

July 30, 2024

VIA EDGAR

U.S. Securities and Exchange Commission  
Division of Corporation Finance  
Office of Life Sciences  
100 F Street, NE.  
Washington, D.C. 20549  
Attention: Doris Stacey Gama and Laura Crotty

**Re: Traws Pharma, Inc.  
Preliminary Proxy Statement on Schedule 14A  
Filed June 27, 2024  
File No. 000-36020**

Ladies and Gentlemen:

Set forth below are the responses of Traws Pharma, Inc. (“we” or the “Company”) to comments received from the staff of the Division of Corporation Finance (the “Staff”) of the U.S. Securities and Exchange Commission (the “Commission”) by letter dated July 24, 2024, with respect to the Preliminary Proxy Statement on Schedule 14A (the “Proxy Statement”). For your convenience, we have restated the Staff’s comments from the July 24, 2024 letter below in their entirety in bold font, followed by the corresponding responses from the Company.

**Preliminary Proxy Statement on Schedule 14A**

**Description of the Transactions**

**Acquisition of Trawsfynydd, page 11**

- 1. Please revise this section, where appropriate, to disclose the operating plan for the business in the near term as well as the intended uses of the proceeds raised through the merger and concurrent financing. State the principal purposes and the approximate amount intended to be used for each such purpose.**

Response: In response to the Staff’s comment, the Company proposes to revise the section referenced above to now state:

“The Company expects to use the proceeds from the Financing, along with the Company’s existing cash before the Transactions, as follows:

- Approximately \$6 million for the completion of the Phase 1 clinical trial in Australia of TRX100;
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- Approximately \$6 million for the completion of the Phase 1 clinical trial in Australia of TRX01;
- Approximately \$3 million for two investigator-initiated studies in the United States of narazaciclib; and
- Approximately \$1 million for the ongoing development of rigosertib.”

2. **You state that in connection with the merger you issued non-transferrable contingent value rights (CVRs) to your stockholders of record as of the close of business of April 15, 2024 who will be entitled to receive certain stock and/or cash payments from proceeds received by you, if any, related to the disposition or monetization of your legacy assets. Please identify the legacy assets referenced, as you do on page 16, and discuss any plan to dispose of or monetize each asset.**

Response: In response to the Staff’s comment, the Company proposes to revise the section referenced above to now state:

“Following the transaction, the Company will primarily pursue the development of four compounds that are all at the clinical stage. Two compounds represent the assets that were acquired from Trawsfynydd in the Merger: tivoxavir marboxil (TRX100) and ratutrelvir (TRX01); and two compounds are legacy assets from the Company: narazaciclib and rigosertib.”

3. **We note you discuss the merger consideration that was issued and delivered by the company to stockholders of Trawsfynydd. Please also include a discussion, where appropriate, to identify all assets acquired by you from Trawsfynydd as part of the acquisition. In this regard, we note you plan to advance development of tivoxavir marboxil (TRX100) and ratutrelvir (TRX01), which were acquired as part of the merger.**

Response: In response to the Staff’s comment, the Company proposes to revise the section referenced above to now state:

“Following the transaction, the Company will primarily pursue the development of four compounds that are all at the clinical stage. Two compounds represent the assets that were acquired from Trawsfynydd in the Merger: tivoxavir marboxil (TRX100) and ratutrelvir (TRX01); and two compounds are legacy assets from the Company: narazaciclib and rigosertib.”

**Opinion of Onconova Therapeutics, Inc.’s Financial Advisor, page 25**

4. **We note that Onconova Therapeutics, Inc. retained H.C. Wainwright & Co. to render an opinion to the Onconova board of directors as to the fairness, from a financial point of view, to Onconova of the exchange ratio pursuant to the merger agreement. Please include, where appropriate, any conclusions Wainwright & Co. reached as to the exchange ratio.**

Response: In response to the Staff’s comment, the Company proposes to revise the section referenced above to include the following disclosure:

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“Based upon and subject to the assumptions, factors, qualifications and limitations set forth in the written opinion described herein and the results of the application by Wainwright of each of the valuation methodologies utilized in connection with its fairness opinion as summarized above, taken as a whole, Wainwright concluded that the Exchange Ratio was fair, from a financial point of view, to Onconova.”

**Description of Business**

**Our Portfolio/Product Candidates/Compounds, page 38**

5. We note the following statements in relation to tivoxavir marboxil and ratutrelvir, both of which were acquired in the merger:

- “Tivoxavir marboxil has completed a first Phase 1 study that generally demonstrated safety and tolerability in healthy volunteers.”
- “We believe ratutrelvir may be effective against the original, delta, and omicron variants of SARS-CoV-2, with potentially superior properties to nirmatrelvir (Pfizer’s Mpro inhibitor, PAXLOVID™).”

