UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark one)

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

For the fiscal year ended December 31, 2025

Or

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

For the transition period from to

Commission file number 001-36020

Traws Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**22-3627252**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
12 Penns Trail, Newtown, PA	**18940**
(Address of principal executive offices)	(Zip Code)

(267) 759-3680

(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer,", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates was approximately $9.8 million, based on the last reported sale price of the registrant's common stock on the Nasdaq Capital Market.

There were 10,157,257 shares of Common Stock outstanding as of April 13, 2026.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's 2026 annual meeting of stockholders to be filed within 120 days after the end of the period covered by this annual report on Form 10-K are incorporated by reference into Part III of this annual report on Form 10-K.

TRAWS PHARMA, INC.
INDEX TO REPORT ON FORM 10-K

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K ("Annual Report") includes forward-looking statements. We may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements appear in a number of places throughout this Annual Report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the implementation of our business model and strategic plans for our business, our ongoing and planned preclinical development and clinical trials, our interactions with the U.S. Food and Drug Administration ("FDA") and similar foreign authorities, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, protection of our intellectual property portfolio, the degree of clinical utility of our products, particularly in specific patient populations, our ability to develop commercial and manufacturing functions, expectations regarding clinical trial data, our results of operations, cash needs, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Annual Report.

You should also read carefully the factors described in the "Risk Factors" section of this Annual Report and elsewhere to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this Annual Report and you should not place undue reliance on any forward-looking statements. These factors include, without limitations, the risks related to:

- our need for additional financing for our future clinical trials and other operations, our ability to obtain sufficient funds on acceptable terms when needed, and our plans and future needs to scale back operations if adequate financing is not obtained;
- our ability to continue as a going concern;
- our ability to achieve the expected benefits or opportunities, and related timing thereof, with respect to the Merger (as defined below) or to monetize any of our legacy assets;
- any future payouts under the contingent value right ("CVR") issued to our holders of record as of the close of business on December 31, 2025;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the success and timing of our preclinical studies and clinical trials, including without limitation site initiation and patient enrollment, and regulatory approval of protocols for future clinical trials;
- our ability to enter into, maintain and perform collaboration agreements with other biotechnology or pharmaceutical companies, for funding and commercialization of our clinical drug product candidates or preclinical compounds, and our ability to achieve certain milestones under those agreements;
- the difficulties in obtaining and maintaining regulatory approval of our product candidates, and the labeling under any approval we may obtain;

- our plans and ability to develop, manufacture and commercialize our product candidates;
- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- the potential for cuts in federal funding;
- recently enacted and future legislation and regulation regarding the healthcare system;
- the success of competing therapies and products that are or may become available;
- our ability to maintain the listing of our securities on a national securities exchange;
- the potential for third party disputes and litigation;
- the performance of third parties, including contract research organizations ("CROs") and third-party manufacturers; and
- the effects of market volatility and macroeconomic factors on our business, our partners and our suppliers.

Any forward-looking statements that we make in this Annual Report speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report or to reflect the occurrence of unanticipated events.

PART I

ITEM 1. *BUSINESS*

Overview

Traws Pharma, Inc. ("Traws," "we," or the "Company") is a clinical stage biopharmaceutical company dedicated to developing novel therapies to target critical threats to human health in respiratory viral diseases. We are advancing novel investigational antiviral agents that have potent activity against difficult to treat or resistant virus strains that threaten human health. Our product candidates are intended to be safe, with simple dosing regimens. We strive to utilize accelerated clinical trial strategies with a commitment to patients who are especially vulnerable.

On April 1, 2024, the Company (then known as Onconova Therapeutics, Inc.) consummated a merger (the "Merger") with Trawsfynydd Therapeutics, Inc. ("Trawsfynydd"), a privately-held biotechnology company developing next-generation, best-in-class antivirals for influenza, COVID-19 and other infectious diseases. Prior to the Merger, the focus of our business was the discovery and development of novel products for patients with cancer. After completion of the Merger, the focus of our business expanded to include the development of novel therapies to target critical threats to human health in respiratory viral diseases. Following the Merger, we have four clinical programs: (i) tivoxavir marboxil, an investigational oral, small molecule CAP-dependent endonuclease inhibitor designed to be administered as a single-dose for the treatment of bird flu and seasonal influenza; (ii) ratutrelvir, an inhibitor of the main protease (also known as 3CL protease) of the SAR-CoV-2 virus, the causative agent in COVID-19; (iii) narazaciclib (ON 123300), a multi-targeted kinase inhibitor in solid tumors and hematological malignancies as a single agent or in combination with other anti-cancer therapies; and (iv) rigosertib, administered alone or in combination for investigation in various cancers. Each of these programs is discussed in additional detail, below.

Product Candidates / Compounds

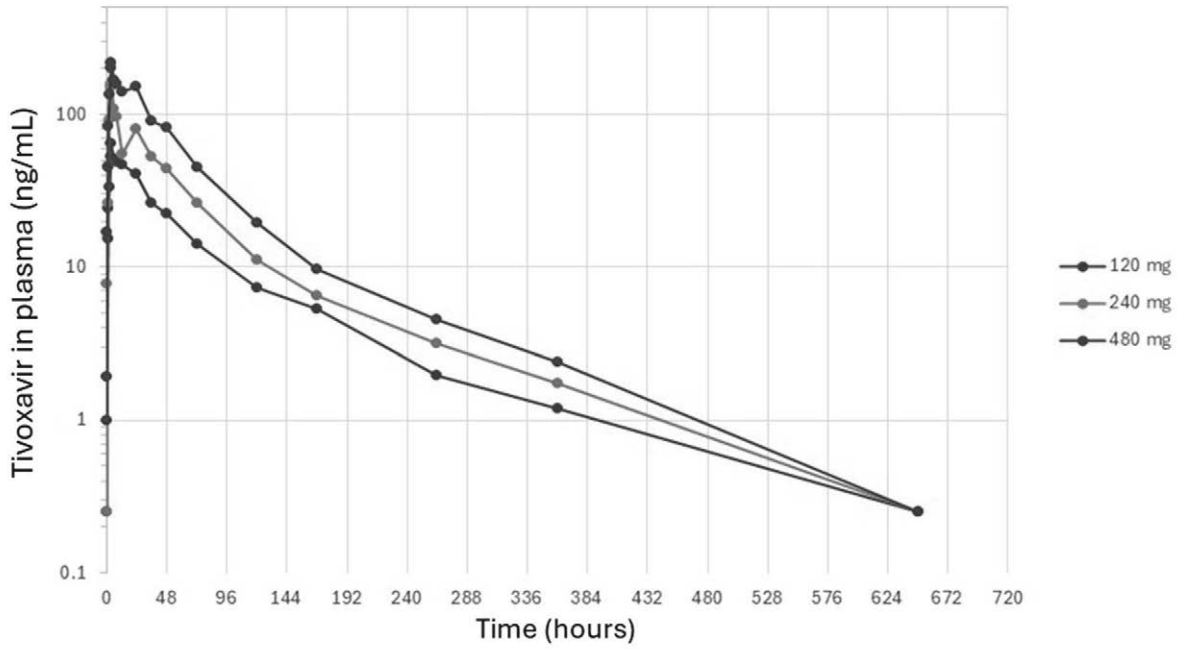
Tivoxavir marboxil — Small Molecule Cap- Dependent Endonuclease Inhibitor

Tivoxavir marboxil, is a small molecule cap-dependent endonuclease inhibitor. Cap-dependent endonuclease ("CEN") is an enzyme that is important for influenza virus replication. Tivoxavir marboxil is intended to inhibit CEN and, thus, is intended to impede influenza virus replication including, the influenza A or B viral strains and bird flu viral strains. It is our intention to develop tivoxavir marboxil as an oral dose given only once for potential treatment and prophylaxis of bird flu and seasonal influenza.

The first-in-man clinical study of tivoxavir marboxil (designated AV5124 in a previous study) was performed from May to September of 2023 in Russia. The study sponsor was Pharmasyntez, JSC. We have 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 tivoxavir marboxil. The study consisted of four dose cohorts that received 20, 40, 80 or 120 mg tivoxavir marboxil 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. In the study, one subject who received a single 40 mg dose of the study drug, experienced two adverse events ("AEs"). This subject experienced hyperglycemia, which was deemed to be mild and believed probably related to tivoxavir marboxil, and erosive gastritis with complications in the form of severe iron deficiency anemia, which was considered to be a serious adverse event ("SAE") believed 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 small food effect for tivoxavir marboxil, with increased exposure when drug was taken after a meal but otherwise showed increasing exposure with increasing dose.

We advanced the development of tivoxavir marboxil with a Traws Pharma sponsored Phase 1 randomized, blinded, and placebo-controlled study in Australia that was approved by the Human Research Ethics Committee. The study

enrolled four cohorts of 8 participants, with 6 participants randomized to receive study drug and 2 participants assigned to receive placebo in each cohort. Participants were required to be healthy males or females ages 18-64 years. Participants took either one dose of the study drug or one dose of placebo, depending on the assigned group. The evaluated dose levels included 80, 120, 240, and 480 mg administered orally in capsule form. The primary endpoints of the study were safety and tolerability; the secondary and other endpoints included determination of a drug pharmacokinetic profile. The study enrolled healthy volunteers, adults 18-64 years old, into 4 cohorts. Topline data showed good overall tolerability and a pharmacokinetic profile. Sixteen AEs were recorded, of which three were possibly related to study drug during the study; all were mild headaches and resolved without treatment. Topline data from this study showed that a single dose of tivoxavir marboxil maintained detectable plasma drug levels for 23 days. Results from the Phase I studies support further investigation into tivoxavir marboxil as a one-time treatment for influenza and development of tivoxavir marboxil as a once-monthly oral drug for influenza prevention



Preclinical efficacy in bird flu models

During 2025, we reported additional preclinical data evaluating TXM in animal model studies using an H5N1 virus (A/Texas/37/2024) isolated from a Texas dairy worker. In mice, ferrets and nonhuman primates, TXM treatment of infected animals significantly reduced disease progression, prevented body weight loss, and increased survival. Lung virus burdens were dramatically lower among treated compared to control animals and histology confirmed the capacity for treatment to preserve lung structure and function. Oral TXM was an effective treatment for this highly virulent A/H5N1 bird flu and should be a consideration for pandemic influenza preparedness and inclusion in the United States Strategic Stockpile.

Regulatory interactions and development strategy

In 2025, we advanced regulatory interactions with the FDA to align on a path forward for tivoxavir marboxil, including the potential applicability of accelerated development approaches for bird flu. We submitted a meeting request and briefing materials to the FDA and received written responses to questions submitted for a Type B pre-Investigational New Drug Application ("pre-IND") interaction. We subsequently submitted additional briefing materials to enable further FDA dialogue ("Type D") on potential paths to approval for bird flu and seasonal influenza. Based on these interactions, and as reflected in our subsequent disclosures, the FDA affirmed its position that clinical trial data (rather than reliance on the "Animal Rule," which allows for approval of therapeutic interventions in cases where there is a risk of severe disease and a controlled human trial would be unethical or infeasible) is the registrational path for bird flu

therapeutics. Accordingly, while we prepared a proposed Phase 2 dose-ranging, non-inferiority seasonal influenza study (including a comparator arm versus XOFLUZA®) with a separate single arm intended to evaluate tivoxavir marboxil in H5N1 bird flu-infected subjects and submitted the protocol for Human Research Ethics Committee ("HREC") review, we determined to defer initiation of the combined seasonal/bird flu Phase 2 study at that time due to the low immediate likelihood of successfully recruiting bird flu-infected subjects. In the meantime, we have disclosed that approvals obtained from Australian and South Korean regulatory authorities for our Phase 2 protocol may allow us to initiate a clinical study more rapidly in either the Southern or Northern Hemispheres, respectively, should epidemiology and feasibility improve.

Stockpiling / preparedness initiatives and subsequent events

During 2025, we also reported plans to pursue stockpiling and pandemic preparedness initiatives and initiated dialogue with relevant U.S. government stakeholders, including BARDA. Subsequent to year-end, in January 2026, we announced the filing of a U.S. IND application for TXM for influenza therapy, which we described as an important step toward formal consideration by BARDA for inclusion in the strategic stockpile. Also in January 2026, we announced plans to progress an additional indication for TXM as a monthly oral tablet for prophylaxis of seasonal influenza, supported by Phase 1 exposure observations from an earlier capsule formulation and formulation work indicating that a compressed tablet may provide extended coverage; we also announced that a time slot was secured for a human influenza prophylaxis human challenge trial targeted for June 2026, contingent on completion of a planned bridging healthy volunteer study. Separately, FDA informed the Company that its US IND for tivoxavir marboxil was being placed on clinical hold due to concerns with the toxicology data package. The Company is actively engaging with the FDA to address the clinical hold and is working to develop and submit a comprehensive response, with the goal of resolving the hold and advancing the program in the US during fiscal year 2027.

We intend to use the combined clinical, preclinical, regulatory feedback and manufacturing/formulation work to inform the next stages of tivoxavir marboxil development, including the design and timing of future clinical studies and engagement with regulatory authorities and preparedness agencies. Our plans remain subject to, among other things, feasibility of enrollment (including incidence of bird flu infections in humans), regulatory feedback, manufacturing readiness, and availability of capital.

Outlook

We intend to prioritize development of TXM as a once-monthly oral prophylactic agent for influenza prevention, and to continue development of TXM as a potential single-dose oral therapy for seasonal influenza or H5N1 bird flu and to advance the program in a manner consistent with regulatory feedback andavailable resources. We note that TXM is generally active against all influenza A and B strains and should be effective against A/H5N1 and other highly virulent avian influenzas that may arise. AS an important step in the development of influenza prevention, we plan to conduct an influenza single-dose virus human challenge trial in the UK wherein subjects receive an oral dose of TXM up to 28 days before an intentional exposure to influenza and the degree of protection is measured. Subject to approval from the United Kingdom's Medicines and Healthcare products Regulatory Agency ("MHRA"), the influenza virus challenge will commence thereafter.

Ratutrelvir — Small Molecule - 3CL Protease Inhibitor

Ratutrelvir (TRX01) is an inhibitor of the main protease (Mpro, also known as 3CL protease) of SAR-CoV-2 coronavirus, the causative agent in COVID-19. The main protease is an essential component in SARS-CoV-2 replication. Ratutrelvir inhibits Mpro and reduces SARS-CoV-2 virus replication. *In vitro* laboratory tests confirmed the impact of ratutrelvir on SARS-CoV-2 replication, including the original SARS-CoV-2 isolates, and variants in the delta and omicron groups. An animal study using the widely adopted K18 transgenic mouse model, demonstrated non-inferiority between ratutrelvir and the combination of nirmatrelvir + ritonavir, in terms of time to death and lung virus burden in this highly lethal model with neurological manifestations. Based on preclinical pharmacokinetic studies in multiple animal species, we intend to develop ratutrelvir for use without co-administration of a human cytochrome P450 ("CYP") inhibitor such as ritonavir.

Ratutrelvir was studied in a Phase 1 clinical trial that included single and multiple ascending dose phases. Participants were required to be healthy males or females ages 18-64 years. The primary endpoint of the study was the measurement of safety and tolerability, and the secondary endpoint included the determination of the drug pharmacokinetic and pharmacodynamic profiles. The Phase 1 trial was conducted in Australia. It was sponsored by the Company and was approved by the Human Research Ethics Committee. The trial administered either the study drug or placebo to 40 participants in the single ascending dose phase, which included 5 cohorts with 8 participants in each cohort (6 received study drug and two received placebo). Subjects in the single ascending dose phase received one oral dose of the study drug or placebo, depending on their assigned group. The single ascending dose portion of the study assessed oral ratutrelvir at 15, 50, 150, 300 and 600 mg doses. Subjects in the multiple ascending dose phase received a daily single oral dose of 150 mg or 600 mg (6 active and 2 placebo) for 10 consecutive days. The study was completed in September 2024. There were few recorded adverse events reported up to the highest dose, and none were determined to be related to study drug.

Topline data also showed that once-daily administration of ratutrelvir for 10 consecutive days, maintained plasma drug levels within the predicted therapeutic window for 12 days. In the cohort receiving a single, daily oral dose of 600 mg, the maximum drug levels were approximately 20 times below the exposure limits established during GLP toxicology studies in rats and Beagle dogs. The toxicology studies did not reach the no adverse event limit (NOAEL) after treating animals with up to 1,000 mg/kg. The 24-hour C_{trough} levels were constant for 10 days, at roughly 110 nM total blood drug concentration, which is 13 times the EC_{50} measured in vitro for a collection of omicron strains of SARS-CoV-2. Pharmacodynamic studies confirmed a direct correlation between drug levels in blood and inhibition of the main protease enzyme in vitro.

During 2025, we initiated a multicenter, open-label, randomized Phase 2a clinical study designed to evaluate the safety and efficacy of ratutrelvir in non-hospitalized symptomatic adults with mild-to-moderate COVID-19. Patients deemed eligible for receiving PAXLOVID® were randomized to receive Ratutrelvir, 600 mg daily for 10 days, or Paxlovid twice daily for 5 days. Patients deemed to be ineligible for ritonavir-boosted regimens due to contraindications or clinically significant drug–drug interactions received Ratutrelvir 600 mg daily for 10 days. In January 2026, we completed enrollment in the planned 90-patient Phase 2 study.

In a prespecified interim analysis reported in January 2026 (50 patients evaluated at the time of the analysis), ratutrelvir-treated patients demonstrated a shorter time-to-sustained symptom alleviation and resolution versus the PAXLOVID® comparator, as assessed using the FLU-PRO Plus/COVID-19 Symptoms Diary, and no symptom or virologic rebound events were observed to date in ratutrelvir-treated patients (compared to one rebound event reported in the comparator arm). Ratutrelvir was generally well tolerated in the interim analysis, with fewer reported adverse events than the comparator arm; the most commonly reported adverse event was mild dyspepsia, and no dysgeusia was reported among ratutrelvir-treated patients. Patients ineligible for PAXLOVID® and receiving ratutrelvir demonstrated symptom improvement dynamics and safety observations described as consistent with the broader ratutrelvir-treated cohort.

With enrollment complete, we expect to complete follow-up and finalize analyses from the Phase 2a study, and we intend to use the resulting data to inform next steps for clinical development and regulatory strategy, including potential additional studies designed to further evaluate clinical rebound and longer-term outcomes following SARS-CoV-2 infection.Subsequent to December 31, 2025, we disclosed additional Phase 2 updates. In January 2026, we reported an updated interim analysis indicating that 76 patients had been included (32 treated with ratutrelvir and 18 treated with PAXLOVID®) and that 95% of the planned 90-patient population had been enrolled. In that updated interim analysis, ratutrelvir-treated patients demonstrated a shorter time-to-sustained symptom alleviation and resolution versus PAXLOVID® (12 days vs. 14 days; $p<0.014$), and no COVID-19 symptom or virologic rebound events had been observed to date in ratutrelvir-treated patients (with one rebound event reported in the PAXLOVID® arm).

