention) by year end 2024

Second Quarter 2024 Financial Results

- **Revenues:** were $40.8 million, an approximately 65% increase over Q1 2024, driven by net product sales

- **Cost of sales:** were $3.0 million, due to manufacturing costs incurred after the approval of XDEMVY, the royalty the Company pays on net product sales and the amortization of the $4.0 million approval milestone paid to our licensor and are amortizing over a 10-year period.

- **Research and development (R&D) expenses:** were $12.3 million compared to $12.5 million for the same period in 2023. The decrease was due to a $0.7 million and $0.5 million decrease in program spend for TP-04 for the treatment of rosacea and TP-05 as an oral tablet for the prevention of Lyme disease, respectively, which was partially offset by $0.8 million of compensation expense (including non-cash stock-based compensation). Total R&D non-cash stock compensation expense was $1.9 million, compared with $1.5 million in the same period in 2023.

- **Selling, general and administrative (SG&A) expenses:** were $58.8 million compared to $20.3 million for the same period

in 2023. The increase was due primarily to $11.0 million of compensation-related expense (including non-cash stock-based compensation), $13.8 million of commercial and market research costs related to the commercial launch of XDEMVY, and $13.6 million of increased IT, legal, professional and other corporate expenses. Total SG&A non-cash stock compensation expense was $5.4 million, compared with $3.7 million in the same period in 2023.

- **Loss on debt extinguishment:** was $1.9 million, which includes an end of term charge and other debt costs of the prior debt facility.

- **Net loss:** was $33.3 million, compared to a net loss of $31.4 million for the same period in 2023. Basic and diluted net loss per share for the quarter ended June 30, 2024 was $(0.88), compared with $(1.17) for the same period in 2023.

- **Cash position:** As of June 30, 2024, cash, cash equivalents and marketable securities were $323.6 million, which includes the receipt of approximately $39.6 million of net proceeds from an initial draw on our new credit facility in April 2024.

Year-to-Date 2024 Financial Results

- **Revenues:** were $68.4 million, driven primarily by $65.5 million in net product sales, and $2.9 million in license fees and collaboration revenue.

- **Cost of sales:** were $4.7 million due to manufacturing costs incurred after the approval of XDEMVY, the royalty the Company pays on net product sales and the amortization of the $4.0 million approval milestone we paid to our licensor and are amortizing over a 10-year period.

- **Research and development (R&D) expenses:** were $24.4 million compared to $24.9 million for the same period in 2023. The decrease was due to $2.2 million less program spend for TP-05 and $1.0 million less in Elanco milestone expenses, partially offset by $2.3 million of increased compensation expense (including non-cash stock-based compensation). R&D non-cash stock compensation expense was $3.3 million, compared with $2.7 million in the same period in 2023.

- **Selling, general and administrative (SG&A) expenses:** were $110.4 million compared to $35.4 million for the same period in 2023. The increase was due primarily to $22.4 million of compensation-related expense (including non-cash stock-based compensation), $26.0 million of commercial and market research costs related to the commercial launch of XDEMVY, and $26.4 million of increased IT, legal, professional and other corporate expenses. SG&A non-cash stock compensation expense was $9.3 million, compared with $6.4 million in the same period in 2023.

- **Loss on debt extinguishment:** was $1.9 million, which includes an end of term charge and other debt costs of the prior debt facility.

- **Net loss:** was $69.0 million, compared to a net loss of $54.8 million for the same period in 2023. Year-to-date basic and diluted net loss per share was $(1.89), compared with $(2.05) for the same period in 2023.

Conference Call and Webcast
Tarsus will host a conference call and webcast to discuss its second quarter and year-to-date 2024 financial results and business highlights today, August 8, 2024, at 1:30 p.m. P.T. / 4:30 p.m. ET. A live webcast will be available on the events section of the Tarsus website. A recorded version of the call will be available on the website shortly after the completion of the call and will be archived there for at least 90 days.

