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

November 13, 2024

Generated $48.1 million in XDEMVY® net product sales driven by more than 41,400 bottles delivered to patients in the third quarter

Strengthened payer coverage highlighted by securing the two remaining large Medicare contracts; broad commercial and Medicare coverage now extends to more than 80% of covered lives

New XDEMVY data demonstrated statistically significant and clinically meaningful improvements from baseline across objective measures of Meibomian Gland Disease and important patient symptoms in Demodex blepharitis patients

Management to host conference call today, November 13, 2024, at 1:30 p.m. P.T. / 4:30 p.m. E.T.

IRVINE, Calif., Nov. 13, 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 third quarter and year-to-date period ended September 30, 2024.

“The third quarter was our most successful to date for the launch of XDEMVY, with continued growth in patients served driven by broad physician adoption and strong payer coverage. We also brought forward groundbreaking new data that demonstrate the immense potential of XDEMVY across a range of patient types, continued to advance our robust pipeline, and further strengthened our executive team and Board with the addition of two world-class clinical leaders, Dr. Elizabeth Yeu and Dr. Kate Goodrich, respectively,” said Bobak Azamian, M.D., Ph.D., Chief Executive Officer and Chairman of Tarsus. “With a sharp focus on execution, education, ease of access, and ongoing evidence generation, we expect to close the year with another strong quarter that we believe is just beginning to reflect the benefits of our expanded sales force and first ever direct-to-consumer TV campaign.”

Recent Business and Clinical Highlights

- The commercial launch of XDEMVY continues to be one of the most successful eye care launches to date. In the third quarter, the Company:
  - Generated $48.1 million in XDEMVY net product sales, an approximately 18% increase over Q2 2024
  - Delivered more than 41,400 bottles of XDEMVY to patients
  - Increased Eye Care Professional (ECP) adoption – more than 13,000 ECPs, as of November 13, 2024, have started patients on XDEMVY launch-to-date with more than 70% prescribing XDEMVY to multiple patients

- Broad commercial and Medicare reimbursement of XDEMVY now extends to more than 80% of covered lives
  - Secured the two remaining large Medicare payer contracts, the benefits of which we expect to begin recognizing in 2025
  - Recognized gross-to-net discount of approximately 40% in Q3 2024, aided in part by a change in the estimated 1H 2024 Medicare accrual, resulting in a reduction to gross-to-net discount of approximately 3%

- Completed recruitment and deployment of approximately 50 new sales force representatives and leaders in Q3 2024

- Presented new positive data from the Ersa and Rhea clinical trials for the treatment of *Demodex* blepharitis in patients with Meibomian Gland Disease (MGD), at the American Academy of Optometry Annual Meeting on November 7, 2024, which demonstrated statistically significant and clinically meaningful improvements in:
  - Three objective measures of MGD: Meibomian Gland Secretion Score, the number of glands secreting normal or clear liquid and the number of glands yielding any liquid
  - The most common and impactful symptoms patients report experiencing, including fluctuating vision, itching, redness and burning

- Appointed Elizabeth Yeu, M.D. to Chief Medical Officer
  - Dr. Yeu transitioned from her role as Chief Medical Advisor and Board Member to Chief Medical Officer, leading the newly created Medical Organization
  - As a distinguished ophthalmologist with more than two decades of clinical experience and leadership, Dr. Yeu’s expertise will be instrumental to the continued advancement of Tarsus’ medical affairs and pharmacovigilance teams, including evidence generation, medical education and oversight of patient safety

- Appointed Katherine H. (Kate) Goodrich, M.D., MHS, to the Board
  - Dr. Goodrich is the Chief Medical Officer for Humana Inc., and former Centers for Medicare and Medicaid Services

(CMS) Chief Medical Officer
    - She brings more than two decades of experience driving innovation and value-based initiatives designed to improve patient outcomes

- Advancing XDEMVY outside the United States
    - No additional Phase 3 study is required for approval in Europe, based on European Medicines Agency feedback
    - Initiating stability testing of a preservative-free formulation of XDEMVY for Europe with potential approval anticipated in 2H 2027
    - Determining a development and regulatory pathway in Japan; results of an ongoing *Demodex* blepharitis prevalence study expected in 2025

- Continuing to advance the pipeline and remain on-track to engage with the FDA on TP-04 (Papulopustular Rosacea) and TP-05 (Lyme disease prevention) by year end 2024 with an update anticipated by the FY 2024 earnings call

Third Quarter 2024 Financial Results

- **Product sales:** were $48.1 million compared to $1.7 million for the same period in 2023, driven by more than 41,400 bottles of XDEMVY delivered to patients compared to 1,700 bottles delivered in the prior year period.

- **Cost of sales:** were $3.2 million compared to $0.4 million for the same period in 2023, 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, which is being amortized over its remaining useful life of 8.9 years.

- **Research and development (R&D) expenses:** were $12.1 million, which remained consistent with $12.1 million for the same period in 2023. The slight increase was primarily due to $0.2 million of increased TP-03 program expenses, $0.2 million of increased payroll and personnel-related costs, and $0.2 million of other indirect expenses. These increases were primarily offset by $0.3 million of decreased TP-04 program expenses and $0.2 million of decreased early-stage programs. Total R&D non-cash stock compensation expense was $1.7 million, which was consistent with $1.7 million in the same period in 2023.

- **Selling, general and administrative (SG&A) expenses:** were $57.9 million compared to $30.3 million for the same period in 2023. The increase was due primarily to $9.5 million of increased compensation and other employee-related expense (including non-cash stock-based compensation), $10.5 million of increased commercial and marketing costs related to the commercial launch of XDEMVY, and $7.5 million of increased information technology, legal, professional and other corporate expenses. Total SG&A non-cash stock compensation expense was $5.6 million, compared with $3.6 million in the same period in 2023.