In February 2026, we announced completion of the clinical analysis of the 90-patient, open-label Phase 2 study of ratutrelvir versus PAXLOVID®, together with a single arm in PAXLOVID®-ineligible subjects. We reported that completed clinical results confirmed a differentiated profile versus PAXLOVID® with fewer adverse events and no viral rebounds and equivalent time to sustained symptom resolution, and that results were recapitulated in PAXLOVID®-ineligible patients. In the PAXLOVID®-ineligible population specifically, we reported fewer treatment-related adverse

events (3 events in 30 subjects; 10%) versus PAXLOVID® (7 events in 30 subjects; 23.3%) and faster symptom resolution compared to PAXLOVID® treatment (HR 1.31; 95% CI 0.78–2.20; p=0.018)

Narazaciclib (ON 123300) — Differentiated Multi-Kinase Inhibitor Targeting CDK4/6

Pursuant to a license agreement with Temple University, dated January 1, 1999, as amended March 21, 2013 (the "Temple Licensing Agreement"), we licensed compounds from Temple University, including our product candidate narazaciclib. Narazaciclib is a multi-targeted kinase inhibitor targeting multiple cyclin-dependent kinases ("CDK's"), AMP-activated protein kinase ("AMPK") related protein kinase 5 ("ARK5"), and colony-stimulating factor 1 receptor ("CSF1R") at low nM concentrations as well as other tyrosine kinases believed to drive tumor cell proliferation, survival and metastasis. As an apoptotic and antiproliferative agent, narazaciclib modulates the levels and activities of regulatory proteins of the cell cycle, including cyclin D1 and inhibits retinoblastoma ("Rb") protein binding. Narazaciclib is believed to inhibit cancer cell growth and suppresses deoxyribonucleic acid ("DNA") synthesis by preventing CDK-mediated G1-S phase transition, followed by tumor cell death by induction of mitochondria-mediated apoptosis. We believe, based on data from preclinical studies, that narazaciclib has the potential to overcome the limitations of the current generation of approved cyclin dependent kinase (CDK) 4/6 inhibitors. The table below depicts the half-maximal in vitro inhibitory concentration (IC_{50}) of narazaciclib palbociclib, ribociclib and abemaciclib. IC_{50} is a quantitative measure indicating the concentration of each drug needed to inhibit, in vitro, these listed kinases by 50%. We believe our CDK inhibitor is differentiated from other agents in the market or in development due to its multi-targeted kinase inhibition profile.

	Narazaciclib	**Palbociclib**	**Ribociclib**	**Abemaciclib**
Sponsor	Traws	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

Source: Reaction Biology 2021

Narazaciclib also inhibits ARK5 ("NUAK1") with a 50% inhibitory concentration (IC50) of 4.95 nM (Report EPR-123300-001 and Reddy 2014) while palbociclib, ribociclib, and abemaciclib do not. ARK5 has been shown to be important in a number of cancer cell regulated survival pathways such as regulating AKT dependent cell survival, cell metabolism through c-MYC activity, tumor cell survival under oxidative stress and tumor cell migration (Faisal, 2020, Lui, 2012, Port, 2018). The combination of CDK and ARK5 inhibitors in the same molecular entity is proposed to have a differentiated effect on cancer cells by simultaneously inhibiting both cell cycle (cytostatic) and cellular metabolism (cytotoxic) pathways through CDK and ARK5, respectively.

Narazaciclib also inhibits CSF1R with IC50 values between 0.7 to 10 nM (Unpublished data and Reddy 2014). The ability of narazaciclib to bind and inhibit CSF1R at low nanomolar values, in both in vitro and cell-based assays suggests that this compound may have an impact in cancers with a dependence on CSF1R signaling.

Unfortunately, several mechanisms of acquired resistance are emerging with the approved CDK4/6 inhibitors leading to progression in patients with HR+/HER2- mBC (Spring, 2019; Knudsen, 2020). Therefore, the unmet medical need supports development of the next (third) generation CDK4/6 inhibitors in advanced HR+/HER- mBC. The inhibitory effect of narazaciclib may provide a therapeutic strategy to optimize efficacy of CDK 4/6 inhibition and

reduce the emergence of resistance and/or provide clinical benefit for patients with progression on palbociclib, ribociclib and/or abemaciclib. Another established driver of resistance to CDK4/6 inhibitors in breast cancer is FGFR1-3.

Cancer cells can also lose Rb function through mutation and become resistant or insensitive to palbociclib. Generally, second generation CDK 4/6 inhibitors agents have not been shown to be suitable for single agent therapy and must typically be used in combination with hormonal therapy in the treatment of HR+/HER2- mBC. In addition, the rate of disease progression that occurs, especially in patients with visceral disease (Hortobagyi 2018), may benefit from the novel inhibitory effects of narazaciclib. This hypothesis needs to be proven in a clinical trial.

We believe narazaciclib has a favorable kinase inhibitory profile in comparison to the approved CDK4/6 inhibitors (palbociclib, ribociclib, and abemaciclib) and may result in both tumorigenic and safety benefits (Perumal, 2016, Divakar, 2016). In addition, the added inhibitory effects of narazaciclib on CSF-1R, and ARK5 is expected to increase the potential of narazaciclib to treat a broader array of cancers such as triple negative breast cancer in combination with chemotherapy and immunotherapy, mantle cell lymphoma in combination with Bruton Tyrosine Kinase ("BTK") inhibitors, relapsed refractory multiple myeloma, and colorectal cancer among others.

In December 2017, we entered into a license and collaboration agreement with HanX Biopharmaceuticals, Inc. ("HanX"), a company focused on development of novel oncology products, for the manufacturing, clinical development, registration and commercialization in China of narazaciclib (the "HanX License Agreement"). Under the terms of the HanX License Agreement, we received an upfront payment, and will receive regulatory and commercial milestone payments, as well as royalties on any future Chinese sales if the drug is approved. The key feature of the 2017 collaboration was that HanX provided all funding required for the Chinese Investigational New Drug Application ("IND"), thereby enabling the studies necessary in order to seek IND approval by the National Medical Products Administration (the "NMPA"), the Chinese equivalent of the FDA. In the fourth quarter of 2019, HanX filed an IND with the NMPA, which was approved on January 6, 2020. We and HanX also intended for these studies underlying the Chinese IND approval, to meet the FDA standards for IND approval. Accordingly, such studies were used by us for an IND filing with the US FDA. In September 2020, a Phase 1 Study with narazaciclib in cancer patients was initiated in China. We maintain global rights to the manufacturing, clinical development, and commercialization of narazaciclib outside of China.

In partnership with HanX, a Phase 1 dose escalation study (Study HX301-I-01) for patients with advanced relapsed/refractory cancer has been initiated in China at three sites and the first patient was enrolled on September 15, 2020. In this study HX301 (narazaciclib) was dosed daily for 21 days followed by 7 days off therapy in each 28-day cycle. This monotherapy study, which is now complete, enrolled a total of 20 patients with solid tumors at doses starting at 40mg daily for 21 of 28 days, which were escalated from 40mg in increments of 40mg up to 200mg. The study is now complete, and the results were presented in abstract form as ASCO in 2024. According to the report, the median age of the patients was 55 years, ranging from 30 to 71. Notably, 15 patients (75%) had metastatic breast cancers. Dose-limiting toxicities ("DLTs") were observed in 2 patients in the 200 mg group. These included a Grade 4 increase in alanine aminotransferase ("ALT") and a Grade 3 decrease in platelet counts with associated epistaxis, both of which resolved after discontinuation of treatment. The most common treatment-related AEs observed were elevated aspartate aminotransferase ("AST") (65.0%), decreased white blood cell count (50%), decreased neutrophil count (50%), elevated ALT (45%), elevated creatine kinase (45%), and elevated creatinine (35%). Additionally, 4 patients experienced Grade 3 or higher treatment-related AEs, including 1 patient in the 160 mg group with Grade 3 elevated γ-glutamyl transferase and alkaline phosphatase, and 3 patients in the 200 mg group with Grade 4 elevated ALT and Grade 3 elevated AST and Dyspepsia, Grade 3 decreased neutrophil and platelet counts, and Grade 3 hyperglycemia. Notably, no AEs led to death. Among the 20 patients evaluable for tumor assessment using RECIST 1.1 by investigators, 4 obtained stable disease, including 2 patients in the 200 mg group, 1 in the 120 mg group, and 1 in the 80 mg group. Furthermore, 1 patient with HR+ breast cancer in the 200 mg group received study drug for over a year (>400 days) and achieved prolonged stable disease for more than 12 months. Another breast cancer patient dosed at 200mg had stable disease lasting more than 6 months. In total, 2 of 3 patients treated with monotherapy at the 200mg dose had stable disease. These are noteworthy early clinical observations, considering that narazaciclib was being administered as a monotherapy in breast cancer patients when in clinical practice this would be combined with anti-estrogen therapy.

Our IND submission to the US FDA was submitted in November 2020 and the FDA Study May Proceed letter was issued in December 2020. Enrollment into the complementary US phase 1 study (Study 19-01) with narazaciclib commenced in May 2021. Study 19-01 was an exploratory Phase 1 clinical trial, conducted in the US, to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of narazaciclib administered orally as escalating daily doses in patients with advanced cancer relapsed or refractory to at least 1 prior line of therapy. In Study 19-01 in the US, narazaciclib was dosed on a continuous daily schedule in 28-day cycles. The study assessed the safety, tolerability, pharmacokinetics and pharmacodynamics of narazaciclib administered orally at increasing doses starting at 40 mg daily for consecutive 28-day cycles in patients with relapsed/refractory advanced cancer. Enrollment in the sixth dose cohort (240 mg orally each day) of the Phase 1 solid tumor study of narazaciclib was completed with one dose limiting toxicity (DLT) observed. The seventh dose cohort (280 mg daily) enrolled 3 patients. In this study, the highest dose tested was 280mg once daily given continuously. This study is now closed to accrual and data analysis is ongoing in preparation for database lock, data analysis and a clinical study report. Based on experience from study 19-01, there were no emergent safety concerns.

The Company initiated a multi-center Phase 1/2a trial evaluating its multi-kinase inhibitor, narazaciclib, in combination with letrozole for the treatment of recurrent metastatic endometrial cancer and other gynecologic malignancies (Study 19-02). Both narazaciclib and letrozole were administered orally in the Phase 1 dose escalation phase. The first patient in this trial was dosed in May 2023 and the initial cohort (160mg) was completed and no DLTs were observed. The 200mg cohort enrolled 6 evaluable subjects but two patients experienced dose limiting toxicities. As a result, the dose of narazaciclib of 160mg once daily in combination with letrozole 2.5mg QD was declared to be the maximum tolerated dose and the recommended Phase 2 dose for women with low grade endometrioid endometrial cancer. This study is now closed to accrual. The database has been locked, and a clinical study report is currently under review.

We believe that the emerging safety profile of narazaciclib is promising and is consistent with what is expected of CDK 4/6 inhibitors, except that the rates of severe neutropenia and diarrhea appear to be lower with narazaciclib in general.

Narazaciclib is also being studied in China by HanX in clinical trials of patients with High-Grade Glioma (Grade III and IV). Four patients have been enrolled to date.

Narazaciclib is our oral CDK4-plus, multi-targeted kinase inhibitor. During 2025, we continued to focus our internal resources on our respiratory antiviral programs and, consistent with that prioritization, narazaciclib was managed as a legacy oncology asset in business development. Our Company-sponsored clinical activities for narazaciclib have been completed and we are not conducting additional Company-sponsored clinical development. Specifically, our Phase 1/2a trial evaluating narazaciclib in combination with letrozole in recurrent/metastatic low-grade endometrioid endometrial cancer is closed to accrual, the database has been locked, and a clinical study report is under review. In addition, the Phase 1 monotherapy study in relapsed/refractory advanced cancers is closed to accrual and data analysis is ongoing.

Our strategic objective for narazaciclib is to establish a development and commercialization partnership (or other strategic transaction) to advance the program. Unless and until such a partnership or transaction is executed, we do not intend to initiate further Company-sponsored development for narazaciclib and expect our activities to be limited primarily to (i) completing analysis and reporting from completed studies, (ii) maintaining intellectual property and other program-enabling documentation, and (iii) supporting business development efforts. Narazaciclib continues to be developed in Greater China under our license agreement with HanX, where development is sponsored by HanX.

Rigosertib as Monotherapy

Recessive dystrophic epidermolysis bullosa (“RDEB”) is an ultra-rare condition with high unmet medical need caused by a lack of type VII collagen protein expression. Type VII collagen protein is responsible for anchoring the skin’s inner layer to its outer layer, and its absence leads to extreme skin fragility and chronic wound formation in RDEB patients. Over time, many of these patients develop squamous cell carcinomas (SCCs) that typically arise in areas of chronic skin wounding and inflammation. Preclinical investigations demonstrated overexpression of polo like kinase 1 (“PLK1”) in RDEB-associated SCC tumor cells. These tumors show a highly aggressive, early metastasizing course,

making them the primary cause of death for these patients, with a cumulative risk of death of 70% and 78.7% by age 45 and 55, respectively (Mellerio, 2016), (Fine, 2016). These neoplasms show limited response rates of mostly short duration to conventional chemo- and radiotherapy as well as targeted therapy with epidermal growth factor and tyrosine kinase inhibitors (Mellerio, 2016), (Stratigos, 2020).

Based on rigosertib's activity as a potent PLK-1 pathway inhibitor (Atanasova, 2019), a Phase 2 open label investigator-initiated program was commenced in patients with advanced/metastatic squamous cell carcinoma associated with recessive dystrophic epidermolysis bullosa ("RDEB-SCC"). The current clinical experience in RDEB SCC is based on the two small phase II, open-label Investigator Sponsored Studies ("ISS") evaluating the anti-tumor activity and safety of oral or IV rigosertib in RDEB patients diagnosed with locally advanced/metastatic SCCs that have failed prior standard of care. These studies were conducted at EB House, Salzburg, Austria (SALK) (EudraCT No.: 2016-003832-19; NCT03786237) and at Thomas Jefferson University, Philadelphia, USA (NCT04177498). Both studies included the use of either IV or oral rigosertib, depending on the clinical need of the patient. This is due to GI obstruction arising as a result of the presence of esophageal strictures complicating oral administration or extreme skin fragility complicating IV administration. It is, therefore, important in these patients that the investigator has both dosing options for the appropriate dosing of their patients. The data presented here are preliminary and may be subject to change.

A total of 5 patients with SCC in the setting of RDEB have been treated with rigosertib to date. These patients had multiple surgical sections and treatments with systemic therapies such as cemiplimab, pembrolizumab and cetuximab, which all failed. Following treatment with rigosertib, there have been 2 complete cutaneous responses in 4 evaluable patients out of the 5 total patients with SCC in the setting of RDEB that were treated with rigosertib. The responses in these patients were durable, lasting 15 months and 16 months, respectively. The third patient had significant tumor shrinkage of the primary lesion, facilitating a successful amputation. Patient four demonstrated some initial tumor shrinkage and stayed on treatment for 6 cycles before being withdrawn due to logistical complications prior to the next scheduled tumor assessment. One patient was not evaluable, and this patient initially completed 2 weeks of oral rigosertib therapy before stopping due to severe stool impaction, likely from opioid-induced constipation, and COVID-19 infection. The patient finished cycle 1 three weeks later, but eventually withdrew during cycle 2 due to inability to take oral medications, abdominal pain from stool impaction, and unwillingness to take IV medication. Results showed that overall rigosertib had an acceptable safety profile.

Although the trial's currently available safety and efficacy data are from only four patients, which may not be representative of a broader patient population, the investigators believe they represent encouraging findings. This is in the backdrop of a well of > 1300 patients who have been treated in other diseases settings to support safety of the product in rigosertib. In addition, the investigators, and we, believe the data generated in preclinical models that suggest rigosertib's activity against PLK1 have now been preliminarily supported in the clinic and suggest that rigosertib may play a role in other more common cancers driven by PLK1.

As we disclosed in December 2021, early preliminary data from this study were presented at the Austrian Society of Dermatology and Venerology Annual Conference 2021, which took place from November 25–27, 2021, and at the World Congress on Rare Skin Diseases which took place in Paris, from June 7-9, 2022. More recently, data was presented at the International Society of Investigative Dermatology ("ISID") International Epidermolysis Bullosa Symposium in Osaka, Japan on May 9, 2023, at the American Society of Clinical Oncology ("ASCO") Annual Meeting in Chicago on June 3, 2023, and at the European Academy of Dermatology and Venereology ("EADV") in Berlin, Germany on October 12, 2023, as well as the SID Society of Investigative Dermatology ("SID") in Dallas, Texas in May 2024, where a poster was presented. There was also a poster presentation and a plenary presentation given by Professor Andrew South at the World Congress of Rare Skin Diseases ("WCRSD") in Paris in June 2024.

Rare Disease Program in "RASopathies"

Preclinical studies with rigosertib are also being conducted in cardiomyopathies which are seen in children with RASopathies such as Noonan Syndrome. Rigosertib normalized and reversed RASopathy-associated hypertrophic cardiomyopathy ("HCM") as well as other syndromic features in Raf1L613V/+ mice. A manuscript has been submitted for publication.

Our near-term activities for rigosertib are expected to be limited primarily to (i) supporting business development efforts to identify a development and commercialization partner, (ii) maintaining program-enabling documentation and intellectual property, and (iii) selectively supporting investigator-initiated activities and scientific dissemination that may facilitate partnering discussions. Our objective for rigosertib is to establish one or more partnerships for further development of the compound, including in RDEB-SCC or other indications.

Research and Development

Since commencing operations, we have dedicated a significant portion of our resources to the development of our clinical-stage product candidates, particularly rigosertib, narazaciclib and, more recently, tivoxavir marboxil and ratutrelvir. We incurred research and development expenses of $12.1 million and $12.8 million during the years ended December 31, 2025 and 2024, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development.

Collaboration and License Agreements

HanX Biopharmaceuticals, Inc. (narazaciclib Agreement)

Under the terms of the HanX License Agreement, we received an upfront payment, and will receive regulatory and commercial milestone payments, as well as royalties on Chinese sales. The key feature of the collaboration is that HanX provides all funding required for Chinese IND enabling studies performed for Chinese health authority IND approval. The Chinese IND was approved in January 2020. We maintain global rights to narazaciclib outside of China.

SymBio Pharmaceuticals Limited

In July 2011, we entered into a license agreement (the "Symbio License Agreement") with SymBio Pharmaceuticals Limited ("Symbio"), as subsequently amended, granting SymBio an exclusive, royalty-bearing license for the development and commercialization of rigosertib in Japan and Korea.

Under the terms of the SymBio License Agreement, we received an upfront payment of $7,500,000. In addition, we could receive regulatory, development and sales-based milestone payments, as well as royalty payments at percentage rates ranging from the mid-teens to 20% based on net sales of rigosertib by SymBio.

Effective April 17, 2025, the Company and Symbio mutually terminated the license agreement originally entered into by and between the parties in 2011. No payments, compensation, reimbursements or settlements shall be due or owed by either party in connection with the termination of the license agreement. As a result, the Company recognized the $2,733,000 of deferred revenue as revenue on April 17, 2025.

Pint International SA

In March 2018, we entered into a License, Development and Commercialization Agreement (the "Pint License Agreement") with Pint International SA (which, together with its affiliate Pint Pharma GmbH, are collectively referred to as "Pint"). Under the terms of the Pint License Agreement, we granted Pint an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product (the "Pint Licensed Product") containing rigosertib in all uses of the Pint Licensed Product in humans in Latin American countries (including Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, French Guiana, British Guiana, Suriname, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela).

