Traws Pharma Reports First Quarter 2024 Financial Results and Provides Business Update

May 16, 2024

Completed acquisition of Trawsfynydd and concurrent $14 million Capital Raise

Excellent pipeline progress, led by candidates for COVID 19, influenza, and oncology programs

Poised to initiate Phase 2 studies in H2 2024 for our influenza candidate and ritonavir-free COVID 19 protease inhibitor

NEWTOWN, Pa., May 16, 2024 (GLOBE NEWSWIRE) -- Traws Pharma, Inc. ("Traws" or "Traws Pharma"), a clinical stage biopharmaceutical company developing oral small molecules for respiratory viral diseases and cancer, today announced financial results for the first quarter of 2024, and provided a business update.

"2024 has already been a transformative year for Traws Pharma to advance our portfolio of novel treatments for serious respiratory infections and oncology programs. We completed the acquisition of Trawsfynydd and concluded a concurrent $14 million private placement financing. In addition, we initiated first-in-human dosing for our COVID 19 product candidate, including completion of the first cohort dosing group. Furthermore, we completed the last dose escalation cohort for our CDK4+ inhibitor, narazaciclib," stated **Werner Cautreels, Ph.D., Chief Executive Officer** of Traws Pharma. "We believe that we are poised to make even more meaningful progress in the second half of 2024, as we advance our influenza treatment and ritonavir-free protease inhibitor for COVID 19 into expanded Phase 1 dose escalation studies and begin Phase 2 development."

"Based on the preclinical profile and early clinical data from our infectious disease candidates and narazaciclib, I am optimistic about the outlook for Traws' portfolio and look forward to updating our investors with our progress through the year," concluded Dr. Cautreels.

Traws Proprietary Portfolio Highlights:

TRX100 (tivoxavir marboxil): a cap-dependent endonuclease inhibitor for influenza: Phase 1

- Targets the cap-dependent endonuclease of influenza and is a potent inhibitor of influenza virus replication including A and B strains
- First Phase 1 study demonstrated safety and tolerability in healthy volunteers with pharmacokinetics and pharmacodynamics (PK/PD) data to support the potential use of a single oral dose for treatment or prophylaxis
- We plan to initiate Phase 1 dose extension to evaluate one additional, higher dose prior to the initiation of Phase 2 studies in H2 2024. Topline data from the Phase 2 study are expected in H1 2025

TRX01 (ratutrelvir): a ritonavir-free Mpro protease inhibitor for COVID19: Phase 1

- Potent oral inhibitor of SARS-CoV-2 Mpro (3CL protease), effective against the original, delta, and omicron variants of SARS-CoV-2, that does not require co-administration with ritonavir, reducing the risk of drug-drug interactions. Preclinical data support once-daily dosing for 10days which could overcome viral rebound seen with other agents.
- We are in the process of conducting a Phase 1 first-in-human single ascending dose/multiple ascending dose (SAD/MAD) study in normal volunteers. The second dosing cohort is underway and topline data are expected H2 2024. A Phase 2 study is also planned to begin in H2 2024 in patients with moderate to severe COVID19. Topline data are expected H1 2025

Narazaciclib: CDK 4+ to treat solid tumors: Phase 1/2

- Available preclinical and clinical data suggest that narazaciclib is active in numerous tumor types, inhibiting CDK 2/4/6, CSF1R and ARK 5/NUAK1. Preclinical studies also showed reduced neutropenia, as compared to palbociclib, and inhibition of palbociclib resistant cancer cells.
- A dose escalation study to define the recommended Phase 2 dose (RP2D) recently enrolled the last cohort. A review of the clinical and PK/PD data is underway. We intend to utilize these data to define the clinical strategy, including selection of a lead indication and next steps in its development.

First Quarter 2024 Financial Results

Cash and cash equivalents as of March 31, 2024, were $16.4 million, compared with $20.8 million as of December 31, 2023.

In April 2024, the Company raised gross proceeds of $14 million from the sale of common and preferred stock to TPAV, LLC, an affiliate of Torrey Pines, and OrbiMed Private Investments VIII, LP, an affiliate of OrbiMed Advisors.

The Company believes that its cash and cash equivalents will be sufficient to fund ongoing clinical trials and business operations into the fourth quarter of 2024.

Revenue was fifty-six thousand dollars for the first quarter of 2024, consistent with the same period in 2023.