- **Net loss:** was $23.4 million, compared to $39.1 million for the same period in 2023. Basic and diluted net loss per share for the quarter ended September 30, 2024 was $(0.61), compared with $(1.28) for the same period in 2023.

- **Cash position:** As of September 30, 2024, cash, cash equivalents and marketable securities were $317.0 million.

Year-to-Date 2024 Financial Results

- **Product sales:** were $113.7 million compared to $1.7 million for the same period in 2023, driven by approximately 104,400 bottles of XDEMVY delivered to patients compared to 1,700 bottles delivered in the prior year period.

- **License fees and collaboration revenue**: were $2.9 million from our China out-license partner driven by $2.5 million for the Termination Payment related to the Novation Agreement and $0.4 million for the Warrant Termination Payment. License fees and collaboration revenue was $2.7 million for the same period in 2023 related to the achievement of a contractual milestone under the China Out-License for $2.5 million and satisfaction of performance obligations under a clinical supply agreement for $0.2 million.

- **Cost of sales:** were $7.9 million compared to $0.4 million for the same period in 2023, 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, which is being amortized over its remaining useful life of 8.9 years.

- **Research and development (R&D) expenses:** were $36.5 million compared to $37.0 million for the same period in 2023. The slight decrease was due to $2.2 million less program spend for TP-05, $1.0 million less in Elanco milestone expenses, and $1.0 million less program spend for TP-04, partially offset by $2.5 million of increased compensation and other employee-related expense (including non-cash stock-based compensation) and $0.9 million of other indirect expenses.

R&D non-cash stock compensation expense was $5.0 million, compared with $4.3 million in the same period in 2023.

- **Selling, general and administrative (SG&A) expenses:** were $168.3 million compared to $65.7 million for the same period in 2023. The increase was due primarily to $31.9 million of increased compensation-related expense (including non-cash stock-based compensation), $36.5 million of increased commercial and marketing costs related to the commercial launch of XDEMVY, and $33.9 million of increased IT, legal, professional and other corporate expenses. SG&A non-cash stock compensation expense was $14.9 million, compared with $10.0 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 $92.4 million, compared to $94.0 million for the same period in 2023. Year-to-date basic and diluted net loss per share was $(2.48), compared with $(3.35) for the same period in 2023.

Conference Call and Webcast
Tarsus will host a conference call and webcast to discuss its third quarter and year-to-date 2024 financial results and business highlights today, November 13, 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. 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 mites 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-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 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 including potential Europe and Japan regulatory pathways and approval for XDEMVY; the results of our clinical studies; our ability to continue investing in our business, the potential benefits of the new executive and board member, 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-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.

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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
Product sales, net	$ 48,118	$ 1,653	$ 113,651	$ 1,653
License fees and collaboration revenue	—	218	2,894	2,718
Total revenues	48,118	1,871	116,545	4,371
Operating expenses:				
Cost of sales	3,242	377	7,900	377
Research and development	12,128	12,105	36,513	37,007
Selling, general and administrative	57,910	30,324	168,280	65,695
Total operating expenses	73,280	42,806	212,693	103,079
Loss from operations before other income (expense)	(25,162)	(40,935)	(96,148)	(98,708)
Other income (expense):				
Interest income	4,120	2,840	11,367	7,359
Interest expense	(2,445)	(858)	(5,537)	(2,357)
Loss on debt extinguishment	—	—	(1,944)	—
Other income (expense), net	67	(48)	613	(89)
Realized/unrealized loss on equity investments	—	(111)	(591)	(161)

Change in fair value of equity warrants issued by licensee	—	(36)	(201)	(35)
Total other income, net	1,742	1,787	3,707	4,717
Net loss	$ (23,420)	$ (39,148)	$ (92,441)	$ (93,991)
Other comprehensive gain:				
Unrealized gain on marketable securities and cash equivalents	522	15	348	66
Comprehensive loss	$ (22,898)	$ (39,133)	$ (92,093)	$ (93,925)
Net loss per share, basic and diluted	$ (0.61)	$ (1.28)	(2.48)	(3.35)
Weighted-average shares outstanding, basic and diluted	38,381,968	30,622,440	37,286,911	28,065,434

TARSUS PHARMACEUTICALS, INC.

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

	September 30, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 176,210	$ 224,947
Marketable securities	140,742	2,495
Accounts receivable, net	29,159	16,621
Inventory	2,846	3,107
Other receivables	1,145	1,093
Prepaid expenses	7,015	7,868
Total current assets	357,117	256,131
Inventory, non-current	2,533	—
Property and equipment, net	2,393	1,468
Intangible assets, net	8,567	3,867
Operating lease right-of-use assets	1,802	1,880
Long-term investments	3,000	631
Other assets	888	1,514
Total assets	$ 376,300	$ 265,491
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 54,543	$ 23,691
Accrued payroll and benefits	11,325	13,245
Total current liabilities	65,868	36,936
Long-term debt, net	71,708	29,819
Other long-term liabilities	1,240	1,748
Total liabilities	138,816	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; 38,196,072 shares issued and outstanding at September 30, 2024 (unaudited); 34,211,190 shares issued and outstanding at December 31, 2023	6	5
Additional paid-in capital	574,229	441,641
Accumulated other comprehensive gain (loss)	346	(2)
Accumulated deficit	(337,097)	(244,656)
Total stockholders' equity	237,484	196,988
Total liabilities and stockholders' equity	$ 376,300	$ 265,491