Under the terms of the Securities Purchase Agreement (the "Pint SPA") entered into by and between the Company and Pint in connection with the Pint License Agreement, Pint agreed to make an upfront equity investment in the Company at a specified premium to the Company's share price. Pursuant to the Pint SPA, closing of the upfront equity investment occurred on April 4, 2018 and Pint purchased 2,179 shares of common stock for $1,250,000. The total amount of the premium was $319,000 and this amount was allocated to the license.

Pint may terminate the Pint License Agreement in whole (but not in part) at any time upon 45 days' prior written notice. The Pint License Agreement also contains customary provisions for termination by either party in the event of breach of the Pint License Agreement by the other party, subject to a cure period, or bankruptcy of the other party.

Knight Therapeutics, Inc.

In November 2019, we entered into a Distribution, License and Supply Agreement (the "Knight License Agreement") with Knight Therapeutics Inc. ("Knight"). Under the terms of the Knight License Agreement, we granted Knight (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and manufacture any product (the "Knight Licensed Product") containing rigosertib for Canada (and Israel, should Knight exercise its option under the agreement) (the "Knight Territory") and in human uses (the "Knight Licensed Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to commercialize the Knight Licensed Product in the Knight Territory and in the Knight Licensed Field.

Knight has also agreed to obtain from us all of Knight's requirements of the Knight Licensed Products for the Knight Territory, and we have agreed to supply Knight with all of its requirements of the Knight Licensed Products. We may, at our discretion, use the services of a contract manufacturer to manufacture and package the Knight Licensed Products.

In addition, we have granted Knight an exclusive right of first refusal with respect to all or any part of the Knight Territory, to store, market, promote, sell, offer for sale and/or distribute any ROFR Products. As used in the Knight License Agreement, "ROFR Products" means all products other than the Knight Licensed Product that are owned, licensed, or controlled by us as of the effective date of the Knight License Agreement and all improvements thereto.

We are eligible to receive clinical, regulatory, and sale-based milestone payments as well as tiered, double-digit royalties based on net sales in the Knight Territory.

The License Agreement has a term of 15 years from the launch, on a country-by-country basis in the Knight Territory, and contains customary provisions for termination by either party in the event of breach of the Knight License Agreement by the other party (subject to a cure period), bankruptcy of the other party, or challenges to the patents by any sublicensee or assignee.

Specialised Therapeutics Asia Pte. Ltd.

In December 2019, we entered into a Distribution, License and Supply Agreement (the "STA License Agreement") with Specialised Therapeutics Asia Pte. Ltd. ("STA"). Under the terms of the STA License Agreement, we granted STA (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and manufacture any product (the "STA Licensed Product") containing rigosertib for Australia and New Zealand (the "STA Territory") and in human uses (the "STA Licensed Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to commercialize the STA Licensed Product in the STA Territory and in the STA Licensed Field.

STA has also agreed to obtain from us all of its requirements of the STA Licensed Products for the STA Territory, and we have agreed to supply STA with all of its requirements of the STA Licensed Products. We may, at our discretion, use the services of a contract manufacturer to manufacture and package the STA Licensed Products.

We are eligible to receive clinical, regulatory, and sale-based milestone payments as well as tiered, double-digit royalties based on net sales in the STA Territory.

The STA License Agreement has a term of 15 years from the launch, on a country-by-country basis, in the STA Territory and contains customary provisions for termination by either party in the event of breach of the STA License Agreement by the other party (subject to a cure period), bankruptcy of the other party, or challenges to the patents by any sublicensee or assignee.

Intellectual Property

Patents and Proprietary Rights

Virology

License Agreement with Viriom, Inc. regarding Influenza Asset

In January 2023, Trawsfynydd entered into a License Agreement (the "Viriom License Agreement") with Viriom, Inc. ("Viriom"), pursuant to which Trawsfynydd obtained an exclusive, royalty-free, sublicensable, world-wide license to certain Viriom patents, applications, and technical information (collectively, the "Viriom Licensed IP") to make, have made, use, sell, offer for sale and import several classes of novel compounds related to the treatment and prevention of viral diseases, specifically for use of the Viriom Licensed IP in the development of treatment and methods to prevent viral disease in Canada, China, the European Union, Hong Kong, Japan, the United States and all areas covered by PCT applications for the Viriom Licensed IP. As consideration for the license, Trawsfynydd issued Viriom a SAFE for the purchase amount of approximately $13 million, which SAFE was converted into shares of Trawsfynydd stock prior to the Merger. No annual license fees, royalties, or milestone payments are required. Additionally, pursuant to the Viriom License Agreement, Trawsfynydd obtained the right to control prosecution, defense of infringement and enforcement. As a result of the Merger, the rights and obligations of Trawsfynydd under the Viriom License Agreement were transferred to the Company (through its subsidiaries).

Unless terminated earlier pursuant to the agreement, the Viriom License Agreement shall remain in force and effect for the life of the last-to-expire patent included in the Viriom Licensed IP or last-to-be abandoned patent application licensed under the agreement, whichever is later. The Viriom License Agreement can be terminated by either party due to the material breach of either party (subject to a cure period).

As of March 2025, pursuant to the Viriom License Agreement, we exclusively licensed patents and patent applications covering compounds, pharmaceutical compositions, methods of producing such compounds and pharmaceutical compositions, methods and uses of such compounds and pharmaceutical compositions in the prophylaxis or treatment of viral infections in, for example, the United States, Europe, Japan, and China, among others. These licensed patents and patents that may result from currently pending patent applications expire in 2040 before any possible patent term extensions. Patent term extensions may be available, depending on various provisions in the law.

Acquisition of Viriom Patent Assets

On September 9, 2025, the Company entered into an Asset Purchase Agreement with Viriom pursuant to which the Company acquired certain intellectual property assets related to a pyrrolidine antiviral compound program, including issued patents, pending patent applications and related rights (the "Purchased IP"). As a result of this transaction, the Company transitioned from holding certain rights under license to owning the acquired patents and applications outright, thereby strengthening its control over the development, prosecution, defense and enforcement of such intellectual property and eliminating any future dependency on the licensed rights with respect to the acquired assets.

Following the acquisition, the Company continues to hold exclusive rights to additional intellectual property under the Viriom License Agreement that was not included in the Purchased IP. The acquired patents and pending applications, together with the remaining licensed intellectual property, cover compounds, pharmaceutical compositions, methods of manufacture and methods of use for the prophylaxis and treatment of viral infections in multiple jurisdictions, including the United States, Europe, Japan and China. The issued patents and any patents that may result from currently pending patent applications are expected to expire in 2040, prior to any potential patent term extensions. Patent term extensions or adjustments may be available depending on regulatory timelines and applicable law.

Virology COVID-19 Asset

In addition to the Viriom Licensed IP that we have rights to pursuant to the Viriom License Agreement, we own several patent applications covering compounds, pharmaceutical compositions, methods of producing such compounds

and pharmaceutical compositions, methods and uses of such compounds and pharmaceutical compositions for the prevention or treatment of a disease, disorder, or condition associated with coronavirus in, for example, Australia, Eurasia, Europe, Mexico, and the United States, among others. These Company-owned patent applications and patents that may result from currently pending patent applications expire in 2043 before any possible patent term extensions. Patent term extensions may be available, depending on various provisions in the law.

Oncology

Narazaciclib Patents

As of March 2024, we owned or exclusively licensed issued patents and pending patent applications covering composition of matter, formulation and various indications for method-of-use for narazaciclib filed worldwide, including in the United States. The U.S. composition-of-matter patent for narazaciclib expires in 2031. We have also filed new patent applications covering methods of treatment in target indications that are projected to extend to 2042-2043 before any possible patent term extensions. Patent term extensions may be available, depending on various provisions in the law.

Rigosertib Patents

As of March 2024, we owned or exclusively licensed issued patents and pending patent applications covering composition-of-matter, process, formulation and various indications for method-of-use for rigosertib filed worldwide, including in the United States. The U.S. composition-of-matter patent for rigosertib, which we in-licensed pursuant to the license agreement with Temple, currently expires in 2026. The novel formulation patent for rigosertib expires in 2037. We have filed new patent applications covering methods of treatment in target indications that are projected to extend to 2042-2044 before any possible patent term extensions. Patent term extensions may be available, depending on various provisions in the law.

License Agreement with Temple University

In January 1999, we entered into the Temple Licensing Agreement with Temple University ("Temple") to obtain an exclusive, world-wide license to certain Temple patents and technical information to make, have made, use, sell, offer for sale and import several classes of novel compounds.

Under the terms of the Temple Licensing Agreement, we paid Temple a non-refundable up-front payment, and are required to pay annual license maintenance fees, as well as a low single-digit percentage of net sales as a royalty. In addition, we agreed to pay Temple 25% of any consideration received from any sublicensee of the licensed Temple patents and technical information, which does not include any royalties on sales, funds received for research and development or proceeds from any equity or debt investment.

On November 17, 2025, Temple provided notice of termination of the Temple Licensing Agreement, and the agreement subsequently terminated in accordance with its terms. As a result of the termination, we no longer hold rights under the Temple Licensing Agreement and do not expect to undertake further development activities under that agreement. We also do not expect to incur ongoing annual license maintenance fees related to the agreement going forward, subject to any obligations that may have accrued prior to termination.

General Considerations

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify a proprietary position for our product candidates will depend upon our success in obtaining effective patent claims and enforcing those claims once granted.

Our commercial success will depend in part upon not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our product candidates or processes, obtain licenses or cease certain activities. The biotechnology and

pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. If a third party commences a patent infringement action against us, or our collaborators, it could consume significant financial and management resources, regardless of the merit of the claims or the outcome of the litigation.

If an application is timely filed with the Patent and Trademark Office, the term of a patent that covers an FDA-approved drug may be eligible for additional patent term extension, which provides patent term restoration to account for the patent term lost during product development and the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is determined based upon the time from the IND effective date to the full NDA submission date, and the time from NDA submission date and the eventual application approval, as further described below. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those products.

Furthermore, we may be able to obtain extension of patent term by adjustment of the said term under the provisions of 35 U.S.C. **§** 154 if the issue of an original patent is delayed due to the failure of the U.S. Patent and Trademark Office. For example, we have received adjustments of 1,139 days extension to the patent term for the rigosertib composition of matter patent (US 7,598,232), 1,155 days extension for the patent covering the process for making rigosertib (US 8,143,453) and 751 days extension for rigosertib formulation patent (US 8,063,109) under the provisions of 35 U.S.C. §154.

In addition to patents and other licensed intellectual property rights, we rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position. We seek to protect our proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors and consultants, and invention assignment agreements with our employees. We also have agreements requiring assignment of inventions with selected consultants and collaborators. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of technologies that are developed through a relationship with a third party.

Competition

The biotechnology and pharmaceutical industries are highly competitive and subject to rapid and significant technological change. While we believe that our development experience and scientific knowledge provide us with competitive advantages, we face competition from both large and small pharmaceutical and biotechnology companies. There are a number of pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may compete with our products. Many of these companies are multinational pharmaceutical or biotechnology organizations, which are pursuing the development of, or are currently marketing, pharmaceuticals that target the key viruses, oncology indications or cellular pathways on which we are focused.

Many of our competitors have significantly greater financial, technical and human resources than we have. Many of our competitors also have a significant advantage with respect to experience in the discovery and development of product candidates, as well as obtaining FDA and other regulatory approvals of products and the commercialization of those products. We anticipate intense and increasing competition as new drugs enter the market and as more advanced technologies become available. Our success will be based in part on our ability to identify, develop and manage a portfolio of drugs that are safer and more effective than competing products.

There are currently various drugs approved for the treatment of influenza, including without limitation the neuraminidase inhibitors oseltamivir phosphate (Tamiflu), zanamivir (Relenza), and peramivir (Rapivab) anti-influenza drugs, which are sold by Gilead, Glaxo SmithKline (GSK), and BioCryst partners, respectively. Additionally, there is currently one cap-dependent endonuclease ("CEN") inhibitor, baloxavir marboxil (Xofluza), sold by Roche, approved for use in the treatment of influenza. In addition, M2 channel inhibitors, generic drugs include amantadine and

rimantadine, both oral tablets that only inhibit the replication of the influenza virus have generally become ineffective because of significant viral resistance to the approved M2 channel inhibitors, especially in the US. Several companies are developing anti-influenza drugs, including for the treatment of bird flu, at present, including, for example, Cidara and Eradivir. Small chemical classes include neuraminidase inhibitors, M2-channel inhibitors, and RDRP inhibitors, among others. There are also monoclonal, polyclonal, and mixed antibodies, as well as enzymes as drugs in development.

Several companies have advanced drug candidates for the management of COVID-19. For example, remdesivir (sold by Gilead), an antiviral drug, and oral Paxlovid (sold by Pfizer), a combination of nirmatrelvir and ritonavir tablets taken together, have both received full FDA approval for the treatment of COVID-19 in certain populations. The FDA has authorized emergency use ("EUA") of oral molnupiravir (sold by Merck and Ridgeback). Several antibodies previously received EUAs, but all of these have been revoked due to loss of efficacy as new variants emerged.

There are several ongoing clinical trials aimed at expanding the use of approved chemotherapeutic and immunomodulatory agents in the diseases we are studying, as well as several new clinical programs testing novel technologies. Companies with marketed CDK 4/6 inhibitors in the HR+/ HER2- metastatic breast cancer space include Pfizer (palbociclib), Novartis (ribociclib) and Eli Lilly (abemaciclib).

Manufacturing

Our product candidates are synthetic small molecules. Manufacturing activities must comply with FDA current good manufacturing practices ("cGMP"), regulations commensurate with the product candidates' stage of development. We conduct our manufacturing activities under individual purchase orders with third-party contract manufacturers ("CMOs"). We have quality agreements in place with our key CMOs. We have also established an internal quality management organization, which audits and qualifies CMOs in the United States and abroad.

We believe that the manufacturing processes for the active biopharmaceutical ingredients and finished drug products for our product candidates are being developed to adequately support future development and commercial demands. If manufacturing challenges occur, they are thoroughly reviewed and, as may be required, reported to health authorities to determine whether the product can be used for clinical trials.

The FDA regulates and inspects or conducts remote regulatory assessments of equipment, facilities and processes used in manufacturing biopharmaceutical products prior to approval. If we or our CMOs fail to comply with applicable cGMP requirements and conditions of product approval, the FDA may seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, refusal to approve applications, seizure or recall of products and criminal prosecution. Although we periodically monitor the FDA compliance of our third-party CMOs, we cannot be certain that our present or future third-party CMOs will consistently comply with cGMP and other applicable FDA regulatory requirements.

Commercial Operations

We do not currently have any relationships with organizations for the sale, marketing and distribution of biopharmaceutical products. In the future, we may rely on licensing and co-promotion agreements with strategic partners for the commercialization of our products in the United States and other territories. If we choose to build a commercial infrastructure to support marketing in the United States, such commercial infrastructure could be expected to include a targeted, sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest significant financial and management resources.

Government Regulation

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation by the FDA, and other federal, state, and local regulatory agencies. The Federal Food, Drug and Cosmetic Act (the "FDC Act"), and its implementing regulations, as well as various other federal and state statutes and regulations, set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety,

effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising, marketing, and promotion of our product candidates. The FDA also has issued a growing body of guidance documents that provide the agency's interpretation of regulatory requirements. As a result of these regulations, product development and the product approval process is very expensive and time consuming.

Regulation by governmental authorities in the United States and other countries is a significant factor in our research and development activities and strategy and will be a significant factor in the manufacture and marketing of our product candidates. Although the discussion below focuses on regulation in the United States, we and/or our partners anticipate seeking approval for, and marketing of, our products in other countries. Additionally, we are conducting certain of our clinical trials outside of the United States, including in Australia. Generally, our activities in other countries are and will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of approval and regulation in Europe are addressed in a centralized way through the EMA, but country-specific regulation remains essential in many respects and enforcement is generally through EU member state authorities. The nature and extent to which such regulation applies to us will vary depending on the nature of any products we may develop.

The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources and may not be successful. In addition, approval in a foreign country does not automatically result in approval in the United States, nor does approval in the United States automatically result in approval in the European Union or elsewhere.

United States Government Regulation

The FDA is the main regulatory body that controls biopharmaceuticals and pharmaceuticals in the United States, and its regulatory authority is based in the FDC Act. Biopharmaceuticals and pharmaceutical products are also subject to other federal, state and local statutes. A failure to comply explicitly with any requirements during the product development, approval, or post-approval periods, may lead to administrative or judicial sanctions. These sanctions could include the imposition by the FDA , an institutional review board ("IRB"), or Independent Ethics Committee ("IEC") of a hold on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, untitled letters, cyber letters, product recalls, product seizures or detention, prohibition on importing or exporting, total or partial suspension of production or distribution, injunctions, fines, civil penalties, adverse publicity, disgorgement, restitution, FDA debarment, debarment from government contracting or refusal of future orders under existing contracts, exclusion from Federal healthcare programs, corporate integrity agreements, consent decrees, or criminal prosecution.

The steps required before a new drug may be marketed in the United States generally include:

- Completion of preclinical or nonclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice ("GLP"), regulations and other applicable laws and regulations;
- Submission to the FDA of an IND to support human clinical testing;
- Approval by an IRB at each clinical site or centrally before each trial may be initiated;
- Performance of adequate and well-controlled clinical trials in accordance with federal regulations and with current good clinical practices ("GCPs") to establish the safety and efficacy of the investigational drug product for each targeted indication;
- Submission of an NDA to the FDA;
- Satisfactory completion of an FDA Advisory Committee review, if applicable;
- Satisfactory completion of an FDA inspection of the manufacturing facilities at which the investigational

product is produced to assess compliance with cGMPs, and to assure that the facilities, methods and controls are adequate, as well as satisfactory completion of FDA inspections of selected clinical trial sites to ensure that clinical trials were conducted in accordance with GCPs; and

- FDA review and approval of the NDA.

Preclinical and Clinical Trials

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Satisfaction of FDA pre-market approval requirements typically takes many years, and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Product development typically begins with preclinical or nonclinical studies. Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, as well as animal studies to assess potential safety and efficacy. Such studies must generally be conducted in accordance with the FDA's GLPs.

Prior to commencing the first clinical trial with a product candidate, an IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols, among other things, to the FDA as part of an IND. Sponsors will also be required to provide FDA with diversity action plans. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. This authorization is required before interstate shipping and administration of any new drug product to humans that is not the subject of an approved NDA. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. During its review, the FDA may determine that study subjects would be exposed to an unacceptable level of risk of harm or injury, and may raise questions or issues related to one or more components of the IND, resulting in the IND being placed on clinical hold. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational drug to patients under the supervision of qualified investigators following GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors. Clinical trials are conducted under protocols that detail the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. The informed written consent of each participating subject is required. Special clinical trial ethical considerations also must be taken into account if a study involves children. The clinical investigation of an investigational drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

- Phase 1. Phase 1 includes the initial introduction of an investigational drug into humans. Phase 1 clinical trials may be conducted in patients with the target disease or condition or healthy volunteers. These studies are designed to evaluate the safety, metabolism, pharmacokinetics and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational product's pharmacokinetics and pharmacological effects may be obtained to permit the design of Phase 2 clinical trials. The total number of participants included in Phase 1 clinical trials varies, but is generally in the range of 20 to 80.

