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): April 16, 2024

Traws Pharma, Inc.

(Exact name of Registrant as specified in its charter)

001-36020

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

Delaware (State or Other Jurisdiction of Incorporation or Organization)

> 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)

D 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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered	
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 \Box

Item 7.01. Regulation FD Disclosure.

On April 16, 2024, Traws Pharma, Inc. (the "Company") made an investor presentation available on its website. A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information in Item 7.01 of this Current Report on Form 8-K, including the information in the presentation attached as Exhibit 99.1 to this Current Report on Form 8-K, is furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act, as amended, or otherwise subject to the liabilities of that section. Furthermore, the information in Item 7.01 of this Current Report on Form 8-K, including the information in the presentation attached as Exhibit 99.1 to this Current Report on Form 8-K, shall not be deemed to be incorporated by reference in the filings of the Company under the Securities Act of 1933, as amended.

Item 9.01.	Financial Statements and Exhibits.
(d) Exhibits	
Exhibit Number	Description
<u>99.1</u>	Investor Presentation, dated April 16, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

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

Date: April 16, 2024



TRAWS PHARMA

Potential best in class product candidates in development for cancer & respiratory viral diseases

1.11.11

April 2024

NASDAQ - TRAW

Forward-looking statements

This presentation contains, and certain oral statements made by management from time to time may contain, "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1993, seating and the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1993, seating and the "securities Act"), and Sectoria 216 of the securities Exchange Act of 1934, as amended the "securities Exchange Act of 1934, as amended. Such statements include actions, events, results, strategies and expectations and expectations and the securities Litigation Reform Act of 1993, new control and the securities act of 1934, as amended. Such statements include actions, events, results, strategies and expectations and this presentation include, but are not limited to, express or implied statements regarding the structure of Traws Pin servers, "securities Resting and value of CNNs (as defined herein); expectations regarding the ownership structure of Traws Pin servers, expectations regarding the structure of the value of CNNs (as defined herein); expectations regarding the ownership structure of Traws Pin servers, expected impact of the Securities Carbon regarding the structure of traws Pin servers, expected milestones; and other statements that are not historical fact. All statements the usance and walue of CNNs (as defined herein); expectations regarding the structure of traws Pin servers, and walue of CNNs (as defined herein); expectations regarding the structure and value of CNNs (as defined herein); expectations the conversion of the Securities Crypteriot stock, and related stuckholder approximation are forward-looking statements. These relates the store of the stor

We is the beliefs and assumptions of management. Increase the to assurance that nutre developments antecting the combined company will be those that nave been anticepated. Forward-looking statements are subject to a number of factors, including but not limited to (i) failure to invely obtain stockholder approval for the transaction, if at all (ii) risks related to Traws' ability to manage its operating expenses and its expenses associated with Merger; (iii) unexpected costs, charges or expenses resulting from the transaction, if at all (ii) risks related to Traws' ability to manage its operating expenses and its expenses associated with Merger; (iii) unexpected costs, charges or expenses resulting from the transaction, if at all (ii) risks related to Traws' ability to manage its busines; related to the mathematication (iv) potential development and regulatory approval of product candidates, including potential delays in the commencement and completion of clinical candidates and unexpected costs that may result therefrom; (viii) risks related to the inality of risks associated with the possible failure to relation and regulatory approval of product candidates, including potential delays in the completion of clinical results and the timing of events could differ materially from those anticipated in the inality of raves and difficulties and didates and unexpected costs that may result therefrom; (viii) risks related to the inaliter to relate any value from product candidates, uncluding the respect to failure finance and indices and expecting frout the respect to failure to relate. Actual results and the timing of events could differ materially from those anticipated with the possible failure to related "Risk factors", in Traws' Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC. Or April 1, 2024, subsequent Quartification (the SEC, and in other filings that Traws makes and with the SEC. You should not place undue reliances on these for earchooking statements, statements,

No offer or solicitation

This presentation is for informational purposes only and does not constitute a solicitation of a proxy, consent or authorization with respect to any securities or in respect of the Merger and shall not constitute an offer to sell or a solicitation of an offer to buy the securities of the Traws, nor shall there be any sale of any such securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities law of such state or jurisdiction. No offer to feed the traveling the requirements of Securities Action 10 of the Securities Action 10 of the Securities Action Action therefrom.

