
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): August 15, 2024

Traws Pharma, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation or Organization)

001-36020
(Commission
File Number)

22-3627252
(I.R.S. Employer
Identification No.)

**12 Penns Trail
Newtown, PA 18940
(267) 759-3680**

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$.01 per share	TRAW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

Item 2.02 Results of Operations and Financial Condition.

On August 15, 2024, Traws Pharma, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2024, a copy of which is attached hereto as Exhibit 99.1 and incorporated herein by reference. The information contained in this Form 8-K (including the exhibit hereto) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit
99.1	Press release issued by the Company dated August 15, 2024
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TRAWS PHARMA, INC.

Date: August 15, 2024

By: /s/ MARK GUERIN
Mark Guerin
Chief Financial Officer

**Traws Pharma Reports Q2 2024 Financial Results,
Provides Recent Business Highlights**

Merger with Trawsfynydd Therapeutics, Inc (“Trawsfynydd”) and concurrent private placement of \$14 million (cash runway to support planned operations through year end), with recently achieved clinical milestones, put Traws on track to achieve key readouts for the clinical pipeline in H2 2024 and beyond

- *Lead antiviral program, tioxavir marboxil, for influenza, including avian flu, is dosing the first cohort in the Phase 1 dose extension study in Australia*
- *COVID-19 program, ratutrelvir, completed the Phase 1 single-ascending dose (SAD) and multiple-ascending dose (MAD) study in Australia*
- *Oncology strategy includes investigator-sponsored trials (ISTs), planned to begin in H2 2024, adding a new dimension to the narazaciclib program, with continued investigator support for rigosertib*
- *Corporate update call planned for August 15, 2024 at 8:00 AM ET*

NEWTOWN, PA, August 15, 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 outlined recent business highlights and reported unaudited financial results for the second quarter ended June 30, 2024. The Company intends to host a conference call and live webcast on Thursday, August 15, 2024 at 8:00 AM ET.

“The last several months have been transformational for Traws Pharma, with strategic and product development progress and an increase in capital,” said **Werner Cautreels, PhD, Chief Executive Officer** of Traws Pharma. “Completion of the merger agreement that created Traws Pharma expanded our investor base to include recognized healthcare investors, Orbimed and Torrey Pines, while broadening our portfolio to include compounds that we believe have best-in-class potential for influenza (flu), including bird flu, and COVID-19. In addition, ISTs are enhancing our multi-kinase inhibitors for cancer, narazaciclib and rigosertib.”

“We expect the antiviral program to advance over the next 6+ months as we complete preparations to report Phase 1 results and initiate Phase 2 studies in flu and COVID-19. Preclinical data and topline data from SAD studies from our influenza candidate, **tioxavir marboxil**, suggest that it has the potential to achieve our target product profile as a single dose treatment that is active against pandemic-potential viruses as well as oseltamivir and baloxavir resistant viruses,” continued **Dr. Cautreels**. “In addition, clinical-trial enabling studies for our COVID-19 candidate, **ratutrelvir**, suggest that it has the potential to be effective without the requirement for co-administration of a CYP-inhibitor, and active against virus strains that may be resistant to other approved agents such as nirmatrelvir. In the coming months, we look forward to completing the Phase 1 studies, finalizing the dosing plan and initiating the Phase 2 program for both tioxavir marboxil and ratutrelvir. We believe these data could pave the way for key readouts in 2025.”

Upcoming Milestones

Tioxavir marboxil -- *Targets the influenza cap-dependent endonuclease, which is highly conserved across flu strains, including avian flu. The compound is intended to be administered as a single dose per treatment*

- Q4 2024: Announcement of topline Phase 1 dose extension results from Australia
 - Q4 2024/Q1 2025: Initiation of Phase 2 efficacy study
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Ratutrelvir – *Targets Mpro (3CL protease). The compound does not require combination use of a CYP-inhibitor such as ritonavir*

- Q4 2024: Announcement of topline results from Phase 1 SAD and MAD studies
- Q4 2024/Q1 2025: Initiation of Phase 2 efficacy study

Narazaciclib – *our multi-kinase inhibitor; including CKD4+, with potential for use in multiple solid tumors*

- H2 2024: Release topline results from our Phase 1/2 study at an upcoming medical meeting. In addition, we plan to announce the recommended Phase 2 dose (RP2D) and initiate ISTs in multiple myeloma, breast cancer and other indications