- Phase 2. Phase 2 includes the controlled clinical trials conducted to evaluate the effectiveness of the investigational product for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.

- Phase 3. Phase 3 clinical trials are controlled clinical trials conducted in an expanded patient population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the investigational product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product, and to provide

an adequate basis for product approval. Phase 3 clinical trials usually involve several hundred to several thousand participants. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug.

Additional kinds of data may also help support an NDA, such as patient experience data and real world evidence. Real world evidence may be used to assist in clinical trial design or support an NDA for already approved products.

The decision to terminate development of an investigational drug product may be made by either a health authority body, such as the FDA or IRB/independent ethics committees ("IECs"), or by a company for various reasons. An IRB approves the initiation of a clinical trial and supervises the conduct of the trial to ensure that the risks to human subjects are reasonable in relation to the anticipated benefits and that there are adequate human subject protections in place. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor. This group provides guidance on whether or not a trial may or should move forward at designated check points. These decisions are based on the limited access to data from the ongoing trial. The suspension or termination of development can occur during any phase of clinical trials if it is determined that the participants or patients are being exposed to an unacceptable health risk, if the product candidate does not show sufficient evidence of efficacy, if the development program does not comply with applicable regulatory requirements, or due to changing sponsor business objectives.

In addition, there are various reporting requirements that clinical trial sponsors and investigators must comply with during the course of a clinical trial. For instance, there are requirements for the registration of ongoing clinical trials of drugs on public registries and the disclosure of certain information pertaining to the trials as well as clinical trial results after completion. Sponsors must also make annual reports to the FDA concerning the progress of their clinical trial programs as well as more frequent reports for certain serious adverse events. Sponsors must submit a protocol for each clinical trial, and any subsequent protocol amendments to the FDA and the applicable IRBs. IRBs must also receive information concerning unanticipated problems involving risks to subjects. Investigators must further provide certain information to the clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA. Moreover, under the 21st Century Cures Act, manufacturers or distributors of investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must have a publicly available policy concerning expanded access to investigational drugs.

Further, the manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDC Act.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of an NDA to request market approval for the product in specified indications.

New Drug Applications

In order to obtain approval to market a drug in the United States, a marketing application must be submitted to the FDA, which provides data establishing the safety and effectiveness of the drug product for the proposed indication. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

In most cases, the NDA must be accompanied by a substantial user fee; there may be some instances in which the user fee is waived. The FDA will initially review the NDA for completeness before it accepts the NDA for filing. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. After the NDA submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. For new molecular entities ("NMEs"), the FDA has the goal of completing its review within 10 months of the application's acceptance for filing. This, however, is just a goal, and the review time may take longer. For instance, the FDA can extend this review by three months to consider certain late-submitted information or information intended to clarify information already provided in the submission.

The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP. The FDA may refer applications for novel drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. For drugs for which no active ingredient (including any ester or salt of active ingredients) has previously been approved by the FDA, the FDA must refer the drug to an advisory committee or provide in an action letter, a summary of the reasons why the FDA did not refer the product candidate to an advisory committee. Product candidates may also be referred to advisory committees for other reasons. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect or conduct a remote regulatory assessment of the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect or conduct a remote regulatory assessment of one or more clinical sites to assure compliance with GCP. After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter indicates that the review cycle of the application is complete and the application is not ready for approval. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application, including additional clinical trials. If a complete response letter is issued, the applicant may either: resubmit the NDA, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect

the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing, clinical trials, and surveillance to monitor the drug's safety or efficacy, or to establish the product's safety and efficacy in a more diverse or representative population. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs, including the imposition of user fees for certain supplements.

Advertising and Promotion

The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses — that is, uses not approved by the FDA and therefore not described in the drug's labeling — because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but may engage in non-promotional, balanced scientific communications regarding off-label use under specified conditions. All statements regarding products must be consistent with the FDA approved label, must be truthful and non-misleading, and must be adequately substantiated with a fair balance between product benefit claims and risks, among other requirements. This means, for example, that we cannot make claims about the superiority of or otherwise compare our products to other treatments without substantiation, which typically are head-to-head clinical studies. FDA's promotional standards are an evolving space. For instance, in 2023, the FDA took a few actions with respect to advertising and promotion, including issuing a final rule and a guidance on risk and efficacy disclosures in direct-to-consumer advertising, and a guidance on communication of off-label scientific information about approved products. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice (the "DOJ"), or the Office of the Inspector General of the Department of Health and Human Services ("HHS"), as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

Post-Approval Regulations

After regulatory approval of a drug is obtained, a company is required to comply with a number of post-approval requirements. For example, as a condition of approval of an NDA, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug. In addition, as a holder of an approved NDA, a company would be required to report adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of its products. Further, under the Drug Quality and Security Act, manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers have obligations concerning the tracking and tracing of drug products, as well as the investigation and reporting of suspect and illegitimate products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to assure and preserve the long-term stability of the drug product. Manufacturing facilities must be registered with FDA and marketed drug products must be listed. Sponsors are also subject to annual program fees, though there may be some exemptions. The FDA periodically inspects or conducts remote regulatory assessments of manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural and substantive record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before

being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing.

Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, such as risk evaluation and mitigation strategies and phase 4 studies. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development or result in additional post-approval requirements.

After a product is approved for commercial sale, in addition to marketing and promotion restrictions, manufacturers are subject to federal and state laws and regulations requiring them to report certain pricing data, transactions with medical professionals, and similar information. Manufacturers participating in federal health care programs are also required to provide statutorily mandated discounts and rebates.

FDA post-approval requirements are continually evolving. For example, in March 2020, the U.S. Congress passed the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which includes various provisions regarding FDA drug shortage and manufacturing volume reporting requirements, as well as provisions regarding supply chain security, such as risk management plan requirements, and the promotion of supply chain redundancy and domestic manufacturing. As part of the CARES Act implementation, the FDA issued a guidance on the reporting of the volume of drugs produced, which reporting requires additional administrative efforts by drug manufacturers. The executive branch has also taken steps to promote domestic manufacturing, and the Consolidated Appropriations Act of 2023, and the reauthorization of the Prescription Drug User Fee Act, which were passed in 2022, included several changes to the FDC Act.

The Hatch-Waxman Amendments to the FDC Act

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product or method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application ("ANDA") or 505(b)(2) application. In an effort to clarify which patents must be listed in the Orange Book, in January 2021, Congress passed the Orange Book Transparency Act of 2020, which largely codified the FDA's existing practices into the FDCA. Listing patents in the Orange Book that do not qualify for listing can be considered to be anticompetitive conduct and, in 2023, the Federal Trade Commission sent letters to a number of companies with respect to certain patents that agency asserted were improperly listed or inaccurate.

An ANDA provides for marketing of a generic drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs

approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug. 505(b)(2) applications provide for marketing of a drug product that may have the same active ingredients as the listed drug and contain the same full safety and effectiveness data as an NDA, but at least some of the information comes from studies not conducted by or for the applicant. 505(b)(2) applicants may rely on published literature or the FDA's prior finding of safety and effectiveness for an NDA approved drug product. The ANDA or 505(b)(2) applicant is required to certify to the FDA concerning any patents listed for the approved product referenced in the marketing application in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA or 505(b)(2) applicant may also elect to submit a statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge or carve out the listed patents, the ANDA or 505(b)(2) application approval will not be made effective until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from making an approval of the ANDA or 505(b)(2) application effective until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant, or such shorter or longer period as may be determined by a court.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity has expired.

Congress, the Administration, and administrative agencies have taken certain measures to increase drug competition and thus, decrease drug prices. For example, measures have been proposed and implemented to facilitate product importation. FDA recently approved a plan for the state of Florida to import drug products from Canada. Congress also passed a bill requiring sponsors of NDA approved products to provide sufficient quantities of drug product on commercially reasonable market-based terms to entities developing generic and similar drug products. This bill also included provisions on shared and individual REMS for generic drug products.

Exclusivity

Upon NDA approval of a new chemical entity ("NCE"), which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot receive any ANDA or a 505(b)(2) application for the same active moiety. Certain changes to a drug, such as the addition of a new indication to the package insert, may be associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA for a generic drug or a 505(b)(2) application that includes the change, if the applicant conducted clinical trials essential to the approval of the application, which are not bioavailability or bioequivalence studies. Such exclusivity in the EU under a broadly equivalent regime is 10 years, though this may be decreased in the future pending current European Commission review.

An ANDA or a 505(b)(2) application may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension of a single unexpired patent, that has not previously been extended. The allowable patent term extension is calculated as half of the drug's testing phase — the time between IND application and full NDA submission — and all of the review phase — the time between full NDA submission and approval up to a maximum of five years. The time can be shortened if the FDA

determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years from the date of approval. Similar extension rules apply in the EU, though the specific calculations are different.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act (the "FCPA"), prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

International Government Regulation

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Some countries outside of the United States have a similar process that requires the submission of a clinical trial application ("CTA"), much like the IND prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to each country's national health authority and an IEC, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed. With the Clinical Trials Regulation (EC) 536/2014 in force since January 31, 2022, it is now possible to make a single application for a cross-border trial within the EU through an EU clinical trial portal. With the departure of the United Kingdom ("UK") from the EU, trials in the UK have to be approved through the portal and a separate application will need to be made to the UK Medicines and Healthcare products Regulatory Agency. Additionally, in the EU there is an increasing move to transparency of trial summary reports and the above Clinical Trial Regulation will include a publicly accessible database of data and information submitted in accordance with this regulation. Companies submitting data will need to justify why it should be kept confidential.

To obtain regulatory approval to commercialize a new drug under European Union regulatory systems, we must submit a marketing authorization application ("MAA"). The MAA is comparable to the NDA.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Expanded Access

Under certain circumstances, regulators may permit unapproved drugs to be used by patients outside of clinical trials. In the U.S., with FDA approval, manufacturers may provide investigational drugs to patients with serious or immediately life-threatening diseases for which there are no comparable or satisfactory alternative therapies. To qualify for U.S. expanded access, the potential benefit must justify the potential risks, and the potential risks must not be unreasonable. Providing the investigational drug must also not interfere with product development. There are additional qualifying criteria depending on the number of patients in the expanded access program, and the expanded access sponsor and investigator must comply with FDA's regulations. U.S. law also permits treatment access to certain investigational drugs under the federal Right to Try law, which permits manufacturers to provide investigational drugs to patients with a life-threatening disease or condition, who have exhausted all approved treatment options, who cannot participate in a clinical trial of the drug, and who provides informed consent, provided that certain conditions are met. Certain reports must be submitted to FDA under the federal Right to Try law. There are also state level Right to Try statutes.

In the European Union, early access programs are authorized by EU legislation and, through national laws, EU member states have implemented regulatory requirements related to these programs. National competent authorities may authorize early access program use. In both the European Union and United States unapproved drug products may not be promoted or marketed.

Compliance

During all phases of development (pre- and post-marketing), failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an IRB of a hold on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, untitled letters, cyber letters, product recalls, product seizures or detention, prohibition on importing or exporting, total or partial suspension of production or distribution, injunctions, fines, civil penalties, adverse publicity, disgorgement, restitution, FDA debarment, debarment from government contracting or refusal of future orders under existing contracts, exclusion from Federal healthcare programs, corporate integrity agreements, consent decrees, or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

Other Special Regulatory Procedures

Animal Rule

In 2002, the FDA amended its requirements applicable to NDAs to permit the approval of certain drugs and biologics that are intended to reduce or prevent serious or life-threatening conditions based on evidence of safety from clinical trial(s) in healthy subjects and effectiveness from appropriate animal studies when human efficacy studies are not ethical or feasible. These regulations, which are known as the "Animal Rule," authorize the FDA to rely on animal studies to provide evidence of a product's effectiveness under circumstances where there is a reasonably well-understood mechanism for the activity of the agent. Under these requirements, and with the FDA's prior agreement, drugs used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear agents not otherwise naturally present may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies and any additional supporting data. Products evaluated under this rule must demonstrate effectiveness through pivotal animal studies, which are generally equivalent in design and robustness to Phase 3 clinical studies. Additionally, the Animal Rule requires post-marketing studies, such as field studies, to verify and describe the product's clinical benefit and assess its safety should an exigency exist that leads to the product being used in humans. Products approved under the Animal Rule are subject to additional requirements, such as restrictions imposed on distribution or labeling requirements to inform patients that the product's approval was based on efficacy studies conducted in animals alone.

Other countries may not at this time have established criteria for review and approval of these types of products outside their normal review process, i.e. there is no "Animal Rule" equivalent in countries other than the U.S., but some may have similar policy objectives in place.

Orphan Drug Designation

The FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or, if the disease or condition affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug would be recovered from sales in the United States. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain orphan designation if there is a product already approved by the FDA that is intended for the same indication and that is considered by the FDA to be the same as the already approved product. This hypothesis must be demonstrated to obtain orphan exclusivity. In the European Union, the EMA's Committee for Orphan Medicinal Products ("COMP") grants Orphan Drug Designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without

incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug.

In the United States, Orphan Drug Designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs for certain kinds of studies, tax credits for certain research and user fee waivers under certain circumstances. Under the 21st Century Cures Act, Congress expanded the potential opportunities for grant funding to include additional kinds of studies. The 2017 Tax Cuts and Jobs Act, however, reduced the available tax credits for orphan products.

The FDA's regulations, provide flexibility in meeting approval standards for new therapies intended to treat persons with life-threatening and severely-debilitating illnesses, especially where no satisfactory alternative therapy exists, such that FDA may exercise scientific judgment in determining the kind and quantity of data required for approval and during development programs. Per guidance issued by FDA in 2023 with respect to rare diseases, "[t]his flexibility extends from the early stages of development to the design of adequate and well-controlled clinical investigations required to demonstrate effectiveness to support marketing approval and to establish safety data needed for the intended use." FDA states that it "is committed to helping sponsors create successful drug development programs that address the particular challenges posed by each disease…."

If a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to seven years of market exclusivity, which means the FDA may not approve any other application for the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

Notably, the exact scope of orphan drug exclusivity is currently in flux. A 2021 judicial decision, *Catalyst Pharms., Inc. v. Becerra,* challenged and reversed an FDA decision on the scope of orphan product exclusivity for the drug Firdapse. Under this decision, orphan drug exclusivity for Firdapse blocked approval of another company's application for the same drug for the entire disease or condition that for which orphan drug designation was granted even though the approved product indication was narrower. This decision was contrary to FDA's interpretation of the FDC Act, which took the position that orphan drug exclusivity only protected a product's approved indication. In January 2023, the FDA published a notice in the Federal Register stating that it interprets the *Catalyst Pharms.*, decision narrowly and intends to continue tying the scope of orphan drug exclusivity to the uses or indications that a drug is approved for. The scope of orphan drug exclusivity will likely be an evolving area.

In the European Union, Orphan Drug Designation also entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following drug approval. This period may be reduced to six years if the Orphan Drug Designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the holder of the marketing authorization for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product. As with the FDA, orphan drug exclusivity does not prevent the EMA from approving a second medicinal product where such second medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior. The European Commission has been reviewing the protection periods and proposes shortening the standard market exclusivity period from 10 to 9 years except for products addressing high unmet medical needs which would remain at 10 years.

Orphan drug designation must be requested before submission of an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Priority Review (United States), Accelerated Review (European Union) and other Expedited Programs

The FDA has various programs, including Fast Track designation, accelerated approval, priority review and breakthrough designation, that are intended to expedite or simplify the process for the development and FDA review of certain drug products that are intended for the treatment of serious or life-threatening diseases or conditions, and

demonstrate the potential to address unmet medical needs or present a significant improvement over existing therapy. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if the product will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy, safety, or public health factors. If Fast Track designation is obtained, drug sponsors may be eligible for more frequent development meetings and correspondence with the FDA. In addition, the FDA may initiate review of sections of an NDA before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information.

Based on results of one or more Phase 3 clinical trials submitted in an NDA, upon the request of an applicant, a priority review designation may be granted to a product by the FDA, which sets the target date for FDA action on the application at six months from FDA filing, or eight months from the sponsor's submission. Priority review is given to drugs intended to treat serious conditions and which, if approved would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of the serious condition. If criteria are not met for priority review, the standard FDA review period is 10 months from FDA filing, or 12 months from sponsor submission. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act ("FDASIA") enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are eligible for the Fast Track designation features as described above, intensive guidance on an efficient drug development program beginning as early as Phase 1 trials, and a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative, cross-disciplinary review.

In addition, products for treating serious or life threatening conditions and that provide a meaningful advantage over available therapies may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA will require a sponsor of a drug receiving accelerated approval to perform post-marketing studies, including completion of Phase 4 clinical trials to demonstrate clinical benefit, and to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoints. By the date of approval of an accelerated approval product, the FDA must specify the conditions for the required post approval studies, including enrollment targets, the study protocol, milestones, and target completion dates. The FDA may also require that the confirmatory Phase 4 studies be commenced prior to the FDA granting a product accelerate approval. Reports on the progress of the required Phase 4 confirmatory studies must be submitted to the FDA every 180 days after approval. The drug may be subject to accelerated withdrawal procedures if such studies do not verify the product's clinical benefit or other evidence shows a lack of safety or efficacy pursuant to a streamlined process that is outlined in the FDC Act. Promotional materials for products approved via the accelerated approval pathway must be submitted to the FDA prior to initial distribution. Such products may also be subject to distribution or use restrictions, if the FDA determines that restrictions are needed to assure safe use. In recent years, the accelerated approval pathway has come under significant FDA and public scrutiny. Accordingly, depending on the results of our studies, the FDA may be more conservative in granting accelerated approval or, if granted, may be more apt to withdrawal approval if clinical benefit is not confirmed.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Sponsors availing themselves of these programs must also be prepared to potentially work on accelerated timelines with respect to other areas of product development, including manufacturing.

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA's Committee for Medicinal Products of Human Use ("CHMP")). On average, an approval is provided by the European Commission after approximately 15 months. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, defined by three cumulative criteria: the seriousness of the disease (e.g., heavy disabling or life-threatening diseases) to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days. There is also a conditional marketing authorization which allows for the early approval of a medicine on the basis of less complete clinical data than normally required, if the medicine addresses an unmet medical need and targets a seriously debilitating or life-threatening disease, a rare disease or is intended for use in emergency situations in response to a public health threat. The benefit to public health must outweigh the risk due to the limited availability of clinical data at the time of marketing authorization.

The EMA has recently been conducting a pilot on 'adaptive pathways' — an iterative process building on existing regulatory processes involving gathering evidence through real-life use to supplement clinical trial data.

Pediatric Information

Under the Pediatric Research Equity Act (the "PREA"), NDAs or certain supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

Also, under the FDA Reauthorization Act of 2017, sponsors submitting applications for product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer must submit, with the application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, using appropriate formulations, to inform potential pediatric labeling. The FDA may grant full or partial waivers, or deferrals, for submission of data under PREA and this requirement.