Traws expects to file a proxy statement with the SEC relating to proposals to be made in connection with the Merger. The definitive proxy statement will be sent to all Traws stockholders. Before making any voting decision, investors and security holders of Traws are urged to read the proxy statement and all other relevant documents filed or that will be filed with the SEC in connection with such proposals as they become available because they will contain important information. Investors and security holders will be able to obtain free copies of the proxy statement and all other relevant documents filed or that will be filed with the SEC by Traws through the website maintained by the SEC at www.sec.gov.

Participants in solicitation

Traws and their respective directors, executive officers and employees may be deemed to be participants in the solicitation of proxies in respect of the Merger. Information regarding Traws' directors and executive officers is available in Traws' Definitive Proxy Statement field with the SEC on June 7, 2023 under "Proposal One – Election of Directors," To the extent holdings of such directors and executive officers are not reported, or have changed since the amounts described in the proxy statement for Traws' annual meeting of stockholders, such changes may be reflected on Initial Statements and Emethical Ownership on Form 3 or Statements of Change in Ownership on Form 4 filed with the SEC. Other information regarding the persons who may, under the rules of the SEC, be deemed participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement and Define the structure of the



TRAWS PHARMA – A clinical stage biopharmaceutical company



TRAWS PHARMA – Experienced Leadership Team



TRAWS PHARMA – Accomplished Board of Directors



TRAWS PHARMA - Pipeline Overview

Virology Programs

Target	Indication	Preclinical	Phase 1	Phase 2
TRX01 (travatrelvir)	COVID19			
TRX100 (viroxavir)	Seasonal or pandemic influenza			

Oncology Programs

Target	Indication	Preclinical	Phase 1/2	Phase 2/3
Narazaciclib (DAILY)	Solid tumors			
Narazaciclib + Letrozole (BOTH DAILY)	2L / 3L Low grade endometrioid endometrial cancer			
Rigosertib	Epidermolysis bullosa-associated squamous cell carcinoma (rare disease)	Rigosertib is in investigator-initiated clinical trials and will become available f out-licensing		



Challenges and Opportunities for COVID19



- COVID19 remains among the top 5 causes of death in the developing world. The [nirmaltrevir +ritonavir] course is 5 days BID; drug:drug interactions limit eligibility and use in many patients (Corritori, 2022, COVID).
- 20.8% of [nirmaltrevir + ritonavir] treated individuals had clinical rebound (Edelstein, 2023, Annals of Internal Medicine).
- Clinical rebound is associated with prolonged shedding of infectious virus and/or symptomatic rebound, which continue to be major obstacles in COVID19 care that were not solved by [nirmaltrevir + ritonavir], molnupiravir, or remdesivir.
- Global COVID19 therapeutics market was estimated at \$30.7B in 2021 and will contract by 8.3% annually but will reach \$16.2B by 2031 (https://www.transparencymarketresearch.com/covid-19-therapeutics-market.html).

TRX01 (travatrelvir) - Investigational Candidate

- Improved potency over nirmatrelvir (up to 9 times more potent in biochemical and cell-based assays); potency advantages greatest among Omicron strains and current VOC
- Does not require co-administered CYP inhibitor
- Exposures >EC90 for >48 h after single oral dose in animals
- GLP toxicology studies using 10 days of daily oral administration provides basis for human dosing
- · Potential for once daily oral therapy for a duration of 10 days
- First-in-man Phase 1 dosing in April 2024



TRX01 (travatrelvir) Superior to nirmatrelvir against Omicron Variants

Virus	m.o.i.	TRX01 EC50 nM	Nirmatrelvir EC50 nM	Remdesivir EC50 μM	Nirmatrelvir EC50 ÷ TRX01 EC50
USA_WA1/2020	0.005	2.6	11	1.7	4.2
Omicron B.1.1.529	0.02	16	26	0.69	1.6
Omicron B.A.2	0.01	7.3	21	0.74	2.9
Omicron B.A.4	0.02	<1	<1	1.2	-
Omicron B.A.5	0.02	<1	<1	2.5	-
Omicron BF.7	0.003	4.7	41	1.8	8.7
Omicron BQ.1	0.003	37	64	1.3	1.7
Omicron BQ.1.1	0.002	6.2	12	1.3	1.9
Omicron XBB	0.002	9.4	29	0.68	3.1