Rigosertib – *our multi-kinase inhibitor targeting cell cycle proteins including PLK-1, with potential for use in the ultra-rare disease, advanced squamous cell carcinoma complicating recessive dystrophic epidermolysis bullosa (RDEB-associated SCC, RDEB)*

- Continue to support the IST-led program, including compassionate use for patients with RDEB

Recent Developments

- **Start of dosing in Phase 1 dose extension study for tivoaxavir marboxil**, a placebo-controlled trial designed to evaluate three doses, including two doses from the successful Phase 1 dose escalation study (80 and 120 mg) and one new, increased dose (240 mg) in healthy volunteers. The study was designed to assess pharmacokinetics, pharmacodynamics and safety, to define the dosing plan for the upcoming Phase 2 efficacy study. The expected dosing schedule will be one single oral dose.
- **Completion of a Phase 1 dose escalation study for ratutrelvir in Australia**, a SAD/MAD study conducted in healthy volunteers. The study was designed to assess SAD (5 doses ranging from 15 mg to 600 mg) and MAD (2 doses, 150 mg, and 600 mg, daily for 10 days) and provide pharmacokinetics, pharmacodynamics and safety data to guide the dosing plan for the upcoming Phase 2 efficacy study. The expected dosing schedule will be one oral dose per day for 10 days.
- **Completion of Phase 1/2 dose escalation studies for narazaciclib**, evaluated as a monotherapy and in combination with letrozole in patients with recurrent metastatic low-grade endometrioid endometrial cancer and other gynecologic malignancies. The studies were designed to define the dose limiting toxicity (DLT) and maximally tolerated dose (MTD) of the combination, and the RP2D for further clinical trials. Topline data are being analyzed.
- **Presentation of further data from ongoing ISTs for rigosertib**, shared at the Society for Investigative Dermatology (SID) held in July, 2024 which highlighted ongoing studies for RDEB-associated SCC, conducted at the University Hospital in Salzburg, Austria and Thomas Jefferson University, Philadelphia, PA.
- **Completion of the merger with Trawsfynydd and concurrent \$14 million private placement in April** expanded the clinical portfolio of the combined entity to include two potentially best-in-class oral small molecule programs, for influenza and COVID-19, as well as oral two agents for solid tumor cancers. The transaction also enhanced the Company's investor base, with the addition of Orbimed and Torrey Pines.

Financial Results:

Traws financial results for the quarter ended June 30, 2024 represent the first post-transaction quarterly report of the combined company. The financial results for the comparable period in 2023 represent a consolidated summary of the combined entity. For simplicity, the explanatory statements below provide a high-level summary of expenses for the quarter ended June 30, 2024.

Cash, cash equivalents and short-term investments: As of June 30, 2024, the Company had cash, cash equivalents, and short-term investments of approximately \$16.9 million, compared to cash, cash equivalents, and short-term investments of approximately \$20.8 million at December 31, 2023. The company believes its cash balance is adequate to support planned operations through year end 2024.

Acquired in-process R&D related to our transaction early in the second quarter resulted in a non-cash charge of \$117.5 million.

Research and development (R&D) expense for the three months ended June 30, 2024, totaled \$4.0 million, compared to \$2.5 million for the comparable period in 2023. Q2 2024 R&D expenses mainly reflect the cost of the Phase 1 SAD/MAD COVID-19 study, the Phase 1 extension study in flu, completion of the narazaciclib Phase 1/2 dose escalation study, regulatory expenses to support planned upcoming studies, and expenses related to stock-based compensation and restructuring costs related to the recent transaction.

General and administrative (G&A) expense for the three months ended June 30, 2024, totaled \$2.0 million compared to \$2.2 million for the comparable period in 2023. Q2 2024 G&A expenses include stock-based compensation and restructuring costs related to the merger.

Net loss: The net loss for the three months ended June 30, 2024 was \$123.1 million, or \$4.87 per basic and diluted common share, which reflects a non-cash charge of \$117.5 million related to in-process R&D from Onconova's April 2024 acquisition of Trawsfynydd. This compares with a net loss of \$4.3 million, or \$0.20 per basic and diluted common share, for the same period in 2023.