The Best Pharmaceuticals for Children Act ("BPCA") provides NDA holders a six-month extension of any exclusivity — Orange Book listed patent or non-patent exclusivity — for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the required timeframe. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. This is not a patent term extension, but it effectively extends the regulatory exclusivity period. Moreover, pediatric exclusivity attaches to all formulations, dosage forms, and indications for products with existing marketing exclusivity or Orange Book listed patent life that contain the same active moiety as that which was studied. Applications under the BPCA for labeling changes receive priority review designation, with all of the benefits that designation confers.

In the European Union all applications for marketing authorization for new medicines have to include the results of studies as described in an agreed pediatric investigation plan, unless the medicine receives a deferral or waiver. Medicines authorized across the EU with the results of studies from a pediatric investigation plan included in the product information are eligible for an extension of their supplementary protection certificate by six months. This is the case

even when the studies' results are negative. For orphan medicines, the incentive is an additional two years of market exclusivity.

Healthcare Regulation

Following approval of any product candidate, the product would be subject to a comprehensive system of laws and regulations on the state and federal level that govern how drug products are reimbursed, healthcare financing, and drug manufacturers' relationships and interactions with healthcare professionals, including potential prescribers. These requirements include permissible fees, rebates, discounts and payment reductions, required price reporting and pricing transparency, caps on price increases, requirements around price negotiation, and requirements to enter into agreements with government agencies and certain healthcare entities that may result in significant limits on the prices we may charge for our products. Failure to comply with these laws, regulations, and/or restrictions could result in a loss of our ability to continue selling our drugs to the federal and state governments or receiving reimbursement for our drugs once approved. It could also result in enforcement actions.

The government is increasingly focused on measures to contain program costs for prescription drugs and there have been a number of U.S. Congressional inquiries, proposed bills, and enacted legislation focused on decreasing prescription drug spending and bringing more transparency to drug pricing. These efforts may result in a decrease in the amount of reimbursement we receive for our drugs from Medicare or other government programs for our drugs, once approved, and any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. These and any additional healthcare reform measures could further constrain our business or limit the amounts that federal and state governments will pay for healthcare products and services, which could result in additional pricing pressures. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition, and results of operations. Because of the significant governmental focus on drug prices, at this time we cannot determine how or if our product candidates will be reimbursed, following approval, or if any reimbursement levels will be sufficient to allow us to attain profitability. Changes in the law may result in additional downward pressure on coverage and the price that we receive for any approved product, or may require increased manufacturer rebates, and could seriously harm our business.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for dug products will allow favorable reimbursement and pricing arrangements of our products.

Other Healthcare Laws and Compliance Requirements

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable in whole or in part under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. The Beneficiary Inducement Civil Monetary Penalties Law imposes similar restrictions on interactions between the pharmaceutical industry and federal healthcare program beneficiaries. Although there are a number of statutory exceptions and regulatory safe harbors protecting some business arrangements from prosecution, the exceptions

and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor, as well as if they do. Failure to meet all the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances.

With respect to the safe harbors, the Office of Inspector General of HHS recently promulgated two additional safe harbor regulations. One safe harbor regulation excludes from the definition of "remuneration" limited categories of manufacturer rebates or other price reductions to a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization plan reflected in point-of sale reductions in price. The second safe harbor regulation excludes from the definition of "remuneration" PBM service fees paid by a manufacturer to a PBM. In addition, the Office of Inspector General of HHS revised the discount safe harbor regulation to exclude from the definition of "discount" a reduction in price by a manufacturer to plan sponsors under Medicare Part D either directly to the plan sponsor, or indirectly through a PBM. The effective date of the two new safe harbors and the revision to the discount safe harbor was delayed by court order until January 1, 2023. Recent legislation further delayed implementation of the new safe harbors and the revision to the discount safe harbor until January 1, 2032. Our practices may not in all cases meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability. The reach of the Anti-Kickback Statute was broadened by the Affordable Care Act, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a per se false or fraudulent claim for purposes of the civil False Claims Act (discussed below), which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce or reward referrals of federal healthcare program business, including purchases of products paid by federal healthcare programs, the statute has been violated.

The federal civil False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government or avoiding, decreasing, or concealing an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Claims under the civil False Claims Act may be brought by the government or private parties on behalf of the government, called "qui tam" actions, which may proceed even if the government does not join as a party.

The civil False Claims Act has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses not expressly approved by the FDA in a product's label, and allegations as to misrepresentations with respect to products, contract requirements, and services rendered, in addition to other allegations. In addition, private payers have been filing follow-on lawsuits alleging fraudulent misrepresentation. Intent to deceive is not required to establish liability under the civil False Claims Act. Rather, a claim may be false for deliberate ignorance of the truth or falsity of the information provided or for acts in reckless disregard of the truth or falsity of that information. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the individual will share in the proceeds from any damages, penalties or settlement funds. If the government declines to intervene, the individual may pursue the case alone. The civil False Claims Act provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement, which can aggregate into tens and even hundreds of millions of dollars. For these reasons, since 2004, False Claims Act lawsuits against biopharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, including settlements in excess of $3.0 billion and, more recently, settlements exceeding $5.0 billion in the aggregate, regarding certain sales practices and promotion of off-label uses." Civil False Claims Act liability may further be imposed for known Medicare or Medicaid overpayments, for example, overpayments caused by understated rebate amounts, that are not refunded within 60 days of identifying the overpayment, even if the overpayment was not caused by a false or fraudulent act.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. The Affordable Care Act amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation. Further, the government may prosecute conduct constituting a false claim under the criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil False Claims Act, requires proof of intent to submit a false claim. Also, many states have fraud and abuse statutes or regulations that are similar to the federal Anti-Kickback Statute and False Claims Act that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

The Affordable Care Act further created new federal requirements for reporting, by applicable manufacturers of covered drugs, of information related to payments and other transfers of value made to or at the request of covered recipients, namely US-licensed physicians and teaching hospitals, as well as ownership and investment interests held by physicians and members of their immediate family. The categories of covered recipients later was expanded to include physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives and certified registered nurse anesthetists. Payments made to physicians, other principal investigators, and certain research institutions for clinical trials are included within the ambit of this law.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act, and their implementing regulations, impose requirements relating to the privacy, security, breach notification, and transmission of protected health information. HIPAA's security and certain privacy standards are directly applicable to "business associates" — persons or organizations, other than a member of a covered entity's workforce, that create, receive, maintain, or transmit protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HIPAA authorizes the imposition of civil and criminal penalties against covered entities and business associates. HIPAA permits state attorneys general to file civil actions for damages or injunctions in federal courts to enforce the HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. HIPAA also imposes requirements with respect to disclosures of protected health information for research purposes, such as clinical trials. In addition, state laws, such as the California Consumer Privacy Act, govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA. In 2023, new state privacy laws became effective in California, Colorado Connecticut, Utah, and Virginia, further complicating privacy compliance efforts. Other states have passed similar consumer privacy laws that will become effective in the coming years. In addition, more onerous foreign data privacy provisions may apply. For instance, the EU General Data Protection Regulation imposes stricter rules on the processing of personal data than apply in the United States and its provisions exclude the export of data relating to identifiable individuals to most countries, including the United States, unless certain safeguards are in place.

In the United States, our activities are potentially subject to additional regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of HHS (e.g., the Office of Inspector General), the DOJ and individual U.S. Attorney offices within the DOJ, and state and local governments. If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 as well as the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, or the OBRA, the Veterans Health Care Act of 1992, Deficit Reduction Act of 2005, Patient Protection and Affordable Care Act, and the Inflation Reduction Act of 2022, each as amended. Among other things, the OBRA requires drug manufacturers to calculate and report complex pricing metrics used to determine rebates paid on prescription drugs to state Medicaid programs. Under the Veterans Health Care Act, or VHCA, drug companies are required to offer "covered drugs" (including all drugs approved under an NDA) at no more than a statutory ceiling price, calculated based on a manufacturer's required price calculations, to four federal agencies including the U.S. Department of Veterans Affairs, Indian Health Service, DoD, and the Public Health Service. Also, under the VHCA, manufacturers are required to offer drugs for sale at no more than a separate statutory ceiling price calculated by the manufacturer to Public Health Service designated entities in order to participate

in other federal funding programs including Medicaid. Legislation subsequent to the VHCA has required that certain discounted prices under the VHCA also be offered for specified DoD purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulation.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government, suspension or debarment prohibiting us from participating in federal procurement and non-procurement transactions, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in some states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/ or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing specified physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit other specified sales and marketing practices. Additionally, some states have enacted laws that cap increases in prices charged for drugs in that state. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

In Europe, most countries have laws or (more commonly) codes of practice which broadly emulate US 'sunshine laws' and require companies to maintain and publish a record of transfers of value to healthcare professionals. These are in addition to national anti-corruption laws similar to the FCPA — for instance the UK Bribery Act 2010 which has a wider scope than the FCPA in many respects including in that it covers relevant decision makers in both the private and public sectors and applies both domestically and internationally.

Human Capital

We believe that our success is largely dependent upon our ability to attract and retain qualified employees. As of December 31, 2025, we had 7 employees (4 of whom were full-time employees), in addition to various independent contractors working for us. We are not party to any collective bargaining arrangements and consider our relations with our employees to be good. Although we believe that the size of our current workforce is appropriate to achieve our objectives, we may hire additional employees with specialized expertise as we continue to grow our business. We believe that we have been successful to date in attracting skilled and experienced scientific and business professionals.

Our compensation philosophy is to pay for performance, which supports the Company's business strategies, and offer competitive compensation arrangements to attract and retain key individuals. The Company has established a Compensation Committee of the Board of Directors, which considers the impact of our corporate performance in determining compensation for named executive officers, as well as each named executive officer's individual performance, macroeconomic conditions generally, and data from peer group companies.

Corporate Information

We were incorporated in Delaware in December 1998. Our principal executive offices are located at 12 Penns Trail, Newtown, PA 18940 and our telephone number is (267) 759-3680. Our website address is www.trawspharma.com. The information contained in, or that can be accessed through, our website is not part of this Annual Report.

ITEM 1A. *RISK FACTORS*

You should carefully consider the following risk factors together with the other information contained in this Annual Report, including our financial statements, the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing in this Annual Report. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business and our financial condition and results of operations. In this event, the market price of our securities could decline and your investment could be lost. You should understand that it is not possible to predict or identify all such risks. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties.

Summary of Principal Risk Factors

- Our recurring operating losses, negative cash flows from operations, and accumulated deficit raise substantial doubt about our ability to continue as a going concern absent obtaining adequate new financings.
- The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, 2025 contains an explanatory paragraph relating to our ability to continue as a going concern.
- We need to obtain additional funding to continue as a going concern; if we are unable to meet our needs for additional funding in the future, we will be required to limit, scale back or cease operations.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- Our product development efforts may not be successful.
- Our future success is dependent primarily on the regulatory approval and commercialization of our product candidates.
- The results of preclinical testing or earlier clinical studies are not necessarily predictive of future results. Any product candidate we advance into clinical trials may not have favorable results in later-stage clinical trials or receive regulatory approval.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.
- Failure to follow the FDA's applicable regulatory requirements may result in enforcement action.
- Changes in product candidate manufacturing or formulation may result in additional costs or delay.
- Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.
- Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- If we breach our license agreements or fail to negotiate new agreements pertaining to our product candidates, we could lose the ability to continue the development and potential commercialization of these product candidates.

- Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.
- We may engage in future business combinations or collaborations that could disrupt our business, cause dilution to our stockholders and harm our financial condition and operating results.
- We depend on information technology and computer systems to operate our business; our business and operations would suffer in the event of any failures or interruptions of our computer system, such as a data breach or cybersecurity incident.
- Climate change, environmental, social and governance and sustainability initiatives may result in regulatory or structural industry changes that could require significant operational changes and expenditures, reduce demand for the Company's products and adversely affect our business, financial condition, and results of operations.
- Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.
- Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.
- Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from international conflicts, international trade disputes and geopolitical tensions.
- Changes in United States and China relations, as well as relations with other countries, and/or regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our shares.
- We currently conduct clinical trials, and may in the future choose to conduct additional clinical trials, of our product candidates in sites outside the US, and the FDA may not accept data from trials conducted in foreign locations.
- Disruptions at the FDA and foreign regulatory authorities caused by funding shortages, staffing limitations or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.
- We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.
- If we lose our relationships with CROs, our drug development efforts could be delayed.
- We have limited experience manufacturing our product candidates on a large clinical or commercial scale and have no manufacturing facility. We are dependent on third-party manufacturers for the manufacture of our product candidates for clinical trials as well as on third parties for our supply chain, and if we experience problems with any third parties, the manufacturing of our product candidates or products could be delayed.
- We have entered into certain related party transactions and may continue to rely on related parties for certain development and support activities.
- We could be required to incur significant expenses to perfect our intellectual property rights, and our intellectual property rights may be inadequate to protect our competitive position. If we are unable to protect our intellectual property rights, our competitive position could be harmed.
- We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful.
- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.
- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.
- If we are unable to maintain compliance with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could affect our common stock's market price and liquidity and reduce our ability to raise capital.

- We have identified material weaknesses in our internal control over financial reporting; if we fail to develop and maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired.
- Our share price and the liquidity of our stock may be volatile and result in substantial losses to our stockholders.
- We may be subject to securities litigation, which is expensive and could divert management attention.
- Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Risks Related to Our Financial Position and Capital Needs

Our recurring operating losses, negative cash flows from operations, and accumulated deficit raise substantial doubt about our ability to continue as a going concern absent obtaining adequate new financings.

Management has concluded that substantial doubt exists about our ability to continue as a going concern for the next twelve months from the date of the financial statements included in this Annual Report. As of December 31, 2025, we had cash and cash equivalents of $3.8 million and current liabilities of $11.6 million. Based on current projections, we do not have sufficient cash and cash equivalents as of the date of this Annual Report to support our operations for more than one year following the date that the financial statements are issued.

We will require substantial additional financing to fund our ongoing clinical trials and operations, and to continue to execute our strategy. To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we plan to explore various dilutive and non-dilutive opportunities, including equity financings, strategic alliances, business development and/or combinations, and other transactions. The future success of the Company is dependent upon our ability to obtain additional funding. There can be no assurance, however, that we will be successful in obtaining such funding in sufficient amounts, on terms acceptable to us, or at all. The failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on our business, results of operations, and financial condition. Accordingly, we have concluded that substantial doubt exists with respect to our ability to continue as a going concern within one year after the date that these financial statements are issued.

The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, 2025 contains an explanatory paragraph relating to our ability to continue as a going concern.

The auditor's opinion on our audited financial statements for the year ended December 31, 2025 includes an explanatory paragraph stating that we have incurred recurring losses from operations that raise substantial doubt about our ability to continue as a going concern for the next twelve months from the date of the financial statements included in this Annual Report. While we believe that we will be able to raise the capital we need to continue our operations, there can be no assurances that we will be successful in these efforts or will be able to resolve our liquidity issues or eliminate our operating losses. If we are unable to obtain sufficient funding, we would need to significantly reduce our operating plans and curtail some or all of our development efforts. Accordingly, our business, prospects, financial condition, and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

We need to obtain additional funding to execute our business plans; if we are unable to meet our needs for additional funding in the future, we will be required to limit, scale back or cease operations.

We do not currently have the funding resources necessary to carry out all of our proposed operating activities. We will need to obtain additional financing in the future in order to fully fund tivoxavir marboxil, ratutrelvir, narazaciclib, rigosertib or any other product candidates through the regulatory approval process. Accordingly, we may be required to delay or pause our planned clinical trials until we secure adequate additional funding. If we seek to proceed with a clinical trial without additional funding, we may receive questions or comments from the FDA, fail to obtain IRB approval, or find it more difficult to enroll patients in the trial. We have scaled down our operations in order to reduce spending on general and administrative functions, research and development, and other clinical trials, but by themselves, those measures may not be sufficient to address our funding needs.

Our future capital requirements will depend on many factors, including:

- timing and success of our clinical trials;
- continued progress of, and increased spending related to, our research and development activities;
- conditions in the capital markets and the biopharmaceutical industry, particularly with respect to raising capital or entering into strategic arrangements;
- progress with preclinical experiments and clinical trials, including regulatory approvals necessary for advancement and continuation of our development programs;
- changes in regulatory requirements and guidance of the FDA and other regulatory authorities, which may require additional clinical trials to evaluate safety and/or efficacy, and thus have significant impacts on our timelines, cost projections, and financial requirements;
- ongoing general and administrative expenses related to our reporting obligations under the Exchange Act;
- cost, timing, and results of regulatory reviews and approvals;
- costs of any legal proceedings, claims, lawsuits and investigations;
- success, timing, and financial consequences of any existing or future collaborative, licensing and other arrangements that we may establish, including potential granting of licenses to one or more of our programs in various territories, or otherwise monetizing one or more of our programs;
- cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- costs of commercializing any of our product candidates;
- technological and market developments;
- compliance with Nasdaq's continued listing requirements;
- cost of manufacturing development; and
- timing and volume of sales of products for which we obtain marketing approval.

These factors could result in variations from our projected operating and liquidity requirements. Additional funds may not be available when needed, or, if available, we may not be able to obtain such funds on terms acceptable to us. If adequate funds are unavailable, we may be required, among other things, to:

- delay, reduce the scope of or eliminate one or more of our research or development programs;

- license rights to technologies, product candidates or products at an earlier stage or for indications or territories than otherwise would be desirable, or on terms that are less favorable to us than might otherwise be available;

- obtain funds through arrangements that may require us to relinquish rights to product candidates or products that we would otherwise seek to develop or commercialize by ourselves; or

- further reduce or cease operations.

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.

We are a clinical-stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate could fail to gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities for marketing and have not generated any revenue from product sales to date, and we continue to incur significant research, development and other expenses related to our ongoing operations. As a result, we are not profitable and have experienced negative cash flows from our operations in every reporting period since our inception in 1998. For the year ended December 31, 2025, we reported net income of $9.2 million, primarily due to non-cash changes in fair value of our warrant liability of $26.6 million. For the year ended December 31, 2024, we reported net loss of $166.5 million and we had an accumulated deficit of $640.0 million as of December 31, 2025.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. These losses may increase as we continue the research and development of, and seek regulatory approvals for, our product candidates, and potentially begin to commercialize any products that may achieve regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

We currently have no source of product revenue and may never become profitable.

To date, we have not generated any revenues from commercial product sales. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability to successfully commercialize products, including any of our current product candidates, or other product candidates that we may in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for these product candidates, we do not know when any of these products will generate revenue from product sales for us, if at all.

In addition, because of the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the development and regulatory process for any product candidates, we anticipate incurring significant costs associated with commercializing these products. Additionally, even if we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or suspend our operations.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until we can generate substantial revenue from product sales, if ever, we expect to continue to seek additional capital through a combination of private and public equity offerings, debt financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms may include

liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include restrictive covenants limiting our ability to take important actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates or formulations that we would otherwise prefer to develop and market ourselves.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

The majority of our cash is held in accounts at U.S. banking institutions. Cash held in depository accounts may exceed the Federal Deposit Insurance Corporation ("FDIC") standard deposit insurance limit of $250,000. If such banking institutions were to fail, such as Silicon Valley Bank when the FDIC took control in March 2023, we could lose all or a portion of those amounts held in excess of such insured amounts. In the future, our access to our cash in amounts adequate to finance our operations could be significantly impaired if the financial institutions with which we have arrangements encounter liquidity constraints or failures. Any future limitation on timely access to our funds or any material loss that we may experience in the future could have a material adverse effect on our financial condition and could materially impact our ability to pay our operating expenses or make other payments.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, including the ongoing military conflicts between Russia and Ukraine and Israel and Hamas and the recent military conflict in Iran. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from any such geopolitical tensions.