Compounds tested with 2 μ M CP-100356 (efflux inhibitor)

EC50: 50% effective concentration

TRX01 (travatrelvir) - Phase 1 Study Plan



Single (A) and Multiple (B) Ascending Doses travatrelvir

A Randomized, Double-Blind, Placebo-Controlled, First-in-Man Study of Orally Administered travatrelvir to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmcodynamics of Single and Multiple Ascending Doses in Healthy Volunteers



TRX01 (travatrelvir) – Phase 2 development

- Phase 1 will provide data on safety and tolerability of a 10-day, daily regimen
- Phase 1 data will guide design of the phase 2 development plan
- Phase 2 is anticipated to be an international, multi-center randomized, double-blind, controlled clinical trial of the efficacy and safety of travatrelvir in patients with moderate to severe COVID19
- Phase 2 planned for H2 2024



TRX01 (travatrelvir) - Summary

- Potent inhibitor of SARS-CoV-2 Mpro (3CL protease)
- Active in vitro against original, delta and omicron variants of SARS-CoV-2
- More potent than nirmatrelvir; does not require ritonavir co-administration in preclinical studies and therefore expected to avoid drug:drug interactions potentially permitting wider patient use
- Under investigation for once-daily oral therapy for 10 days to prevent viral rebound
- Phase 1 study dosing April 2024 with Phase 2 planned for H2 2024



Challenges and Opportunities for Influenza Therapy

- · New drugs are needed to treat influenza strains resistant to oseltamivir or baloxavir
- Long-acting antiviral drugs will increase influenza resistance among elderly and immunocompromised populations
- The ongoing risk from virus emerging out of natural virus reservoirs requires high potency antivirals effective against pandemic-potential strains
- 80-90% of seasonal influenza deaths occur in persons >65 years old despite the fact that 70% of persons 65 years and older (in the US) receive seasonal vaccine
- 31% of persons 65 years and older, within 2 days of symptom onset, were prescribed influenza antiviral medication



TRX100 (viroxavir) - Investigational Candidate Cap-Dependent Endonuclease (CEN) Inhibitor for Influenza

The oral prodrug viroxavir targets the cap-dependent endonuclease of Influenza and is a potent inhibitor of influenza virus replication including A or B strains

Inhibits pandemic-potential influenza viruses circulating in nature during 2022 as well as oseltamivir or baloxavir-resistant viruses in cell-based assays

Completed a Phase 1 study that showed positive safety and tolerability data in healthy volunteers; will enter Phase 1 dose extension and Phase 2 studies in 2024

PK/PD data from the Phase 1 study support the potential use of a single oral dose administration for either treatment or prophylaxis.



TRX101: The active metabolite of viroxavir, in cell-based assays



TRX101 - potent inhibition of baloxavir-resistant influenza A virus replication

TRX-101 inhibits replication of influenza A/California/04/2009(H1N1)pdm09 and A/Texas/71/2017(H3N2) viruses containing PA I38-WT, I38T, or I38M substitutions

	Plaque-reduction assay (EC $_{50}$ \pm SEM, nM)						
Influenza A virus subtype	TRX101			BXA			
	138-WT	138T	138M	138-WT	138T	138M	
A/California/04/2009 (H1N1)pdm09	0.2 ± 0	1.8 ± 1.7	2.2 ± 0.2	0.2 ± 0.1	14.3 ± 2.0	1.2 ±0.2	
A/Texas/71/2017 (H3N2)	0.2 ± 0	8.1 ± 4.4	3.0 ± 0.3	0.2 ± 0.1	22.7 ± 4.7	2.5 ± 1.3	

TRX-101 was more potent than BXA for inhibiting replication (plaque forming units) of the BXA-resistant influenza A(H1N1)pdm09 virus carrying PA I38T and the A(H3N2) virus carrying PA I38T

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TRX100 (viroxavir) - Summary of Available Phase 1 Clinical Data

A randomized, double-blind, placebo-controlled study of the safety, tolerability, and pharmacokinetics of single doses of viroxavir administered orally in healthy volunteers on an empty stomach and after a meal

