Tarsus Reports Strong Fourth Quarter and Full-Year 2023 Financial Results and Recent Business Achievements

February 27, 2024

Launched XDEMVY® (lotilaner ophthalmic solution) 0.25%, for the treatment of Demodex blepharitis and generated fourth quarter net product sales of $13.1 million, and $14.7 million in the first four months since launch

Delivered more than 17,400 bottles of XDEMVY to patients

Continued pipeline execution – reported positive proof-of-concept results across entire clinical portfolio

Management to host conference call today, February 27, 2024, at 5 a.m. PT / 8 a.m. ET

IRVINE, Calif., Feb. 27, 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 fourth quarter and full-year ended December 31, 2023, and recent business achievements.

"Tarsus is establishing the next category in eye care and these strong results reflect our team's ability to execute and deliver on our mission to bring revolutionary new medicines to patients," said Bobak Azamian, M.D., Ph.D., Chief Executive Officer and Chairman of Tarsus. "2024 is off to a great start, driven by the approval, launch and rapid uptake of XDEMVY, and the momentum we've already established is setting the tone for what we expect to be an impactful year ahead."

Recent Business Highlights and Corporate Update

- Generated strong prescription and sales growth of XDEMVY in 2023 enabled by execution of key commercial initiatives, including deployment of an experienced sales force targeting 15,000 Eye Care Providers (ECPs) representing >80% of all eye care prescriptions, and high-impact disease education leading to ECP adoption. Additionally:
  - Reported $14.7 million in XDEMVY net product sales
  - Delivered more than 17,400 bottles of XDEMVY to patients
  - Approximately 6,000 ECPs have started patients on XDEMVY with more than 50% of ECPs prescribing XDEMVY to multiple patients as of February 23, 2024
- Six manuscripts published in peer-reviewed journals in 2023 including:
  - Saturn-1, one-year extension data highlighting the safety and durable response of XDEMVY
  - Two independent meta-analyses validating efficacy, safety and impact of our study results
- Continued to advance our pipeline with the recent reporting of positive topline data:
  - Ersa Phase 2a clinical trial evaluating TP-03 for the treatment of Meibomian Gland Disease in patients with *Demodex* mites
  - Carpo Phase 2a clinical trial evaluating TP-05 for the prevention of Lyme disease
- Additionally, today we are announcing positive topline results from the Phase 2a Galatea trial evaluating TP-04 for the treatment of Papulopustular Rosacea (PPR), which demonstrate:
  - Statistically significant improvements ($p<0.05$) in inflammatory lesions and Investigator's Global Assessment (IGA) score (change in baseline and success rate) compared to vehicle at Week 12
  - TP-04 was generally well tolerated

Achieved Milestones

Program	Milestone	Anticipated Indication	H2 2023	Q1 2024
XDEMVY	FDA Approval	*Demodex*blepharitis	X	
TP-03	Topline Phase 2a (Ersa)	Meibomian Gland Disease	X	
TP-04	Topline Phase 2a (Galatea)	Papulopustular Rosacea		X
TP-05	Topline Phase 2a (Carpo)	Lyme Disease Prevention		X

Fourth Quarter 2023 Financial Results

- Fourth quarter revenues were $13.1 million, driven by XDEMVY net product sales.
- Cost of sales were $1.2 million, due to manufacturing costs incurred after the approval of XDEMVY, the royalty we pay 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 $13.3 million in the fourth quarter, compared to $10.0 million in the same period last year. The increase was due to $2.2 million of increased payroll and personnel-related costs (including non-cash stock-based compensation), $0.3 million of increased other indirect expenses, and $0.6 million of increased program spend for TP-03. Total R&D non-cash stock compensation expense incurred was $1.5 million in the fourth quarter, compared with $1.1 million in the same period last year.
- Selling, general and administrative (SG&A) expenses were $43.0 million in the fourth quarter compared to $14.6 million in the same period last year. The increase was due primarily to $11.7 million of increased payroll and personnel-related costs, $7.7 million of increased commercial costs related to the commercial launch of XDEMVY, $5.1 million of increased office and administrative expenses and $3.6 million of increased IT applications, legal and other professional expenses to support corporate infrastructure. Total SG&A non-cash stock compensation expense incurred was $3.8 million in the fourth quarter, compared with $2.6 million in the same period last year.
- Net loss for the fourth quarter was $41.9 million, compared to a net loss of $13.6 million in the same period last year. Basic and diluted net loss per share for the fourth quarter was $(1.31), compared with $(0.51) for the same period last year.
- As of December 31, 2023, cash, cash equivalents and marketable securities were $227.4 million, which includes the receipt of $99.3 million of net proceeds received from our follow-on offering completed in August 2023.