U.S. and global markets are experiencing volatility and disruption, and the global economy has been, and may continue to be, negatively impacted by Russia's ongoing military conflict with Ukraine. Although our business has not been materially impacted by the ongoing military conflicts between Russia and Ukraine or Israel and Hamas or geopolitical tensions to date, it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which the conflict may impact our business, such as by potentially making it more difficult for us to access liquidity in capital markets. The extent and duration of the conflicts in Ukraine and the Middle East, geopolitical tensions, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described herein.

International trade disputes have resulted in tariffs and other protectionist measures that could have a material adverse effect on our business, financial condition and results of operations.

In recent years, the U.S. has instituted or proposed changes in trade policies that include the negotiation or termination of trade agreements, the imposition of higher tariffs on imports into the U.S., economic sanctions on individuals, corporations or countries, and other government regulations affecting trade between the U.S. and other countries where we conduct our business, in particular China, Mexico and Canada. A number of other nations have proposed or instituted similar measures directed at trade with the United States in response. As a result of these developments, there may be greater restrictions and economic disincentives on international trade that could adversely affect our business. Additionally, tariffs could increase our costs, which could have a negative impact on our financial condition and results of operations. As additional trade-related policies are instituted, we may need to modify our business operations to comply and adapt to such developments, which may be time-consuming and expensive.

Changes in United States and China relations, as well as relations with other countries, and/or regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our shares.

The US government, including the SEC, has made statements and taken certain actions that led to changes to US and international relations, and will impact companies with connections to the United States or China, including

imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with significant China-based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the U.S. or to China, our industry or on us. Any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with significant China-based operations, capital controls or tariffs, may affect our ability to raise capital and the market price of our shares.

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated or if the U.S. or Chinese governments take retaliatory actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our shares.

We may be adversely affected by the effects of inflation.

Inflation has the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, supply shortages, increased costs of labor, components, manufacturing and shipping, as well as weakening exchange rates and other similar effects. As a result of inflation, we have experienced and may continue to experience cost increases. Although we may take measures to mitigate the effects of inflation, if these measures are not effective, our business, financial condition, results of operations and liquidity could be materially adversely affected. Even if such measures are effective, there could be a difference between the timing of when these beneficial actions impact our results of operations and when the costs of inflation are incurred.

Risks Related to Our Business and Industry

Our product development efforts may not be successful.

Clinical and non-clinical development is expensive, time-consuming, and uncertain as to the outcome. The focus of our development efforts is currently on tivoxavir marboxil and ratutrelvir, while we consider strategic options for narazaciclib and rigosertib. Although we believe that there are opportunities for us to develop our drug candidates in various indications, clinical drug development is expensive, can take many years to complete, and its outcome is inherently uncertain. Even if our clinical development programs are successful, we may not be able to successfully commercialize any product. There can be no assurance that our focus on tivoxavir marboxil and ratutrelvir and the strategic options available for narazaciclib and rigosertib will be successful, and that we will be able to successfully develop a product candidate or, even if we do, that we will be able to successfully commercialize such candidate.

Our future success is dependent primarily on the regulatory approval and commercialization of our product candidates.

Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical studies and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. A failure of one or more preclinical tests or clinical trials can occur at any stage of testing. Changes to product candidates may also impact their performance in subsequent studies.

If we are unable to obtain regulatory approval or designations we may seek, such as orphan designation, for our product candidates in one or more jurisdictions, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our product candidates.

The results of preclinical testing or earlier clinical studies are not necessarily predictive of future results. Any product candidate we advance into clinical trials may not have favorable results in later-stage clinical trials or receive regulatory approval.

Encouraging results in preclinical testing and earlier clinical studies do not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. Additionally, mechanisms of action, studies in small or single patient populations, and interim study results may not be predictive of later stage studies. The development of a product candidate for one indication may further impact its development for other indications. If our clinical trials do not produce favorable results for our product candidates, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

We may experience delays in our ongoing or future clinical trials, and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. Regulatory authorities may also find that our development programs do not support product approval. There can be no assurance that the FDA, an IRB, or a comparable foreign regulatory authority will permit our clinical trials to commence and will not put clinical trials of any of our product candidates on clinical hold in the future. Study results may also cause us to discontinue trials. Clinical trials may be delayed, suspended or prematurely terminated and development programs may not be successful for a variety of reasons, including:

- delay or failure in reaching identifying, contracting with, and retaining contract research organizations ("CROs") and clinical trial sites;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial and/or retaining subjects;
- failure to follow the study procedures or applicable regulatory requirements;
- change in standards of care, which may necessitate the modification of our clinical trials or the conduct of new trials;
- negative or ambiguous study results;
- manufacturing or product quality issues;
- the need to conduct additional development work, including clinical trials;
- unanticipated clinical trial costs or insufficient funding, including paying substantial application user fees;
- changes in governmental laws, regulations, policies, or administrative actions; and
- regulatory authority disagreements regarding the design or implementation of our clinical trials.

If we experience delays in the completion or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority.

As a result of undesirable side effects or safety or toxicity issues that we may experience in our clinical trials, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidates for any or all targeted indications. These side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. They could also result in restrictive labeling for any approved products.

Failure to follow the FDA's applicable regulatory requirements may result in enforcement action.

If we or our third-party contractors are not able to follow the FDA's or comparable foreign regulatory authorities' regulatory requirements, we or they may face enforcement actions that may materially harm our business, including, but not limited to:

- warning letters, untitled letters, cyber letters or otherwise unacceptable inspectional findings;
- injunctions, penalties, fines, restitution, consent decrees, corporate integrity agreements, suspension or debarment;
- suspension or termination of any ongoing clinical studies, imposition of a clinical hold, or regulatory authority refusal to approve pending marketing applications;
- modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing;
- restrictions on operations, product seizure or detention, refusal to permit the import or export of products, or product recalls; or
- adverse publicity.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to later-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. During the course of a development program, sponsors may also change the contract manufacturers used to produce the product candidates. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of clinical trials. Such changes may also require additional testing, notification to, or approval from the FDA or comparable foreign regulatory authority. This could delay completion of clinical trials; require the conduct of bridging clinical trials or studies, or the repetition of one or more clinical trials; increase clinical trial costs; delay approval of our product candidates; and jeopardize our ability to commence product sales and generate revenue.

We currently conduct clinical trials, and may in the future choose to conduct additional clinical trials, of our product candidates in sites outside the US, and the FDA may not accept data from trials conducted in foreign locations.

We currently conduct, and expect in the future to conduct, clinical trials outside the US for our product candidates. The acceptance of study data from clinical trials conducted outside the US or another jurisdiction by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the US, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the US population and US medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for marketing approval unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the US or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the US, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements for clinical trial materials and supplies as well as shipment and storage of biological samples;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

Disruptions at the FDA and foreign regulatory authorities caused by funding shortages, staffing limitations, government shutdowns or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review or approve new products can be affected by a variety of factors, including government budget and funding levels, government shutdowns, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions including a rapid substantial influx of applications from numerous sponsors, as occurred with COVID-19. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the US government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. If a prolonged government shutdown occurs, or funding shortages, staffing limitations, or renewed global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities on a timely basis, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

The regulations that govern, among other things, marketing approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country and our ability to commercialize any products will depend, in part, on the extent to which coverage and adequate reimbursement for our products is available. In the United States and some foreign jurisdictions, including the European Union, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, limit coverage and reimbursement or restrict the prices we may charge including through payments of increased manufacturer rebates and penalties, and affect our ability to successfully sell any product candidates for which we obtain marketing approval. Furthermore, in the United States private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates. These and any additional healthcare reform measures in the United States, the European Union and other potentially significant markets could further constrain our business or limit the amounts that governments will pay for healthcare products and services, which could result in additional pricing pressures.

Certain states in the US have also enacted laws requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, cap or regulate price increases, negotiate or pay increased supplemental rebates and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing specified physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit other specified sales and marketing practices.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country.

Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval. We cannot be sure that timely coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of coverage and reimbursement will be.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA, Centers for Medicare & Medicaid Services, or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, comply with the FDA's laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of

conduct for our directors, officers and employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidate that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of certain disease indications for which we are developing our product candidates.

For example, large pharmaceutical companies such as Roche, GSK and BioCryst Partners successfully market the commercialized anti-influenza drugs neuraminidase inhibitors oseltamivir phosphate (Tamiflu), zanamivir (Relenza), and peramivir (Rapivab) anti-influenza drugs, respectively. Additionally, Roche's antiviral, baloxavir marboxil (Xofluza), a CEN inhibitor, is also approved for the treatment of influenza. Gilead, Pfizer and Merck have commercialized drugs for the management of COVID-19 in certain populations, including remdesivir and, nirmatrelvir + ritonavir, or molnupiravir, respectively.

Furthermore, other companies such as Pfizer, Novartis, Eli Lilly successfully market commercialized CDK 4/6 inhibitors palbociclib, ribociclib and abemaciclib and have done so for a number of years. More recently, G1 Therapeutics secured FDA approval of the CDK 4/6 triaciclib for the prevention of myelosuppression following chemotherapy.

The approved antiviral drugs baloxavir marboxil, oseltamivir and CDK 4/6 inhibitor drugs palbociclib, ribociclib and abemaciclib are well established therapies or products and are widely accepted by physicians, patients and third-party payors. By the time our drug candidates are possibly approved in the future, insurers and other third-party payors may also encourage the use of generic products. This may make it difficult for us to achieve market acceptance at desired levels in a timely manner to ensure viability of our business.

More established companies may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources.

If we breach our license agreements or fail to negotiate new agreements pertaining to our product candidates, we could lose the ability to continue the development and potential commercialization of these product candidates.

If we fail to meet our obligations under our current license agreements or if we fail to negotiate future license agreements, our rights under the licenses could be terminated, and upon the effective date of such termination, our right to use the licensed technology would terminate. While we would expect to exercise all rights and remedies available to us, including attempting to cure any breach by us, and otherwise seek to preserve our rights under the patents and other technology licensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under the license agreement could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for the applicable product candidates.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, and patients, healthcare providers or others using, administering or selling our products in third party studies, expanded access programs, or commercially, if we receive product approval. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, the clinical development and commercialization of our product candidates could be adversely affected or terminated, and we could incur substantial liabilities.

We may engage in future business combinations or collaborations that could disrupt our business, cause dilution to our stockholders and harm our financial condition and operating results.

While we currently have no specific plans to acquire any other specific business, we may, in the future, make acquisitions of, or investments in, or otherwise engage in business combinations or collaborations with companies that we believe have products or capabilities that are a strategic or commercial fit with our current product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may: issue stock that would dilute our existing stockholders' percentage of ownership; incur debt and assume liabilities; and incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We may not be able to complete any future business combination or collaborations on favorable terms, if at all. If we do complete a business combination or collaboration, we cannot assure you that it will ultimately strengthen our competitive position or that it will be viewed positively by customers, financial markets or investors. Furthermore, future business combinations could pose numerous additional risks to our operations, including, but not limited to problems integrating the businesses, products or technologies, increases to our expenses, the failure to discover undisclosed liabilities of an acquired asset or transaction partner, diversion of management's attention from their day-to-day responsibilities, and harm to our operating results or financial condition.

We may not be able to complete any collaboration or business combination or effectively integrate the operations, products or personnel gained through any such business combination.

We depend on information technology and computer systems to operate our business; our business and operations would suffer in the event of any failures or interruptions of our computer system, such as a data breach or cybersecurity incident.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Cybersecurity attacks are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information, and corruption of data. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability or damage to our reputation, and the further development of our product candidates could be delayed.

Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients or other business partners, may be exposed to unauthorized persons or to the public. There can be no assurance that our efforts, or the efforts of our partners and vendors, will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could

result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches.

Climate change, environmental, social and governance and sustainability initiatives may result in regulatory or structural industry changes that could require significant operational changes and expenditures, reduce demand for the Company's products and adversely affect our business, financial condition, and results of operations.

Climate change, environmental, social and governance ("ESG") and sustainability are a growing global movement. Continuing political and social attention to these issues has resulted in both existing and pending international agreements and national, regional and local legislation, regulatory measures, reporting obligations and policy changes. Also, there is increasing societal pressure in some of the areas where we operate, to limit greenhouse gas emissions as well as other global initiatives. These agreements and measures may require, or could result in future legislation, regulatory measures or policy changes that would require operational changes or increase expenses.

Furthermore, increasing attention to climate change, ESG and sustainability has resulted in governmental investigations, and public and private litigation, which could increase our costs or otherwise adversely affect our business or results of operations. In addition, organizations that provide information to investors on corporate governance and related matters have developed ratings processes for evaluating companies on their approach to ESG matters. Such ratings are used by some investors to inform their investment and voting decisions. Unfavorable ESG ratings may lead to increased negative investor sentiment toward us, which could have a negative impact on the price of our securities and our access to and costs of capital.

Any or all of these ESG and sustainability initiatives may result in significant operational changes and expenditures, cause us reputational harm, and could materially adversely affect our business, financial condition, and results of operations.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. The ultimate impact on us, our significant suppliers and our general infrastructure of being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent upon members of our executive management team and other employees. Although we have employment agreements with our executive officers, these agreements are at-will and do not prevent such persons from terminating their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

The widespread outbreak of a communicable disease, such as the recent COVID-19 pandemic, could adversely impact our business, including our clinical trials, drug manufacturing and nonclinical activities.

We face risks related to epidemics and other outbreaks of communicable diseases, such as the recent COVID-19 pandemic, which could adversely impact our business, including our clinical trials and clinical trial operations. These potential disruptions may include but are not limited to delays or difficulties in clinical site initiation and patient

recruitment, patient withdrawals, postponement of planned clinical or preclinical studies, redirection of site resources from studies, study modification, suspension, or termination, the introduction of remote study procedures and modified informed consent procedures, study site changes, direct delivery of investigational products to patient homes requiring state licensing, study deviations or noncompliance, diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials, delays in receiving approval from local regulatory authorities to initiate our planned clinical trials, delays in obtaining supplies of our product candidate or other materials that may be necessary for the conduct of our development program, delays in obtaining necessary inspections from the FDA or other regulatory authorities, changing laws and regulations, and changes or delays in site monitoring. The foregoing may require that we consult with relevant review and ethics committees, IRBs, and the FDA or foreign regulatory authorities. The foregoing may also impact the integrity of our study data, which may not become evident until later in our development programs. The effects of a health crisis may also increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs, as well as clinical trial sites for the conduct of our clinical trials. There is no guarantee that we will be able to maintain the relationships with these third parties, that we will be able to enter into additional relationships, or that we will be able to find replacement sites or CROs should any of our agreements terminate. We rely on these parties for execution of our preclinical and clinical trials, and we control only some aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and sites does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices ("GLP") and the Animal Welfare Act requirements. We, our clinical trial sites, and our CROs are required to comply with federal regulations and current GCPs, which are international standards meant to protect the rights and health of patients that are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, the Australian Human Research Ethics Committee and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our sites or CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We or they may also face regulatory enforcement. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process. We may also face liability and/or regulatory enforcement action should any of the third parties that we rely upon fail to comply with legal and/or regulatory requirements.

Our CROs and the employees at clinical sites are not our employees, and except for remedies available to us under our agreements with such CROs and sites, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If CROs or sites do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Moreover, while we are required to monitor the activities of third parties providing services on our behalf, there is no guarantee that we will be able to detect activities that do not comply with the applicable regulatory requirements or our study plans and protocols. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs and clinical trial sites, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If we lose our relationships with CROs, our drug development efforts could be delayed.

We rely on third-party vendors and CROs for preclinical studies and clinical trials related to our drug development efforts. Switching or adding additional CROs would involve additional cost and requires management time and focus. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. We may also terminate a CRO for a number of reasons. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms.

We have limited experience manufacturing our product candidates on a large clinical or commercial scale and have no manufacturing facility. We are dependent on third-party manufacturers for the manufacture of our product candidates for clinical trials as well as on third parties for our supply chain, and if we experience problems with any third parties, the manufacturing of our product candidates or products could be delayed.

We do not own or operate facilities for the manufacture of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently rely on a single source CMO, for the chemical manufacture of active pharmaceutical ingredient for each of our product candidates. To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing, the CMOs with whom we currently work will need to increase the scale of production. We may need to identify additional CMOs for continued production of supply for our product candidates. In addition, regulatory authorities enforce cGMP through periodic inspections and remote regulatory assessments of active pharmaceutical ingredient ("API") and drug product manufacturing sites, quality control contract laboratories and distribution centers. If we or our CMO fail to comply with applicable cGMPs, the manufacturing data generated and subsequent API lots and drug product batches in our supply chain may be deemed unreliable. Clinical trials using the product candidate may also be deemed to be unreliable. As such, the FDA or comparable foreign regulatory authorities may require us to perform additional API and drug product manufacturing and manufacturing development before continuing clinical trials or approving our marketing applications, may require us to conduct additional studies, and any such deficient product we supply to any collaboration partner may subject us to certain obligations under relevant agreements. We or our contractors may also face enforcement actions. We have not yet qualified alternate suppliers in the event the current CMO we utilize is unable to scale production, or if we otherwise experience any problems with them. By example, our third-party manufacturers may not be able to obtain sufficient quantities of any necessary supplies such as due to changing trade policies or supply shortages. Although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, as we have experienced with respect to our existing CMOs, it could be expensive and take a significant amount of time to arrange for alternative suppliers. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to synthesize and manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMPs and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMPs or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties. Noncompliance with the applicable manufacturing requirements may also require costly corrective and preventative actions. The manufacturing facilities that we use must also be approved by the FDA under a pre-approval inspection. If the facilities cannot pass these inspections, the FDA will not approve our marketing application. These manufacturing facilities will further be subject to continuing regulatory oversight and inspection, and, thus, they must continue to expend time and resources to maintain regulatory compliance.

We have entered into certain related party transactions and may continue to rely on related parties for certain development and support activities.

We have entered into, and may continue to enter into, transactions with related parties for certain development and support activities. For example, we have entered into master research and development agreements with ChemDiv, Inc. and Viriom, Inc., both of which are related parties, to provide certain research and development related services for virology product candidates. For additional information related to these and other related party transactions, please see Note 12, Research and Development Arrangements and Related Party Transactions, to our consolidated financial statements included in Part IV in this Annual Report. Such related party transactions may not have been entered into on an arm's-length basis, and we may have achieved more favorable terms because such transactions were entered into with our related parties. We rely on, and will continue to rely on, our related parties to maintain these services. If the pricing for these services changes, or if our related parties cease to provide these services, including by terminating agreements with us, we may be unable to obtain replacements for these services on the same terms without disruption to our business. This could have a material effect on our business, results of operations and financial condition.

Risks Related to Our Intellectual Property

We could be required to incur significant expenses to perfect our intellectual property rights, and our intellectual property rights may be inadequate to protect our competitive position. If we are unable to protect our intellectual property rights, our competitive position could be harmed.