- Healthy Caucasian men 18-45 years, single ascending dose, 20, 40 80 or 120 mg on empty stomach followed by 8-15 days washout before receiving the same dose after a meal.
- Study confirmed high exposure and long-half life after single oral dose; exposure was roughly dose proportional, and exposures were greater when taken after a meal.
- Total of 2 adverse events (AE) recorded during the entire study, both in the same participant and one was a serious adverse event (SAE), deemed unrelated to study drug
- · The relationship of non-serious AE (hyperglycemia) to the study drug was deemed probable
- In the range of 20 mg to 120 mg, a single administration of viroxavir was well tolerated in human volunteers

TRX100 (viroxavir) - Phase 1 Study – Acute Influenza

Dose Extension Study – to start H1 2024

A single ascending dose, placebo-controlled study on safety and tolerability of viroxavir in healthy volunteers. This study tests a 200 mg dose level to determine the impact(s) of a higher dose on safety and pharmacokinetics. Viroxavir 120* mg single dose

Viroxavir 200 mg single dose

Placebo

* Repeats highest dose cohort from previous Phase 1 study



TRX100 (viroxavir) – Phase 2 development

- Phase 1 data will define further design of the phase 2 development plan
- Phase 2 is planned to be an international multicenter randomized, double-blind, controlled clinical trial of the efficacy and safety of viroxavir in patients with Influenza
- Potentially as a single oral administration
- Phase 2 is planned for H2 2024



TRX100 (viroxavir) - Summary

- Potent at nM or sub-nanomolar concentrations against a panel of influenza A and influenza B viruses including highly pathogenic avian influenza strains circulating in 2022
- Demonstrated in animals preferential accumulation in lung, which may improve antiviral potency in the respiratory tract
- Inhibited baloxavir-resistant influenza viruses bearing I38T or I38M mutations in the PA gene
- Showed positive safety/tolerability results in a completed Phase 1 study with healthy volunteers
- PK/PD data from the Phase 1 study support the potential use of a single oral dose administration for either treatment or prophylaxis.
- Phase 1 study extension will evaluate two additional (higher) doses prior to Phase 2 in H2 2024
- · Properties make viroxavir suitable for further evaluation as stockpiling

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CDK 4/6 Inhibitors Represent an Important Class of Cancer Therapeutics

Graphic: San Antonio Breast Cancer Symposium, 2023 Poster

- Overexpression of CDK 4/6 causes cell-cycle deregulation in certain cancers
- Role of Rb pathway in tumor initiation and progression is well-established
- Inhibition of Rb prevents CDK-mediated G1-S phase transition, suppressing DNA synthesis and inhibiting cancer cell growth
- Multiple therapeutic opportunities
- Utilization of CDK 4/6 inhibitors changed the face of care for HR+ / HER2-metastatic breast cancer
- Worldwide sales of \$6B in 2020



Narazaciclib has Demonstrated Differentiation in Preclinical Studies

Potential to be used where other CDK4/6 inhibitors have failed

Active in numerous tumor types in preclinical results with acceptable and differentiated safety profile

· Narazaciclib causes less myelosuppression and, thus less neutropenia

A potent inhibitor of CSF1R

- CSF1 promotes the infiltration of immunosuppressive Tumor-Associated Macrophages (TAMs), which support tumor
 progression
- Blockade of CSF1R or inhibition of its kinase activity promote antitumor immunologic effects

Inhibits ARK 5/NUAK1

 ARK 5/NUAK1 overexpression is found in multiple tumors and is associated with poor prognosis in metastatic breast cancer, multiple myeloma, and hepatocellular carcinoma

Demonstrated BBB penetration in non-human primates

BBB: Blood Brain Barrier. CSF1R: Cancer Res 2006; 66: (8). April 15, 2006, J Med Chem. 2014 Feb 13;57(3):578-99. ARF5/NUAK1: Cancer Res (2016) 76 (5): 1225–1236 and BBB: data on file

Recurrent Metastatic Low-grade Endometrioid Endometrial Cancer (LGEEC) is an Area of High Unmet Need

Improved treatment options are needed for patients failing first-line therapy

Endometrial Cancer

arises in the uterine lining and is the most common cancer of the female reproductive organs

Estimated U.S. peak sales potential of \$240MM¹

Positive Published Data with CDK 4/6 agents

suggest a clinical program evaluating narazaciclib + letrozole in LGEEC is worth pursuing