General and administrative (G&A) expenses were $3.4 million for the first quarter of 2024, compared with $2.1 million for the same period in 2023. The increase in G&A expenses was caused by higher legal and professional fees related to the Trawsfynydd acquisition on April 1, 2024, partially offset by lower bonus accrual as well as lower insurance, meeting, and public company expenses.

Research and development (R&D) expenses were $1.9 million for the first quarter of 2024, compared with $4.1 million for the same period in 2023. The decrease was primarily caused by lower costs related to narazaciclib drug substance and drug product manufacturing, a reduction in clinical development and consulting costs and lower personnel expenses due to lower bonus accrual.

Net loss for the first quarter of 2024 was $5.0 million, or $0.24 per share on 20.8 million weighted average shares outstanding, compared with a net loss of $5.8 million, or $0.28 per share for the same period in 2023, based on 20.8 million weighted average shares outstanding.

About Traws Pharma, Inc.

Traws Pharma is a clinical stage biopharmaceutical company developing oral small molecule therapies for the treatment of respiratory viral diseases and cancer. The viral respiratory disease program includes an oral inhibitor of the SARS-CoV-2 Mpro (3CL protease), ratutrelvir, and tivoxavir marboxil, a new oral antiviral drug candidate for influenza which targets the influenza cap-dependent endonuclease and has shown activity in cell-based assays against drug resistant viruses as well as against avian flu.

In the cancer program, Traws is developing the novel, proprietary multi-kinase CDK4-plus inhibitor narazaciclib potentially for refractory endometrial cancer and other solid tumor cancers. Narazaciclib targets pathways involved in the development of resistance to CDK inhibitors.

Traws Pharma is committed to delivering novel compounds for unmet medical needs using state-of-the-art drug development technology. With a focus on product safety and a commitment to patients in need or that are specifically vulnerable, we build solutions for important medical challenges, aiming to alleviate the burden of viral infections and cancer.

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and involve risks and uncertainties including statements regarding the Phase 1 study of ratutrelvir in Australia and its design, timing and potential results and the timing of a planned Phase 2 study. Traws has attempted to identify forward-looking statements by terminology including “believes”, “estimates”, “anticipates”, “expects”, “plans”, “intends”, “may”, “could”, “might”, “will”, “should”, “preliminary”, “encouraging”, “approximately” or other words that convey uncertainty of future events or outcomes. Although Traws believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including the success and timing of Traws’ clinical trials, collaborations, market conditions and those discussed under the heading “Risk Factors” in Traws’ filings with the Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of its date. Traws undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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Traws Pharma, Inc.
Condensed Consolidated Balance Sheets

	March 31, 2024	December 31, 2023
Assets	**(unaudited)**	
Current assets:		
Cash and cash equivalents	$ 16,390,000	$ 20,821,000
Receivables	18,000	18,000
Prepaid expenses and other current assets	1,745,000	1,821,000
Total current assets	18,153,000	22,660,000
Property and equipment, net	18,000	22,000
Other non-current assets	1,000	1,000

Total assets	$ 18,172,000	$ 22,683,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,568,000	$ 5,619,000
Accrued expenses and other current liabilities	2,628,000	3,375,000
Deferred revenue	226,000	226,000
Total current liabilities	9,422,000	9,220,000
Deferred revenue, non-current	2,735,000	2,791,000
Total liabilities	12,157,000	12,011,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value, 5,000,000 shares authorized, none issued and outstanding at March 31, 2024 and December 31, 2023	—	—
Common stock, $0.01 par value, 125,000,000 shares authorized, 21,085,935 and 21,003,409 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	211,000	210,000
Additional paid in capital	493,448,000	493,116,000
Accumulated deficit	(487,614,000)	(482,631,000)
Accumulated other comprehensive loss	(30,000)	(23,000)
Total stockholders' equity	6,015,000	10,672,000
Total liabilities and stockholders' equity	$ 18,172,000	$ 22,683,000

Traws Pharma, Inc.
Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
	2024	**2023**
Revenue	$ 56,000	$ 56,000
Operating expenses:		
General and administrative	3,356,000	2,113,000
Research and development	1,912,000	4,080,000
Total operating expenses	5,268,000	6,193,000
Loss from operations	(5,212,000)	(6,137,000)
Other income, net	229,000	362,000
Net loss	$ (4,983,000)	$ (5,775,000)
Net loss per share, basic and diluted	$ (0.24)	$ (0.28)
Basic and diluted weighted average shares outstanding	20,803,746	20,960,171