Please revise these statements to remove the implications of safety and efficacy, as such determinations are within the sole purview of the FDA. You may present clinical trial end points and objective data resulting from trials without concluding safety and efficacy, and you may state that your product candidates are well tolerated, if accurate. In addition, to the extent head-to-head trials have not been conducted, please remove comparisons to other approved products.

Response: In response to the Staff’s comment, those statements have been removed.

6. You state that you have completed a first Phase 1 study of tivoxavir marboxil that also provided pharmacokinetics and pharmacodynamics data. Please expand your description of this trial to provide specific details, parameters and results, including, to the extent applicable:

- dates of the trial and location(s);
  - identity of trial sponsor(s);
  - trial design;
  - patient information (e.g., number of patients enrolled and treated and the criteria for participation in the study);
  - duration of treatment and dosage information;
  - primary and secondary endpoints; and
  - discussion of results, including adverse events and serious adverse events, if any.
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Response: In response to the Staff's comment, the Company proposes to revise the section referenced above to include the following disclosure:

"The first-in-man clinical study of TRX100 (designated AV5124 in a previous study) was performed from May to September of 2023 in Russia. The study sponsor was Pharmasynitez, JSC. Traws Pharma has the right to use the data resulting from the study outside of Russia and the Eurasian Economic Community countries. The trial was a single ascending dose study, and, as such, each study participant only received one dose of TRX100. The study consisted of four dose cohorts that received 20, 40, 80 or 120 mg TRX100 delivered as 20 mg strength tablets, or placebo. The study enrolled 28 healthy males ages 18-45 years who received either the study drug or placebo. The primary study endpoint was measurement of the safety and tolerability of single drug doses in healthy volunteers. The secondary endpoint was the measurement of pharmacokinetic parameters of single drug doses in healthy volunteers on an empty stomach or after a meal. The study demonstrated a favorable safety profile for TRX100, with only one subject, that had received a single 40 mg dose of the study drug, experiencing two adverse events (AEs). This subject experienced hyperglycemia, which was deemed to be mild and we believe probably related to TRX100 and erosive gastritis with complications in the form of severe iron deficiency anemia which was considered to be a serious adverse event (SAE) and we believe unlikely to be related (doubtful per the protocol) to the study drug. There were no other AEs in the trial, including at higher doses. The pharmacokinetic measurements indicated a food effect for TRX100, with increased exposure when drug was taken after a meal, but otherwise showed increasing exposure with increasing dose."

7. **We note your statement that trivoxavir marboxil is a "cap-dependent endonuclease inhibitor" intended to inhibit influenza virus replications. We also note your disclosure that ratutrelvir is an "Mpro protease inhibitor" intended for the treatment of COVID19. Where appropriate, please explain "cap-dependent endonuclease inhibitors" and "Mpro protease inhibitors" in plain English.**

Response: In response to the Staff's comment, the Company proposes to revise the language referenced above to now state:

"**Tivoxavir marboxil (TRX100)**, which we acquired as part of the Merger, is a small molecule cap-dependent endonuclease inhibitor. Cap-dependent endonuclease (CEN) is an enzyme that is important for viral replication. TRX100 is intended to inhibit CEN and, thus, is intended to impede influenza virus replication including, the influenza A and B viral strains and bird flu viral strains. It is Traws Pharma's intention to develop TRX100 as a single oral dose for treatment and prophylaxis of seasonal influenza and bird flu."

"**Ratutrelvir (TRX01)**, which we acquired as part of the Merger and is an inhibitor of the main protease (also known as 3CL protease) of the SAR-CoV-2 virus, the virus that causes COVID19. The main protease is an essential component in the mechanism for SARS-CoV-2 replication. TRX01 is intended to inhibit this protease and, thus SAR-CoV-2 viral replication."

8. **You state that you plan to develop Ratutrelvir (TRX01) which does not require co-administration with a human cytochrome P450 (CYP) inhibitor such as ritonavir, avoiding potential significant drug-on-drug interactions, with the opportunity to expand the number of eligible patients. Please discuss the basis for such claims and if you have conducted any studies or clinical trials to date.**
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Response: In response to the Staff's comment, the Company proposes to revise the section referenced above to include the following disclosure:

“Based on preclinical animal studies, we intend to develop TRX01 without co-administration with a human cytochrome P450 (CYP) inhibitor such as ritonavir.”