We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our commercial success will depend in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. Where we have the right to do so under our license agreements, we seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain.

The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our licensed compounds will result in the issuance of patents that protect our technology or products, or if any of our issued patents will effectively prevent others from commercializing competitive technologies and products. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Further, the examination process may require us or our licensor to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

Even if patents are granted that cover commercially valuable molecules or compounds, we may decide to allow such patents to lapse, or if in-licensed, return the patents to the licensor. The effects of doing so are uncertain. In the case of returning granted patents to a licensor, we may encounter a scenario in which we need the patents in the future and are unable to obtain a new license to such patents on commercially reasonable terms or at all. The licensor may license the returned patents to a competitor, who may then enforce the patents against us.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or a court may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates, and to use our proprietary technologies without infringing the proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings

before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer.

Risks Related to Ownership of Our Securities

We may be required to raise additional financing by issuing new securities with terms or rights superior to those of our existing securityholders, which could adversely affect the market price of shares of common stock and our business.

We will require additional financing to fund future operations, including for research and development, clinical trials, expansion in current and new markets, development and acquisition, capital costs and the costs of any necessary implementation of technological innovations or alternative technologies. We may not be able to obtain financing on favorable terms, if at all. If we raise additional funds by issuing equity securities, the percentage ownership of our current stockholders will be reduced, and the holders of the new equity securities may have rights superior to those of our existing securityholders, which could adversely affect the market price of our common stock and the voting power of shares of our common stock. If we raise additional funds by issuing debt securities, the holders of these debt securities would similarly have some rights senior to those of our existing securityholders, and the terms of these debt securities could impose restrictions on operations and create a significant interest expense for us which could have a materially adverse effect on our business.

If we are unable to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could affect our common stock's market price and liquidity and reduce our ability to raise capital.

Our common stock is listed on the Nasdaq Capital Market ("Nasdaq"), a national securities exchange, which imposes continued listing requirements with respect to issuers whose securities are listed on Nasdaq. If we fail to satisfy the continued listing standards, such as, for example, Nasdaq's minimum bid price requirement or stockholders equity requirements, Nasdaq may issue a non-compliance letter or initiate delisting proceedings.

As previously disclosed, on November 20, 2024, we received a letter from the staff (the "Staff") of the Listing Qualifications Department of Nasdaq notifying us that the Company was no longer in compliance with the minimum $2.5 million stockholders' equity requirement for continued listing on Nasdaq as set forth in Listing Rule 5550(b)(1) (the "Rule"). After a hearing, the Nasdaq Hearings Panel granted the Company an exception until February 18, 2025 to demonstrate compliance with the Nasdaq listing rules. On February 25, 2025, we received a letter from Nasdaq confirming that the Company had regained compliance with the Rule. Pursuant to Listing Rule 5815(d)(4)(B), the

Company will be subject to a mandatory panel monitor for a period of one year from the date of such letter. If, within that one-year monitoring period, the Staff finds that the Company is no longer in compliance with the Rule, then, notwithstanding Rule 5810(c)(2), we will not be permitted to provide the Staff with a plan of compliance with respect to such deficiency and the Staff will not be permitted to grant additional time for us to regain compliance with respect to such deficiency, nor will we be afforded an applicable cure or compliance period pursuant to Rule 5810(c)(3). Instead, the Staff will issue a Delist Determination Letter and we will have an opportunity to request a new hearing with the initial Hearings Panel or a newly convened Hearings Panel if the initial Hearings Panel is unavailable.

If we are unable to maintain compliance with the continued listing requirements of Nasdaq, our common stock could be delisted, making it could be more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our securities could suffer a material decline. Delisting could also impair our ability to raise capital.

We are obligated to develop and maintain proper and effective internal control over financial reporting. We have in the past identified, and in the future may identify, material weaknesses in our internal control over financial reporting. If we fail to develop and maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired.

We are a public company and are required, pursuant to Section 404(a) of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of its internal control over financial reporting on our annual report on Form 10-K. Effective internal control over financial reporting is necessary for reliable financial reports and, together with adequate disclosure controls and procedures, such internal controls are designed to prevent fraud. Undetected material weaknesses in internal controls could lead to financial statement restatements and require us to incur the expense of remediation. The process of designing, implementing and testing the internal control over financial reporting required to comply with this obligation is time-consuming, costly and complicated. We are required to disclose changes made in internal control and procedures on a quarterly basis.

As discussed elsewhere in this Annual Report, we completed the Merger in April 2024. Prior to the Merger, Trawsfynydd was a private company and, therefore, its controls were not required to be designed or maintained in accordance with Rules 13a-15 and 15d-15 under the Exchange Act. The design and implementation of internal control over financial reporting post-Merger has required, and will continue to require, significant time and resources from management and other personnel. Although we had internal controls in place prior to the Merger, and our management has determined in recent years that such internal controls over financial reporting were effective, during its assessment of our internal controls over financial reporting as of December 31, 2024 it was determined that our controls were not effectively updated and implemented to reflect the changes in processes and staffing during the period between completion of the Merger and December 31, 2024. Additionally, it was determined that there was an inadequate segregation of duties over the preparation, review and posting of manual journal entries, which was the result of not having a sufficient risk assessment process in place post-Merger to identify and analyze risk of misstatement due to fraud and/or error.

In connection with the audit of our financial statements for the year ended December 31, 2024, we identified material weaknesses in our internal control over financial reporting, which relate to the determinations of management discussed above. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As of December 31, 2025, these material weaknesses have been remediated, see “Part II – Item 9A – Remediation of Material Weakness in Internal Control over Financial Reporting” in this Annual Report on Form 10-K. Although we were able to remediate these material weaknesses, there is no guarantee that we will not experience additional material weaknesses in the future or that we will be able to remediate any such material weakness in a timely manner or at all. If we identify future material weaknesses in our internal control over financial reporting, or if we generally fail to establish and maintain effective internal controls appropriate for a public company, we may be unable to produce timely and accurate financial statements, which could adversely impact our investors' confidence and our stock price.

We could also become subject to investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities, which could require additional financial and management resources.

Future issuances of stock or other securities could dilute the holdings of stockholders and could materially affect the price of the shares of our common stock.

As discussed elsewhere in this Annual Report, we will need to obtain additional financing in the future to carry out our business objectives. We may do so through the sale and issuance of shares of our common stock or securities convertible or exercisable for shares of our common stock. Additionally, as of December 31, 2025, there are warrants to purchase an aggregate of 3,375,457 shares of our common stock outstanding and shares of Series C Preferred Stock convertible into an aggregate of 2,694,757 shares of our common stock outstanding. Any issuance of shares of our common stock, including upon the exercise or conversion of outstanding warrants and shares of Series C Preferred, respectively, or issuance of securities exercisable for or convertible into shares of our common stock, will result in the dilution of the ownership interests of our existing stockholders. Additionally, the issuance of a significant number of shares of our common stock could result in a decrease in the price of our common stock.

We have used and intend to continue to use equity incentives for employees, advisors, directors, key consultants and select affiliates. Any issuance of stock upon the conversion of options, restricted stock units and/or other incentive rights will result in the dilution of the ownership interests of our existing stockholders.

Our share price and the liquidity of our stock may be volatile and result in substantial losses to our stockholders.

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of these risks or any of a broad range of other risks could have a dramatic and material adverse impact on the market price of our common stock.

We may be subject to securities litigation, which is expensive and could divert management attention.

In the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our Tenth Amended and Restated Certificate of Incorporation, as amended ("Certificate of Incorporation") and Amended and Restated Bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include provisions that will:

- permit our board of directors to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and

privileges as they may designate (as of December 31, 2025, we had shares of 6,737 Series C Preferred stock issued and outstanding);

- provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;

- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and

- provide that special meetings of our stockholders may be called only by the board of directors or by such person or persons requested by a majority of the board of directors to call such meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our Certificate of Incorporation or Amended and Restated Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

None.

ITEM 1C. *CYBERSECURITY*

Risk Management and Strategy

Due to the size of our company, we have not yet developed robust policies and processes for assessing, identifying, and managing material risk from cybersecurity threats. We have implemented access controls with respect to our systems, which we monitor regularly. We currently rely heavily on products and services provided by third-party suppliers to operate certain critical business systems, including without limitation, cloud-based infrastructure, encryption and authentication technology, email, and other functions. We rely on third party providers and outsourced IT services to protect, detect, monitor, mitigate and address cybersecurity related risks, including installing software for threat protection and malware. Such third party providers are tasked with notifying management of any material risks or cybersecurity concerns that they identify, which management then assesses and may bring to our audit committee or board of directors to discuss if deemed necessary or appropriate. We also alert employees to significant new cybersecurity issues on a regular basis.

We rely heavily on third party service providers for our clinical development activities and cloud-based documentation and communications. A cybersecurity incident at a vendor or other third-party service provider could

have a material and adverse impact on our business, results of operations and financial condition. We do not currently have a formal process in place for evaluating or reviewing third party vendor cybersecurity risks and procedures and rely on such third parties to implement adequate protectionary and detection measures.

We do not specifically utilize assessors, consultants, auditors, or other third parties to evaluate or enhance our cybersecurity programs. On an annual basis, our information technology risks, controls and procedures are reviewed by third-party experts as part of our Sarbanes-Oxley review and testing.

Board Governance and Risk Management

Management Oversight

Our management team is primarily responsible for assessing and managing our strategic risk exposures, including material risks from cybersecurity threats, with assistance from third-party service providers. Due to the size of our company, we rely on outsourced information technology ("IT") and cybersecurity service providers to support certain operational and security functions, and our internal oversight is led by members of senior management.

Management's role in assessing and managing material risks from cybersecurity threats is led by our Chief Operating Officer and Chief Financial Officer, with oversight from our Chief Executive Officer. The Chief Operating Officer brings operational and technology-related experience, including prior experience in the information technology sector, and supports management oversight of our third-party IT environment. The Chief Financial Officer brings extensive experience in finance and accounting leadership, including experience with public company reporting, internal control environments and third-party service provider oversight. Collectively, these management roles provide the Company with executive-level oversight of cybersecurity risk governance, vendor coordination and incident escalation.

Prevention, Detection, Mitigation and Remediation; Escalation and Reporting

Our management team, in coordination with our outsourced IT and cybersecurity service providers, is responsible for monitoring and coordinating processes intended to support the prevention, detection, mitigation and remediation of cybersecurity incidents affecting our information systems and information residing with third-party providers. These processes are designed to be commensurate with our size, resources and risk profile and are informed by, among other things, the security capabilities embedded in key third-party systems we use (including cloud-based infrastructure and related security tools) and the ongoing monitoring and alerting performed by our outsourced IT providers.

In general, our outsourced IT providers are expected to notify management of significant cybersecurity risks, suspicious activity or cybersecurity incidents that they identify in the course of providing services. Management evaluates such information to determine appropriate response actions, which may include engaging external technical specialists (as needed), containing and remediating the issue, restoring systems and data (as applicable), and implementing corrective actions intended to reduce the likelihood of recurrence. Management also coordinates internal communication and, where appropriate, external communications and notifications.

Our board of directors has oversight responsibility for enterprise risk management, including risks from cybersecurity threats, which it administers directly and with assistance from its committees, primarily the audit committee. Throughout the year, the board and its committees engage with management to discuss a wide range of enterprise risks, including cybersecurity. The audit committee assists the board of directors by overseeing management's processes to assess and manage cybersecurity risks and receives updates from management regarding our cybersecurity program periodically, including at least annually, and more frequently as circumstances warrant. Cybersecurity incidents that are determined by management to be material, as well as significant cybersecurity matters (including significant changes in our risk profile), are escalated promptly to the audit committee, and the audit committee may report such matters to the full board, as appropriate.

To date, we are not aware of any cybersecurity incident that has had or is reasonably likely to have a material impact on our business or operations; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for us to be adversely impacted. This impact could result

in reputational, competitive, operational or other business harm as well as financial costs and regulatory action. See "Part I —Item 1A. Risk Factors" for further discussion of these risks.

ITEM 2. *PROPERTIES*

Our corporate headquarters is located in Newtown, Pennsylvania, where we lease short-term flexible office space. We believe that suitable additional or alternative space would be available on commercially reasonable terms if required in the future.

ITEM 3. *LEGAL PROCEEDINGS*

For a description of our material pending legal proceedings, please see Note 6, Commitments and Contingencies, to our consolidated financial statements included in Part IV in this Annual Report. We may, in the ordinary course of business, face various claims brought by third parties, and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights as well as claims relating to employment matters and the safety or efficacy of our products. Any of these claims could subject us to costly litigation. If this were to happen, the payment of any such awards could have a material adverse effect on our business, financial condition and results of operations. Additionally, any such claims, whether or not successful, could damage our reputation and business.

ITEM 4. *MINE SAFETY DISCLOSURES*

Not applicable.

PART II

ITEM 5. *MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES*

Market Information

Our common stock is listed under the symbol TRAW on the Nasdaq Capital Market.

Stockholders

As of April 13, 2026, there were approximately 55 holders of record for shares of our common stock. This does not reflect beneficial stockholders who held their common stock in "street" or nominee name through brokerage firms.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities

During the fiscal year ended December 31, 2025, there were no unregistered sales of our securities that were not reported in a Current Report on Form 8-K or our Quarterly Reports on Form 10-Q.

Issuer Repurchases of Equity Securities

There were no repurchases of our capital stock during the fourth quarter of 2025.

ITEM 6. *RESERVED*

ITEM 7. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS*

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

As of December 31, 2025, the Company had an accumulated deficit of $640.0 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development of, and seek regulatory approval for, our product candidates, even if milestones under our license and collaboration agreements may be met.

As of December 31, 2025, the Company had $3.8 million in cash and cash equivalents. Based on current projections, we do not have sufficient cash and cash equivalents as of the date of this Annual Report to support our operations for at least the 12 months following the date that the consolidated financial statements included herein are

issued. Accordingly, substantial doubt exists with respect to our ability to continue as a going concern within one year after the date that such financial statements are issued.

We are exploring various sources of funding for development and applying for regulatory approval of our research compounds as well as for our ongoing operations. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that are not favorable to us. There can be no assurance, however, that we will be successful in obtaining such financing in sufficient amounts, on terms acceptable to us, or at all. In addition, there can be no assurance that we will obtain approvals necessary to market our product candidates or achieve profitability or sustainable, positive cash flow. If we are unable to successfully raise sufficient additional capital, through future financings or through strategic and collaborative arrangements, we will not have sufficient cash to fund our ongoing trials and operations.

Our Portfolio/ Product Candidates/ Compounds

We are a clinical-stage biopharmaceutical company aiming to address unmet medical needs in respiratory viral diseases and cancer. Following the closing of the Merger in which we acquired Trawsfynydd Therapeutics, Inc. on April 1, 2024, we have four clinical programs:

- Tivoxavir marboxil, 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 influenza virus replication. Tivoxavir marboxil is intended to inhibit CEN and, thus, is intended to impede influenza virus replication including, the influenza A or B viral strains and bird flu viral strains. It is our intention to develop tivoxavir marboxil as an oral dose given only once for potential treatment and prophylaxis of bird flu and seasonal influenza.

  The first-in-man clinical study of tivoxavir marboxil (designated AV5124 in a previous study) was performed from May to September of 2023 in Russia. The study sponsor was Pharmasyntez, JSC. We have 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 tivoxavir marboxil. The study consisted of four dose cohorts that received 20, 40, 80 or 120 mg tivoxavir marboxil 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. In the study, one subject who received a single 40 mg dose of the study drug, experienced two adverse events ("AEs"). This subject experienced hyperglycemia, which was deemed to be mild and believed probably related to tivoxavir marboxil, and erosive gastritis with complications in the form of severe iron deficiency anemia, which was considered to be a serious adverse event ("SAE") believed 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 small food effect for tivoxavir marboxil, with increased exposure when drug was taken after a meal but otherwise showed increasing exposure with increasing dose.

  We advanced the development of tivoxavir marboxil with a Traws Pharma sponsored Phase 1 randomized, blinded, and placebo-controlled study in Australia that was approved by the Human Research Ethics Committee ("HREC"). This study enrolled four cohorts of 8 participants each, with 6 participants randomized to receive study drug and 2 participants assigned to receive placebo in each cohort. Participants were required to be healthy males or females ages 18-64 years. Participants took either one dose of the study drug or one dose of placebo. Dose levels evaluated in this study included 80, 120, 240 and 480 mg in capsules, taken orally. The primary endpoint of the study was the determination of safety and tolerability; the secondary and other endpoints included the determination

of the drug pharmacokinetic profile. Topline data showed good overall tolerability and a pharmacokinetic profile that appears to support the potential use of tivoxavir marboxil as a one-time treatment for influenza. Sixteen AEs were recorded, of which three were reported as possibly related to study drug during the study; all were mild headaches. Topline data from this study showed that a single dose of tivoxavir marboxil maintained plasma drug levels consistently above the EC90 and within the predicted therapeutic window for more than 23 days. On March 21, 2025, we submitted a request for a meeting with the FDA to align on a path forward, including to seek guidance regarding the potential for accelerated approval utilizing the "Animal Rule" for further development of tivoxavir marboxil in the treatment of H5N1 bird flu. The FDA "Animal Rule" allows approval of therapeutic interventions in cases where there is a risk of severe disease and a controlled human trial would be unethical or infeasible. Our meeting request was granted, and we submitted our briefing package to the FDA on April 24, 2025. On May 27, 2025, we received written responses from the FDA for a Type B pre-Investigational New Drug Application meeting ("pre-IND"). The FDA provided feedback on development paths for potential approval of tivoxavir marboxil for bird flu and seasonal flu, including on the potential use of the Animal Rule. On June 30, 2025, we announced our submission of briefing materials for a Type D meeting to enable further FDA dialog on a potential path to accelerated approval for bird flu, as a follow up to the pre-IND FDA interactions.

In addition, on June 30, 2025, we announced our proposed Phase 2 dose-ranging, non-inferiority study, which will evaluate the effects of tivoxavir marboxil in patients with seasonal influenza. A separate single arm will evaluate the effects of tivoxavir marboxil in patients infected with H5N1 bird flu. The proposed study has been submitted for HREC review and, once initiated, is expected to enroll subjects in Australia and selected countries in Southeast Asia with high rates of human bird flu infections. During a Type D meeting, the FDA affirmed its position that clinical trial data, rather than reliance on the Animal Rule, is the registrational path for bird flu therapeutics. We have determined to defer the initiation of this study at this time due to the low immediate likelihood of successfully recruiting a Phase 2 study incorporating bird flu-infected subjects. However, we believe that recent approval of our Phase 2 bird flu/seasonal flu phase 2 protocol by Australian and South Korean regulatory authorities will allow us to quickly initiate a clinical study in either the Southern or Northern Hemispheres, respectively, should the incidence rate of bird flu increase. On January 26, 2026, we announced our progression of an additional indication for tivoxavir marboxil as a single monthly oral tablet for the prophylactic treatment of seasonal influenza.