Narazaciclib Phase 1 Study (19-01)

Phase 1, Dose Escalation/Dose Finding (MTD/RP2D), Safety, Tolerability, PK, PD; Dose Expansion; 3+3 design

Completed Cohort 6 (240 mg/day); N=6 patients; 1 DLT (Gr 3 uveitis); SMC meeting \rightarrow proceed to next cohort

Total of 2 patients with uveitis: Gr 3, Non-SAE, related, resolved with treatment

With 2 DLTs in last 2 cohorts leads to believe we are near MTD for Narazaciclib monotherapy

Preliminary evidence suggesting target engagement at 200 mg/day: decreased neutrophils, Thymidine Kinase 1 activity decrease



Narazaciclib Phase 1: Study 19-01 Single Agent in Solid Tumors

Cohort 6 – 240mg; Pharmacodynamic DiviTum[®] (TKa) assay

Decreased TK1 levels suggest target engagement

VISIT	001-015	001-016	001-017	002-015	002-017	005-009
Tumor type	Ovarian	Oropharynx SCC	Pancreatic	NSCLC	SCC	LGSOC
Screening (Day -14 to -1)	82	79	82	155	126	79
Cycle 1 Day 1	70	54	73	129	152	85
Cycle 1 Day 8	<50	52	52	59	79	<50
Cycle 1 Day 15	<50	51	55	66	<50	<50
Cycle 1 Day 22	67	57	64		<50	<50
Cycle 2 Day 1	57	<50			55	<50
Cycle 3 Day 1					151	
Cycle 4 Day 1					209	
End of Treatment	336			163		
Status	PD	Ongoing	Ongoing	DLT	Ongoing	Ongoing
A DiviTies [®] TKp score <250 DoA provides a reach lower risk of progres bookies and for all time internals. (Berggivist M, et al. Thymatine kinas	uion within 30/60 days after blood draw a activity levels in serum can identify HB+	, the negative predictive value (NPV) was 96.2% and 93 measatatic benast cencer patients with a low risk of early	.5%, respectively, Patienti <250 DzA exper progression (SWOG 50226), <u>Biomorkers Jo</u>	ienced significantly langer progression-free so many 2023)	rvival and overall servival, demonstrated at	TRAWS PHARM

In Vitro Multi-Kinase Activity with nM Potency for the CDK Family and Other High Potential Kinase Targets*

Reaction Biology 2021; Data on file. *Note that kinase activity is based on IC_{50} values, a quantitative measure indicating the concentration needed to inhibit the listed kinase by 50%

	Narazaciclib	Palbociclib	Ribociclib	Abemaciclib
Sponsor	Onconova	Pfizer	Novartis	Lilly
CDK Family				
CDK4/cyclin D1	2	2	3	0.8
CDK6/cyclin D1	0.6	0.8	6.0	0.6
CDK1/cyclin A	2190	>10,000	>10,000	270
CDK2/cyclin E	69	2300	>10,000	130
CDK9/T1	48	630	390	7
Other Kinases				
CSF1R	0.7	>10,000	>10,000	>10,000
ARK 5/NUAK 1	5	1,400	1,540	773
FLT3	6.0	496	753	72

Colony-Stimulating Factor-1 Antibody Reverses Chemoresistance in Human MCF-7 Breast Cancer Xenografts



Preclinical Results Show Reduced Neutropenia with Narazaciclib (ON123300) Compared to Palbociclib



30 Xenograft = MDA MB 435. (AACR; Cancer Res 2017; 77 (13 Suppl): Abstract nr 2172)

Narazaciclib Inhibits Growth of Palbociclib Resistant Cancer Cell Lines





Rigosertib identified as lead PLK1 inhibitor in RDEB cSCC



Clin Cancer Res March 7 2019 DOI:10.1158/1078-0432.CCR-18-2661. PMID: 30846478

Rigosertib's Promising Single-agent Activity in RDEB-associated SCC

Complete remission of all cancerous skin lesions in 2 of 2 evaluable participants



RDEB: Recessive dystrophic epidermolysis bullosa; SCC: Squamous cell carcinoma; Source: Laimer et al. Austrian Society of Dermatology and Venerology Annual Conference 2021



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