



Traws Pharma Provides Business Update and Reports Q3 2024 Financial Results

Nov 14, 2024

- **COVID:** Phase 1 pharmacokinetic profile supports the potential for ratutrelvir to be dosed as a once-a-day, single drug, 10-day treatment course, without ritonavir, and with a lower likelihood of clinical rebound and good overall tolerability
- **Flu:** Phase 1 pharmacokinetic profile supports the potential for tivoxavir marboxil to be a one-time treatment for flu, including pandemic and avian flu, with good overall tolerability

NEWTOWN, Pa., Nov. 14, 2024 (GLOBE NEWSWIRE) -- Traws Pharma, Inc. ("Traws" or "Traws Pharma"), a clinical stage biopharmaceutical company developing oral small molecules for respiratory viral diseases, today outlined recent business updates and reported unaudited financial results for the third quarter ended September 30, 2024.

"Traws is making excellent progress with its clinical pipeline. Phase 1 data for each of the antiviral programs for COVID and influenza are particularly exciting," said **Werner Cautreels, PhD, Chief Executive Officer** of Traws Pharma. "Based on our recent Phase 1 pharmacokinetic results, we believe that **ratutrelvir** has the potential to be used as a monotherapy to treat COVID, without ritonavir, with a lower likelihood of clinical rebound. In addition, recent Phase 1 pharmacokinetic data suggest that **tivoxavir marboxil** could be a single-dose treatment for influenza, including potential pandemic settings such as avian flu. These distinct characteristics support the potential for each agent to be a differentiated, best-in-class treatment and progress to Phase 2 studies expected to commence in 2025."

Upcoming Milestones

Tivoxavir marboxil: Flu: an oral influenza cap-dependent endonuclease, highly conserved across flu strains, including avian flu. Intended as a one dose treatment or prevention of seasonal and pandemic flu

- Initiation of Phase 2 clinical proof of concept study in community-acquired setting

Ratutrelvir: COVID: an oral Mpro/3CL protease inhibitor, without the need for a CYP-inhibitor such as ritonavir. Intended as a once-a-day, single-dose, 10-day antiviral regimen for the treatment of COVID

- Initiation of Phase 2 clinical proof of concept study in community-acquired setting

Recent Developments

Antiviral programs advancing as potential best-in-class agents, poised to begin Phase 2

- **COVID: Phase 1 data affirms ratutrelvir's potential to be dosed without ritonavir, with lower rebound risk :** Data from the Phase 1 healthy volunteer study, with once-a-day ratutrelvir dosing for 10 days showed no treatment related adverse events and demonstrated consistent plasma drug levels in the predicted therapeutic window. The study showed that ratutrelvir achieved plasma concentrations that were consistently above the EC90 against a panel of SARS-COV-2 viruses, without the need for ritonavir co-administration, which can be a source of drug-drug interactions and severe side effects. Pharmacokinetic data also suggest that ratutrelvir may have a reduced likelihood of clinical rebound, helped to define the dose for Phase 2 studies. Previous preclinical testing in animal models showed that levels of ratutrelvir in the lung were higher than in plasma. Taken together, the data further suggest that ratutrelvir has the potential to be a once-a-day, single-dose, 10-day antiviral therapy for COVID and support Phase 2 studies.
- **Flu: Phase 1 data support tivoxavir marboxil's potential to treat flu with a single dose, with potential for pandemic/avian flu:** Data from the Phase 1 healthy volunteer study, with one-time tivoxavir marboxil dosing showed good overall tolerability and a pharmacokinetic profile that appears to support potential use as a one-time treatment for flu, including pandemic flu. The study showed that a single dose of tivoxavir maintained plasma drug levels above the EC90 for more than five days and helped to define a Phase 2 dose. Prior preclinical studies have shown that tivoxavir has broad activity against drug resistant viruses and highly pathogenic strains such as avian flu. In addition, preclinical data showed that a single dose of tivoxavir has more than 15X higher accumulation in the lung compared to plasma. The combined dataset support further development of tivoxavir marboxil as a potential treatment of community-acquired influenza or for use in case of an avian flu outbreak or pandemic, with further potential to prevent virus spread in households and congregant settings.

Additional Updates: Luba Greenwood, J.D. added to the Board: Ms. Greenwood brings a rich depth of experience as a Board Member, Investor, Strategic Advisor and Company Executive through her industry roles, including as a board member for public life science companies across a range of

therapeutic areas. In addition, Traws **continues ongoing investigator-sponsored trial driven (IST) development** of narazaciclib and rigosertib.

Financial Results:

Cash, cash equivalents and short-term investments: As of September 30, 2024, the Company had cash, cash equivalents, and short-term investments of approximately \$5.4 million, compared to cash, cash equivalents, and short-term investments of approximately \$20.8 million at December 31, 2023.