Full-Year 2023 Financial Results

- Total revenues were $17.4 million, driven primarily by $14.7 million in XDEMVY net product sales, representing approximately four months of sales following the launch in late August.
- Cost of sales were $1.6 million, due to manufacturing costs incurred after the approval of XDEMVY, period costs associated with launching one month earlier than expected, the royalty we pay 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.
- R&D expenses were $50.3 million in 2023 compared to $42.6 million in 2022. The increase was due to $10.6 million of increased payroll and personnel-related costs (including non-cash stock-based compensation), $1.0 million of milestone expense related to the Galatea trial, $0.6 million of increased other indirect expenses, $2.1 million of increased program spend for TP-05, and $0.6 million of increased spend for other early-stage programs. The increase was partially offset by decreases of $6.1 million and $1.1 million, respectively, for the TP-03 and TP-04 programs. Total R&D non-cash stock compensation expense incurred was $5.8 million in 2023, compared with $3.7 million in 2022.
- SG&A expenses were $108.7 million in 2023 compared to $44.9 million in 2022. The increase was due primarily to $28.6 million of increased payroll and personnel-related costs, $22.3 million of increased commercial costs related to the commercial launch of XDEMVY, $6.4 million of increased office and administrative expenses, and $6.2 million of increased IT applications, legal and other professional expenses to support corporate infrastructure. Total SG&A non-cash stock compensation expense incurred was $13.8 million in 2023, compared with $9.7 million in 2022.
- Net loss for 2023 was $135.9 million, compared to a net loss of $62.1 million in 2022. Basic and diluted net loss per share for 2023 was $(4.62), compared with $(2.52) for 2022.

Conference Call and Webcast

Tarsus will host a conference call and webcast to discuss its full-year 2023 financial results and business highlights today, February 27, 2024, at 5 a.m. PT / 8 a.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 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, the timing, objectives, and results of the clinical trials including the complete clinical results of the Ersa, Carpo, and Galatea trials, 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, 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
(In thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenues:				
Product sales, net	$ 13,076	$ —	$ 14,729	$ —
License fees and collaboration revenue	—	10,000	2,718	25,816
Total revenues	13,076	10,000	17,447	25,816
Operating expenses:				
Cost of sales	1,216	—	1,593	—
Cost of license fees and collaboration revenue	—	400	—	955
Research and development	13,305	10,028	50,312	42,624
Selling, general and administrative	43,005	14,633	108,700	44,949
Total operating expenses	57,526	25,061	160,605	88,528
Loss from operations	(44,450)	(15,061)	(143,158)	(62,712)
Other income (expense):				
Interest income	2,978	2,127	10,337	3,499
Interest expense	(989)	(692)	(3,346)	(2,199)
Other (expense) income, net	(13)	(50)	(102)	86
Unrealized gain (loss) on equity investments	420	58	259	(268)
Change in fair value of equity warrants issued by licensee	152	19	117	(501)
Total other income, net	2,548	1,462	7,265	617
Loss before income taxes	(41,902)	(13,599)	(135,893)	(62,095)
Benefit from income taxes	—	—	—	4
Net loss	$ (41,902)	$ (13,599)	$ (135,893)	$ (62,091)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities and cash equivalents	6	(64)	72	(74)
Comprehensive loss	$ (41,896)	$ (13,663)	$ (135,821)	$ (62,165)
Net loss per share, basic and diluted	$ (1.31)	$ (0.51)	$ (4.62)	$ (2.52)
Weighted-average shares outstanding, basic and diluted	31,944,237	26,685,563	29,383,276	24,619,700

TARSUS PHARMACEUTICALS, INC.

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

	December 31,	
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 224,947	$ 71,660
Marketable securities	2,495	145,366
Accounts receivable, net	16,621	—
Inventory	3,107	—
Other receivables	1,093	3,582
Prepaid expenses	7,868	4,767
Total current assets	256,131	225,375
Property and equipment, net	1,468	957
Intangible assets, net	3,867	—
Operating lease right-of-use assets	1,880	575

Long-term investments	631	371
Other assets	1,514	585
Total assets	$ 265,491	$ 227,863
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 23,691	$ 9,910
Accrued payroll and benefits	13,245	5,519
Total current liabilities	36,936	15,429
Term loan, net	29,819	19,434
Other long-term liabilities	1,748	100
Total liabilities	68,503	34,963
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; 34,211,190 shares issued and outstanding at December 31, 2023; 26,727,458 shares issued and outstanding at December 31, 2022	5	5
Additional paid-in capital	441,641	301,732
Accumulated other comprehensive loss	(2)	(74)
Accumulated deficit	(244,656)	(108,763)
Total stockholders' equity	196,988	192,900
Total liabilities and stockholders' equity	$ 265,491	$ 227,863