About XDEMVY®
XDEMVY (lotilaner ophthalmic solution) 0.25%, formerly known as TP-03, is a novel prescription eye drop designed to treat *Demodex* blepharitis by targeting and eradicating the root cause of the disease – *Demodex* mite infestation. XDEMVY was evaluated in two pivotal trials collectively involving more than 800 patients. Both trials met the primary endpoint and all secondary endpoints, with statistical significance and no serious treatment-related adverse events. Most patients found the XDEMVY eye drop to be neutral to very comfortable. The most common ocular adverse reactions observed in the studies were instillation site stinging and burning which was reported in 10% of patients. Other ocular adverse reactions reported by less than 2% of patients were chalazion/hordeolum (stye) and punctate keratitis.

XDEMVY Indication and Important Safety Information

INDICATIONS AND USAGE
XDEMVY is indicated for the treatment of *Demodex* blepharitis.

Most common side effects: The most common side effect in clinical trials was stinging and burning in 10% of patients. Other side effects in less than 2% of patients were chalazion/hordeolum and punctate keratitis.

For additional information, please see full prescribing information available at: https://xdemvy.com/.

About TP-03
TP-03 (lotilaner ophthalmic solution) 0.25% is a novel therapeutic designed to treat *Demodex* blepharitis by targeting and eradicating the root cause of disease – *Demodex* mite infestation. It was approved by the FDA in 2023 under the brand name XDEMVY® for the treatment of *Demodex* blepharitis

and is being evaluated as an investigational therapy for the treatment of Meibomian Gland Disease (MGD) in patients with *Demodex* mites. Lotilaner is a well-characterized anti-parasitic agent that paralyzes and eradicates *Demodex* mites by selectively inhibiting parasite-specific gamma-aminobutyric acid-gated chloride (GABA-Cl) channels. It is a highly lipophilic molecule, which may promote its uptake in the oily sebum of the eye lash follicles where the mites reside.

About TP-04
TP-04 is an aqueous gel formulation of lotilaner, a well-characterized anti-parasitic agent that paralyzes and kills ticks by selectively inhibiting parasite-specific GABA-Cl channels. Tarsus is studying TP-04 for the treatment of papulopustular rosacea (PPR).

About TP-05
TP-05 is an oral systemic formulation of lotilaner, a well-characterized anti-parasitic agent that selectively inhibits parasite-specific GABA-Cl channels. TP-05 is believed to be the only non-vaccine, drug-based, preventative therapeutic in development designed to kill ticks to potentially prevent Lyme disease transmission.

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. XDEMVY (lotilaner ophthalmic solution) 0.25% is FDA approved in the United States for the treatment of *Demodex* blepharitis. Tarsus is also developing TP-03 as an investigational therapy for the treatment of Meibomian Gland Disease, TP-04 for the treatment of rosacea and TP-05 as an oral tablet for the prevention of Lyme disease, all of which are in Phase 2.