Research and development (R&D) expense for the three months ended September 30, 2024, totaled \$5.1 million, compared to \$2.5 million for the comparable period in 2023. This increase was primarily attributable to the initiation and completion of our Phase 1 study for TRX100 in Australia, partially offset by the reductions in research and development costs attributable to the Australian tax incentive receivable.

General and administrative (G&A) expense for the three months ended September 30, 2024, totaled \$3.5 million, compared to \$2.7 million for the comparable period in 2023. This increase was primarily attributable to a \$1.2 million increase in professional and consulting fees associated with seeking strategic alternatives for our investors. This increase was offset by a \$0.7 million decrease in public company costs.

Net loss: The net loss for the three months ended September 30, 2024 was \$8.5 million, or \$8.81 per basic and diluted common share. This compares with a net loss of \$4.7 million, or \$5.64 per basic and diluted common share, for the same period in 2023.

Traws had 3,025,554 shares outstanding as of November 11, 2024. The shares outstanding reflect a 25:1 reverse split, effective as of September 20, 2024.

About Traws Pharma, Inc.

Traws Pharma is a clinical stage biopharmaceutical company developing potential oral small molecule therapies for the treatment of respiratory viral diseases and cancer. The viral respiratory disease program includes two oral, novel, Phase 2-ready, potentially best-in-class, small molecule drug candidates: tivoxavir marboxil, in development for flu and pandemic flu, targeting the influenza cap-dependent endonuclease (CEN); and ratutrelvir, in development as a COVID treatment, targeting the Mpro (3CL protease), without the need for co-administration of ritonavir.

In the cancer program, Traws is utilizing a partnering strategy, supported by investigator sponsored studies, to advance two novel proprietary multi-kinase inhibitors, narazaciclib, targeting CDK4+, and rigosertib, targeting cell cycle proteins including PLK-1.

Traws 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 aim to build solutions for important medical challenges and alleviate the burden of viral infections.

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 Company, its business and product candidates, including the potential opportunity, benefits and the regulatory plans for tivoxavir marboxil and ratutrelvir, as well as narazaciclib and rigosertib. The Company has attempted to identify forward-looking statements by terminology including "believes", "estimates", "anticipates", "expects", "plans", "intends", "may", "could", "might", "will", "should", "supports", "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 U.S. Securities and Exchange Commission and assumes the Company is successful in its fundraising activities. 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 (unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,410,000	\$ 20,821,000
Tax incentive and other receivables	2,121,000	18,000
Prepaid expenses and other current assets	1,392,000	1,821,000

Total current assets	8,923,000	22,660,000
Property and equipment, net	12,000	22,000
Other non-current assets	1,000	1,000
Total assets	<u>\$ 8,936,000</u>	<u>\$ 22,683,000</u>
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	\$ 5,472,000	\$ 5,619,000
Accrued expenses and other current liabilities	2,650,000	3,375,000
Deferred revenue	226,000	226,000
Total current liabilities	<u>8,348,000</u>	<u>9,220,000</u>
Deferred revenue, non-current	2,621,000	2,791,000
Total liabilities	<u>10,969,000</u>	<u>12,011,000</u>
Commitments and contingencies		
Stockholders' (deficit) equity:		
Series C Preferred stock, \$0.01 par value, 5,000,000 shares authorized, 7,440 shares issued and outstanding at September 30, 2024 and no shares issued and outstanding at December 31, 2023	—	—
Common stock, \$0.01 par value, 250,000,000 shares authorized, 3,025,554 and 840,251 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	30,000	9,000
Additional paid in capital	617,202,000	493,317,000
Accumulated deficit	(619,232,000)	(482,631,000)
Accumulated other comprehensive loss	(33,000)	(23,000)
Total stockholders' (deficit) equity	<u>(2,033,000)</u>	<u>10,672,000</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 8,936,000</u>	<u>\$ 22,683,000</u>

Traws Pharma, Inc.
Condensed Consolidated Statements of Operations (unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Revenue	\$ 57,000	\$ 57,000	\$ 170,000	\$ 170,000
Operating expenses:				
Acquired in-process research and development	—	—	117,464,000	—
Research and development	5,113,000	2,460,000	10,989,000	8,996,000
General and administrative	3,480,000	2,686,000	8,813,000	7,010,000
Total operating expenses	<u>8,593,000</u>	<u>5,146,000</u>	<u>137,266,000</u>	<u>16,006,000</u>
Loss from operations	(8,536,000)	(5,089,000)	(137,096,000)	(15,836,000)
Other income, net	61,000	350,000	495,000	1,072,000
Net loss	<u>\$ (8,475,000)</u>	<u>\$ (4,739,000)</u>	<u>\$ (136,601,000)</u>	<u>\$ (14,764,000)</u>
Net loss per share, basic and diluted	<u>\$ (8.81)</u>	<u>\$ (5.64)</u>	<u>\$ (130.87)</u>	<u>\$ (17.59)</u>
Basic and diluted weighted average shares outstanding	<u>961,530</u>	<u>840,117</u>	<u>1,043,781</u>	<u>839,243</u>