Conference Call and Webcast Information

Traws Pharma will host a conference call and webcast today, August 15, 2024, at 8:00 AM ET to discuss recent business progress and second quarter financial results. To access the call, please dial: 1 (877) 407-0789 (United States) or 1 (201) 689-8562 (International) and reference the conference ID "13748066". To access the webcast, please click: [Traws Pharma Corporate Update Call](#). The live and archived webcast can also be accessed by visiting the "[Corporate Events & Presentations](#)" tab of the *Events and Presentations* section of the Investor Relations page. A replay of the webcast will be archived for 90 days.

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 two potentially best-in-class oral small molecules in Phase 1 studies: tioxavir marboxil, a novel oral antiviral drug candidate for influenza and avian flu, targeting the influenza cap-dependent endonuclease, and ratutrelvir, targeting Mpro (3CL protease).

In the cancer program, Traws is developing the novel, proprietary multi-kinase CDK4-plus inhibitor narazaciclib, with potential for refractory endometrial cancer and potentially other solid tumor cancers, and rigosertib, multi-kinase inhibitor targeting cell cycle proteins including PLK-1, with potential for use in advanced squamous cell carcinoma complicating recessive dystrophic epidermolysis bullosa (RDEB-associated SCC, RDEB).

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 aim to build solutions for important medical challenges and 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 Traws Pharma, its respective businesses, the merger agreement with Trawsfynydd Therapeutics, Inc. and concurrent private placement and the use of proceeds from such financing and the Company's financing strategies, as well as statements regarding the milestones, preclinical studies and clinical studies for its four product candidates, tivoxavir marboxil for influenza including avian flu, ratutrelvir for COVID-19, and narazaciclib and rigosertib for cancer, related to the design, timing and potential results and the timing of next steps. 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, merger integration, 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.

Consolidated Balance Sheets

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,886,000	\$ 20,821,000
Receivables	18,000	18,000
Prepaid expenses and other current assets	1,767,000	1,821,000
Total current assets	18,671,000	22,660,000
Property and equipment, net	14,000	22,000
Other non-current assets	1,000	1,000
Total assets	\$ 18,686,000	\$ 22,683,000
Liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	\$ 6,174,000	\$ 5,619,000
Accrued expenses and other current liabilities	3,509,000	3,375,000
Deferred revenue	227,000	226,000
Total current liabilities	9,910,000	9,220,000
Deferred revenue, non-current	2,677,000	2,791,000
Total liabilities	12,587,000	12,011,000
Commitments and contingencies		
Series C redeemable convertible preferred stock; \$0.01 par value, 5,000,000 shares authorized; 12,472 and zero shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	111,619,000	—
Stockholders' (deficit) equity:		
Common stock, \$0.01 par value, 125,000,000 shares authorized, 25,306,509 and 21,003,409 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	253,000	210,000
Additional paid in capital	505,017,000	493,116,000
Accumulated deficit	(610,757,000)	(482,631,000)
Accumulated other comprehensive loss	(33,000)	(23,000)
Total stockholders' (deficit) equity	(105,520,000)	10,672,000
Total liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity	\$ 18,686,000	\$ 22,683,000

Traws Pharma, Inc.

Condensed Consolidated Statements of Operations (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	\$ 57,000	\$ 57,000	\$ 113,000	\$ 113,000
Operating expenses:				
Acquired in-process research and development	117,464,000	—	117,464,000	—
Research and development	3,964,000	2,456,000	5,876,000	6,536,000
General and administrative	1,977,000	2,211,000	5,333,000	4,324,000
Total operating expenses	<u>123,405,000</u>	<u>4,667,000</u>	<u>128,673,000</u>	<u>10,860,000</u>
Loss from operations	(123,348,000)	(4,610,000)	(128,560,000)	(10,747,000)
Other income, net	205,000	360,000	434,000	722,000
Net loss	<u>\$ (123,143,000)</u>	<u>\$ (4,250,000)</u>	<u>\$ (128,126,000)</u>	<u>\$ (10,025,000)</u>
Net loss per share, basic and diluted	<u>\$ (4.87)</u>	<u>\$ (0.20)</u>	<u>\$ (5.53)</u>	<u>\$ (0.48)</u>
Basic and diluted weighted average shares outstanding	<u>25,310,774</u>	<u>20,979,766</u>	<u>23,177,117</u>	<u>20,970,022</u>