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 commercial success and growth of XDEMVY in *Demodex* blepharitis, including market size, acceptance, demand, prescription fill rate and adoption rate for XDEMVY; our ability to successfully implement our sales force expansion and new planned direct-to-consumer campaign; our ability to achieve distribution and patient access for XDEMVY and timing and breadth of payer coverage; our ability to continue to educate the market about *Demodex* blepharitis, anticipated regulatory and development milestones, our ability to continue investing in our business, 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 is heavily dependent on the successful commercialization of its lead product, XDEMVY for the treatment of *Demodex* blepharitis and the development and regulatory approval and commercialization of its current and future product candidates; Tarsus’ ability to obtain and maintain regulatory approval for and successfully commercialize its products, including XDEMVY for the treatment of *Demodex* blepharitis, and its product candidates to meet existing and future regulatory standards; 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’ capital requirements are difficult to predict and may change; Tarsus may need to obtain additional funding to achieve its goals and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force Tarsus to delay, reduce, or eliminate its product development programs, commercialization efforts or other operations; Tarsus may not be successful in educating healthcare professionals and the market about the need for treatments specifically for *Demodex* blepharitis and other diseases targeted by XDEMVY or our product candidates; the development and commercialization of Tarsus products is dependent on intellectual property it licenses from Elanco Tiergesundheit AG; Tarsus expects to expand its development, regulatory, operational and sales and marketing capabilities and Tarsus may encounter difficulties in managing its growth, which could disrupt its operations; the sizes of the market opportunity for XDEMVY and Tarsus’ product candidates, particularly TP-03 for the treatment of 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; 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; and if Tarsus is unable to access capital (including but not limited to cash, cash equivalents, and credit facilities) and/or loses capital, as a result of potential failure of any financial institutions that Tarsus does business with directly or indirectly. Further, there are other risks and uncertainties that could cause actual results to differ from those set forth in the forward-looking statements 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, 2023 filed on February 27, 2024 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 earnings 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenues:				
Product sales, net	$ 40,813	$ —	$ 65,533	$ —
License fees and collaboration revenue	—	—	2,894	2,500
Total revenues	40,813	—	68,427	2,500
Operating expenses:				
Cost of sales	3,004	—	4,658	—
Research and development	12,319	12,546	24,385	24,902
Selling, general and administrative	58,792	20,275	110,370	35,371
Total operating expenses	74,115	32,821	139,413	60,273
Loss from operations before other income (expense)	(33,302)	(32,821)	(70,986)	(57,773)
Other income (expense):				
Interest income	4,130	2,226	7,247	4,519
Interest expense	(2,109)	(815)	(3,092)	(1,499)
Loss on debt extinguishment	(1,944)	—	(1,944)	—
Other (expense) income, net	(59)	(47)	546	(41)
Realized/unrealized (loss) gain on equity investments	(6)	15	(591)	(50)
Change in fair value of equity warrants issued by licensee	—	18	(201)	1
Total other income, net	12	1,397	1,965	2,930
Net loss	$ (33,290)	$ (31,424)	$ (69,021)	$ (54,843)
Other comprehensive loss:				
Unrealized (loss) gain on marketable securities and cash equivalents	(113)	47	(174)	51
Comprehensive loss	$ (33,403)	$ (31,377)	$ (69,195)	$ (54,792)
Net loss per share, basic and diluted	$ (0.88)	$ (1.17)	(1.89)	(2.05)
Weighted-average shares outstanding, basic and diluted	37,823,233	26,815,733	36,530,756	26,779,203

TARSUS PHARMACEUTICALS, INC.

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

	June 30, 2024 (unaudited)	**December 31, 2023**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 181,095	$ 224,947
Marketable securities	142,485	2,495
Accounts receivable, net	29,529	16,621
Inventory	2,195	3,107
Other receivables	1,312	1,093
Prepaid expenses	5,972	7,868
Total current assets	362,588	256,131

Inventory, non-current	2,533	—
Property and equipment, net	2,241	1,468
Intangible assets, net	3,667	3,867
Operating lease right-of-use assets	1,969	1,880
Long-term investments	3,000	631
Other assets	846	1,514
Total assets	$ 376,844	$ 265,491
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 43,526	$ 23,691
Accrued payroll and benefits	8,045	13,245
Total current liabilities	51,571	36,936
Term loan, net	71,578	29,819
Other long-term liabilities	1,449	1,748
Total liabilities	124,598	68,503
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 38,030,385 shares issued and outstanding at June 30, 2024 (unaudited); 34,211,190 shares issued and outstanding at December 31, 2023	6	5
Additional paid-in capital	566,093	441,641
Accumulated other comprehensive loss	(176)	(2)
Accumulated deficit	(313,677)	(244,656)
Total stockholders' equity	252,246	196,988
Total liabilities and stockholders' equity	$ 376,844	$ 265,491