**Information Incorporated by Reference, page 58**

9. **The pro forma financial information included as Exhibit 99.3 to your amended Form 8-K dated June 17, 2024 indicates that Traws Pharma was determined to be the accounting acquirer in the share exchange agreement with Trawsfynydd and that the merger was accounted for as an asset acquisition as the primary assets acquired consisted of cash and in-process research and development (IPR&D) and the assets acquired did not include any processes, such as an organized workforce. Please provide us with a detailed analysis explaining how you determined the accounting acquirer in this transaction, considering the guidance in ASC 805-10-55-10 through 55-15. In this regard, your disclosure on page 26 indicates that the stockholders of Trawsfynydd immediately prior to the merger will own 75.3% of the outstanding equity of Traws Pharma (formerly Onconova) on a fully diluted basis immediately following the closing and after giving effect to the concurrent financing transaction. Further, the inclusion of contingent value rights (CVRs) in the transaction raises the question as to whether you plan to dispose of or monetize your legacy assets. Please explain how this factored into your analysis.**

Response: The Company acknowledges the Staff's comment and respectfully advises the Staff that it concluded that Trawsfynydd is a Variable Interest Entity (“VIE”) and the Company is the primary beneficiary. Under paragraph 805-10-25-5, the primary beneficiary is always the accounting acquirer. As such, the factors within ASC 805-10-55-11 through 55-15 were not relevant to the determination.

The Company concluded that Trawsfynydd is a VIE because it has insufficient equity at risk. ASC 810-10-15-14(a) indicates that an entity is a VIE if its total equity at risk is insufficient for it to finance its activities without additional subordinated financial support. The Company evaluated whether Trawsfynydd had sufficient equity at risk by assessing whether it could fund its operations to the next development stage without obtaining additional subordinated financial support. In reaching this conclusion, the Company considered the current stage of development for Trawsfynydd's two main programs, Tivoxavir marboxil (“TRX100”) and Raturelvir (“TRX01”).

- TRX100 will be a Phase 2 ready asset after the Company completes a Phase 1 dose extension to evaluate additional, higher doses of TRX100 prior to the initiation of a Phase 2 study which cannot be commenced until additional capital is raised. Completion of the Phase 2 study is estimated to occur in 2025 with estimated costs of \$24.5 million.
  - TRX01 is a Phase 1 asset to which the Company plans to complete a Phase 2 study in 2025 with estimated costs of \$16.0 million.
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Prior to the Merger, Trawsfynydd had less than \$100,000 of cash available to fund its two main programs which are estimated to require an aggregate of \$40.5 million in funding to complete each product candidate's Phase 2 stage of development. Further, the Company has disclosed that it has sufficient liquidity to fund ongoing clinical trials and business operations into the fourth quarter of 2024. The existing funding required for the Trawsfynydd products require funding beyond the current fourth quarter of fiscal 2024.

After determining that Trawsfynydd is a VIE, the primary beneficiary was identified in accordance with ASC 810-10-25-38A. The Company holds a variable interest in Trawsfynydd as it owns 100% of Trawsfynydd's equity post-merger. The Company also has the obligation to absorb the losses from the continued development of the Trawsfynydd programs, the power to direct the activities that could potentially be significant to Trawsfynydd and the right to receive all benefits of Trawsfynydd in the future. Therefore, the Company is considered the primary beneficiary and, for accounting purposes, the Company is considered to be the acquirer of Trawsfynydd in the business combination.

In addition, the Company respectfully advises the staff that the nature of the Contingent Value Rights ("CVRs") are protective in nature to the legacy stockholders of Traws Pharma, Inc. (formerly Onconova) in the event the continuing company elects to cease development of the legacy oncology assets (which is not the continuing company's current intention). Each CVR entitles the holder to distributions from any net proceeds associated with the sale, license or disposition of Rigosertib or Narazaciclib and the right to receive distributions in the form of a single digit royalty rate on future net sales for Rigosertib or Narazaciclib, if any. The continuing company's future development efforts are inclusive of both its virology programs acquired from Trawsfynydd and the legacy oncology programs of Traws Pharma, Inc. (formerly Onconova). This is further evidenced by the Company's disclosures of its current pipeline that can be found on its website and within its most recent 10-Q filing for the quarter ended March 31, 2024 to which the Company describes itself as a clinical stage biopharmaceutical company aiming to address unmet medical needs in respiratory viral diseases and cancer. Additionally, as stated in the Background and Reasons for the Transaction and The Board of Directors Reasons for Approval of the Transactions within the Company's preliminary proxy statement, the Company sought to identify potentially synergistic businesses and believed that the continuing company would have greater financial resources and additional funding opportunities to fund the near term development of its anti-viral and oncology product candidates.

If you require any additional information on these issues, or if we can provide you with any other information that will facilitate your review, please contact me at 617-610-4711.

Sincerely,

**/s/ Werner Cautreels**

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Werner Cautreels  
Chief Executive Officer

Cc: Joanne R. Soslow

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