- Ratutrelvir ("TRX01"), which we acquired as part of the Merger, is an inhibitor of the main protease (also known as 3CL protease) of the SAR-CoV-2 virus, the causative agent in COVID-19. The main protease is an essential component in the mechanism for SARS-CoV-2 replication. TRX01 is intended to inhibit this protease and reduce SARS-CoV-2 virus replication. In vitro laboratory tests that measured the impact of TXR01 on SARS-CoV-2 replication, demonstrated that TRX01 inhibited the replication of viral isolates of the original SARS-CoV-2 isolates, and viral variants in the delta and omicron types. An animal study using the widely adopted K18 transgenic mouse model, demonstrated non-inferiority between TRX01 and the combination of nirmatrelvir + ritonavir, in terms of time to death and lung virus burden in this highly lethal model with neurological manifestations. Based on preclinical pharmacokinetic studies in multiple animal species, we intend to develop TRX01 for use without co-administration of a human cytochrome P450 ("CYP") inhibitor such as ritonavir.

TRX01 was studied in a Phase 1 clinical trial that included single and multiple ascending dose phases. Participants were required to be healthy males or females ages 18-64 years. The primary endpoint of the study was the measurement of safety and tolerability, and the secondary endpoint included the determination of the drug pharmacokinetic and pharmacodynamic profiles. The Phase 1 trial was conducted in Australia. It was sponsored by the Company and was approved by the Human Research Ethics Committee. The trial administered either the study drug or placebo to 40 participants in the single ascending dose phase, which included 5 cohorts with 8 participants in each cohort (6 received study drug and two received placebo). Subjects in the single ascending dose phase received one oral dose of the study drug or placebo, depending on their assigned group. The single ascending dose portion of the study assessed TRX01 at 15, 50, 150, 300 and 600 mg doses. Subjects in the multiple ascending dose phase received a daily single oral dose of 150 mg or 600 mg (6 active and 2 placebo) for 10 consecutive days. The study was completed in September 2024. There were few recorded adverse events reported up to the highest dose, and none were determined to be related to study drug. Topline data from the study showed no treatment related adverse events reported up to the highest dose. Topline data also showed that once-daily administration of TRX01 for 10 consecutive days maintained plasma drug levels within the predicted therapeutic window for 12 days.

TRX01 was studied in a Phase 1 clinical trial that included single and multiple ascending dose phases. Participants were required to be healthy males or females ages 18-64 years. The primary endpoint of the study was the measurement of safety and tolerability, and the secondary endpoint included the determination of the drug pharmacokinetic and pharmacodynamic profiles. The Phase 1 trial was conducted in Australia. It was sponsored by the Company and was approved by the Human Research Ethics Committee. The trial administered either the study drug or placebo to 40 participants in the single ascending dose phase, which included 5 cohorts with 8 participants in each cohort (6 received study drug and two received placebo). Subjects in the single ascending dose phase received one oral dose of the study drug or placebo, depending on their assigned group. The single ascending dose portion of the study assessed TRX01 at 15, 50, 150, 300 and 600 mg doses. Subjects in the multiple ascending dose phase received a daily single oral dose of 150 mg or 600 mg (6 active and 2 placebo in each cohort) for 10 consecutive days. The study was completed in September 2024. There were few recorded AEs reported up to the highest dose, and none were determined to be related to study drug. Topline data from the study showed no treatment related adverse events reported up to the highest dose. Topline data also showed that once-daily administration of TRX01 for 10 consecutive days maintained plasma drug levels within the predicted therapeutic window for 12 days. On June 30, 2025, we announced our proposed Phase 2 non-inferiority study, which will evaluate the effects of ratutrelvir in newly diagnosed COVID-19 patients, and on August 18, 2025, we announced receipt of approval from the HREC to proceed with the Phase 2 study. The study is intended to enroll patients on a 10-day treatment regimen for ratutrelvir compared to the approved 5-day regimen for PAXLOVID®. In addition to efficacy and safety endpoints, the proposed study will also evaluate the rates of disease rebound as well as the incidence of Long COVID-19. On October 14, 2025, we announced the dosing of the first subject in our Phase 2 study to evaluate ratutrelvir. We intend to initiate a separate single arm to evaluate the safety and efficacy of ratutrelvir in newly diagnosed COVID-19 patients who are ineligible for treatment with PAXLOVID®. On December 17, 2025, we reported positive interim Phase 2 data showing ratutrelvir had a favorable tolerability profile versus PAXLOVID® and no viral rebound events were observed in ratutrelvir-treated patients, while a rebound occurred in the PAXLOVID® arm. Interim results also showed activity in PAXLOVID® -eligible patients. On January 13, 2026, we reported interim data in a larger sample of 50 patients, suggesting faster time to sustained symptom resolution for ratutrelvir versus PAXLOVID®, continued no rebounds with ratutrelvir, and consistent safety/benefit signals in PAXLOVID®-eligible patients. On January 26, 2026, we announced the completion of enrollment of our ongoing 90-patient, open-label Phase 2 study of ratutrelvir versus PAXLOVID® in patients with mild-to-moderate COVID-19, together with a single arm in PAXLOVID®-ineligible subjects.

- Narazaciclib is our oral CDK4-plus inhibitor intended initially to treat low grade endometrioid endometrial cancer and other cancers. Narazaciclib is a multi-targeted kinase inhibitor targeting

multiple CDK's, AMP-activated protein kinase ("AMPK"), related protein kinase 5 ("ARK5"), and colony-stimulating factor 1 receptor ("CSF1R") at low nM concentrations, as well as other tyrosine kinases believed to drive tumor cell proliferation, survival and metastasis. We initiated a multi-center Phase 1/2a trial evaluating narazaciclib in combination with letrozole as a second or third-line therapy for recurrent metastatic low-grade endometrioid endometrial cancer in the first calendar quarter of 2023. In this study, both narazaciclib and letrozole were administered orally in the Phase 1 dose escalation phase. The first patient in this trial was dosed in May 2023 and the initial cohort (160mg) was completed and no DLTs were observed. The 200mg cohort enrolled 6 evaluable subjects but two patients experienced dose limiting toxicities. As a result, the dose of narazaciclib of 160mg once daily in combination with letrozole 2.5mg QD was declared to be the maximum tolerated dose and the recommended Phase 2 dose for women with low grade endometrioid endometrial cancer. This study is now closed to accrual. The database has been locked, and a clinical study report is currently under review.

Another Phase 1 study of narazaciclib as a monotherapy has also been conducted in patients with relapsed and/or refractory advanced cancer. The objectives of this study were to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of narazaciclib administered orally as escalating daily doses in patients with advanced cancer relapsed or refractory to at least 1 prior line of therapy. Narazaciclib was dosed on a continuous daily schedule in 28-day cycles. In this study, the highest dose tested was 280mg once daily given continuously. This study is now closed to accrual and data analysis is ongoing.

Narazaciclib is also being developed in greater China, under a 2017 license agreement between our company and HanX. The development in greater China is entirely sponsored by HanX. The compound is being studied in China in a clinical trial of patients with Grade III and IV glioma.

Our objective for narazaciclib is to establish additional partnerships for further development of the compound.

- Rigosertib is our second asset in oncology. Rigosertib is currently being studied in investigator initiated trials for epidermolysis bullosa-associated squamous cell carcinoma. Both studies included the use of either IV or oral rigosertib, depending on the clinical need of the patient. This is due to GI obstruction arising as a result of the presence of esophageal strictures complicating oral administration or extreme skin fragility complicating IV administration. It is, therefore, important in these patients that the investigator has both dosing options for the appropriate dosing of their patients. The data presented here are preliminary and may be subject to change. Our objective for this program is to establish partnerships for the development of rigosertib in this indication.

Recent Developments

April 2026 Financing

On April 15, 2026, we completed a financing transaction, with funding expected April 16, 2026, for aggregate gross proceeds of up to $60.0 million (the "April 2026 Financing"). The April 2026 Financing consisted of (i) $10.0 million of upfront gross proceeds at closing from the sale of 5,982,919 shares of our common stock (including pre-funded warrants in lieu thereof), (ii) the issuance of milestone-based warrants with an aggregate exercise price of $10.0 million that becomes exercisable upon receipt of approval from the Medicines and Healthcare products Regulatory Agency ("MHRA") to conduct the human challenge trial in the UK, (iii) the issuance of additional milestone-based warrant with an aggregate exercise price of $10.0 million that becomes exercisable upon shareholder approval and the announcement of data from the human challenge trial and (iv) the issuance of common warrants, subject to shareholder approval, with a three-year term to purchase shares of our common stock, providing potential additional gross proceeds of $30.0 million if fully exercised. The milestone-based warrants and the common warrants each have an exercise price equal to the per share purchase price in the April 2026 Financing. The common warrants are subject to a forced exercise provision if the trading price of our common stock equals or exceeds 200%

of the applicable exercise price for 30 consecutive trading days. The milestone-based warrants become exercisable only upon achievement of the applicable milestone conditions, and there can be no assurance that we will receive any additional proceeds from the exercise of the milestone-based warrants or the common warrants, or as to the timing thereof.

At close, we paid transaction costs including a cash success fee equal to 6% of the upfront gross proceeds, and we intend to use the net proceeds for working capital and general corporate purposes, including funding our clinical and regulatory activities.

Asset Acquisition

On September 9, 2025, we entered into an Asset Purchase Agreement (the "Purchase Agreement") with Viriom, Inc. ("Viriom"), a related party, pursuant to which we purchased a patent from Viriom in exchange for $2,350,000 in cash. The patent includes certain intellectual property and other assets related to a pyrrolidine antiviral compound. We also incurred legal costs in consummating the Purchase Agreement of $235,000 to the acquired patent. See Note 3, Asset Acquisition, to our consolidated financial statements included in Part I of this Quarterly Report for more information regarding the Purchase Agreement.

At the Market Offering Agreement

On March 10, 2025, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with Citizens JMP Securities, LLC ("Citizens"), pursuant to which the Company may offer and sell shares of its common stock, having aggregate sales price of up to $50,000,000 (subject to certain limitations set forth in the ATM Agreement, including the "baby shelf" limitation under General Instruction I.B.6. of Form S-3), from time to time, to or through Citizens, acting as sales agent and/or principal. The Company is not obligated to make any sales of common stock under the ATM Agreement and no assurance can be given that the Company will sell any shares under the ATM Agreement, or, if it does, as to the price or amount of shares that the Company will sell, or the dates on which any such sales will take place. The ATM Agreement may be terminated by the Company at any time with five business days' notice to Citizens, by Citizens at their discretion, or as otherwise permitted in the ATM Agreement.

The shares of common stock sold to Citizens under the ATM Agreement will be sold pursuant to the Company's effective shelf registration statement on Form S-3 and an accompanying prospectus (Registration Statement No. 333-273081), filed with the SEC on June 30, 2023, and declared effective by the Commission on July 11, 2023, including the base prospectus contained therein, as supplemented by those prospectus supplements dated March 10, 2025 and April 7, 2025 (the "Prospectus Supplements") and filed with the SEC pursuant to Rule 424(b) under the Securities Act, or subsequently filed prospectus supplements as applicable. In accordance with the terms of the ATM Agreement, the Company may offer and sell shares of its common stock having an aggregate offering price of up to $7.4 million (which is in addition to the gross proceeds of approximately $0.1 million from sales completed prior to April 7, 2025), from time to time, to or through Citizens, which was the Company's current "baby shelf" limitation under General Instruction I.B.6. of Form S-3 as of the date of filing the Prospectus Supplement. In the year ended December 31, 2025, the Company sold and issued an aggregate of 2,517,270 shares of its common stock under the ATM Agreement for net proceeds of $5.2 million.

The Company will pay Citizens a commission at a fixed rate of 3.0% of the gross proceeds of each sale of shares of common stock sold through or to Citizens under the ATM Agreement and will reimburse Citizens for the fees and disbursements of its legal counsel incurred in connection with entering into the transactions contemplated by the ATM Agreement in an amount not to exceed $50,000 in the aggregate, in addition to up to $5,000 per "Representation Date" (as defined in the ATM Agreement) in connection with ongoing diligence arising from the transactions contemplated by the ATM Agreement.

The Company made certain customary representations, warranties and covenants in the ATM Agreement concerning the Company and its subsidiaries, the registration statement and base prospectus contained therein, prospectus

supplement and other documents and filings relating to the offering of the shares under the ATM Agreement. In addition, the Company has also provided Citizens with customary indemnification rights.

Warrants

On February 17, 2025, the Company held a special meeting of its stockholders, at which, the Company's stockholders approved (i) in accordance with Nasdaq Listing Rule 5653(d), the issuance of more than 19.99% of the outstanding shares of the Company's common stock upon exercise of the pre-funded warrants and Series A Warrants sold and issued to investors in a private placement on December 31, 2024 (the "December 2024 Offering"), and (ii) in accordance with Nasdaq Listing Rule 5653(c), the issuance of shares of the Company's common stock upon exercise of the pre-funded warrants and Series A Warrants sold and issued to certain insiders in the December 2024 Offering. As a result of such approvals, the pre-funded warrants became immediately exercisable and limitations on the exercisability of the Series A Warrants under applicable Nasdaq rules were lifted. Subsequent to such shareholder meeting, and through December 31, 2025, certain purchasers have exercised their pre-funded warrants for an aggregate of 2,628,962 shares of the Company's common stock.

On February 18, 2025, the Company and certain of the purchasers of units in the December 2024 Offering entered into amendments to the Series A Warrants issued to such purchasers in the offering (the "Series A Warrant Amendment"), pursuant to which the Series A Warrants issued to such purchasers were amended to (i) increase the threshold for a change of control, for purposes of determining whether a Fundamental Transaction (as defined in the Series A Warrants) has occurred, from 50% of the outstanding common stock of the Company to greater than 50% of the outstanding common stock of the Company, (ii) revise the expected volatility rate to be applied for purposes of determining the Black Scholes Value of the Series A Warrants to be utilized for calculating consideration payable to the holders of the Series A Warrants in connection with a Fundamental Transaction that is not within the Company's control, and (iii) remove Section 3(h) of the Series A Warrants, which, under certain circumstances, provided for adjustments to the exercise price of the Series A Warrants in the event of a reverse stock split, stock consolidation, or a recapitalization or similar event involving the Company's common stock based on the volume weighted average price of the Company's common stock over the eleven trading day period commencing five trading days immediately preceding such event and the five trading days immediately following such event.

On March 27, 2025, the Company and the holders of all outstanding pre-funded warrants issued in the December 2024 Offering entered into amendments to the pre-funded warrants issued to such purchasers in the offering (the "PFW Amendment"), pursuant to which the pre-funded warrants issued to such purchasers were amended to increase the threshold for a change of control, for purposes of determining whether a Fundamental Transaction (as defined in the pre-funded warrants) has occurred, from 50% of the outstanding common stock of the Company to greater than 50% of the outstanding common stock of the Company.

Changes in Management and the Board of Directors

Effective as of the close of business on March 31, 2025, Werner Cautreels retired and resigned from his role as Chief Executive Officer of the Company and Iain Dukes, who was serving as Executive Chairman as of such date, was appointed as Interim Chief Executive Officer and his director role changed from Executive Chairman to Chairman of the Board. Dr. Cautreels continues to serve as a director on the Company's Board of Directors (the "Board") and now provides certain consulting services to the Company.

On April 15, 2025, Dr. Dukes stepped down as Chairman of the Board, and the Board appointed Jack Stover, an independent director who has served as a member of the Board since 2016, as Chairman. Dr. Dukes continues to serve as a member of the Board. On October 1, 2025, the Board eliminated the "interim" notation in Dr. Iain Dukes' title, who now holds the title of Chief Executive Officer.

On July 2, 2025, Nora Brennan notified the Company of her decision to resign from her role as Interim Chief Financial Officer of the Company, effective as of July 5, 2025, which was the final day of the interim period contemplated by that offer letter entered into by and between the Company and Ms. Brennan on February 5, 2025. Effective as of July 5, 2025, Charles Parker was appointed to serve as the Company's Interim Chief Financial Officer. On October 1, 2025,

the Board eliminated the "interim" notation in Mr. Parker's title, who now holds the title of Chief Financial Officer. Mr. Parker has been retained to provide such services as a non-employee consultant of the Company.

On October 1, 2025, the Board appointed John Leaman, MD as an independent director of the Company, with a term expiring at the Company's 2025 annual meeting of stockholders. Dr. Leaman was also appointed as a member of the Audit Committee of the Board.

Financial Overview

Revenue

During the years ended December 31, 2025 and 2024, our revenues were derived exclusively from activities conducted in accordance with our collaboration arrangement with SymBio Pharmaceuticals Limited ("Symbio"). Effective April 17, 2025, the Company and Symbio mutually terminated the license agreement originally entered into by and between the parties in 2011. No payments, compensation, reimbursements or settlements shall be due or owed by either party in connection with the termination of the license agreement.

We have not generated any revenue from commercial product sales. In the future, if any of our product candidates currently under development are approved for commercial sale in the United States or other territories where we have retained commercialization rights, we may generate revenue from product sales, or alternatively, we may choose to select a collaborator to commercialize our product candidates in these markets.

Operating Expenses

In-Process Research and Development

Research and development costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility which includes manufacturing, clinical, intellectual property and/or regulatory success which has no alternative future use. The licenses purchased by us require substantial completion of research and development and regulatory and marketing approval efforts in order to reach technological feasibility. As such, and since our inception, the purchase price of licenses acquired is classified as acquired in-process research and development expenses in the statements of operations.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials and preclinical studies;
- the cost of acquiring, developing and manufacturing clinical trial materials;
- direct expenses for maintenance of research equipment, clinical trial insurance and other supplies; and
- costs associated with preclinical activities and regulatory operations.

Research and development costs are expensed as incurred. License fees and milestone payments we make related to in-licensed products and technology are expensed if it is determined that they have no alternative future use. We record

costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

Our research and development expenses are related to tivoxavir marboxil, ratutrelvir, narazaciclib, rigosertib, and potentially in-licensed products. We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis because we are organized and record expense by functional department and our employees may allocate time to more than one development project. Accordingly, we do not allocate expenses to individual projects or product candidates, although we do allocate some portion of our research and development expenses by functional area.

It is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates, or if, when or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, an assessment of each product candidate's commercial potential and our available funds.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for executive and other administrative personnel, including stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, communication expenses, insurance, board of directors expenses and professional fees for legal, patent review, consulting and accounting services.

We anticipate that our general and administrative expenses will remain consistent in the short-term, but would increase in the future with the continued research and development and potential commercialization of our product candidates. These increases will likely include increased costs for insurance, costs related to the hiring of additional personnel and payments to outside consultants among other expenses. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

Change in fair value of warrant liability

Change in fair value of warrant liability represents the remeasurement of the warrant liability upon amendment of the pre-funded and Series A Warrants issued in the December 2024 Offering, the exercise of pre-funded warrants, and the remaining Series A Warrants.

Series A Warrant and pre-funded warrant expense

Series A Warrant and pre-funded warrant expense represents the excess of the warrant liability compared to the net proceeds received as part of the December 2024 Offering.

Other Income, Net

Other income, net consists principally of interest income earned on cash and cash equivalent balances and foreign exchange gains and losses.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

	Year ended December 31,		
	2025	2024	Change
Revenue	$ 2,790,000	$ 226,000	$ 2,564,000
Operating expenses:			
Acquired in-process research and development	—	117,464,000	(117,464,000)
Research and development	12,143,000	12,847,000	(704,000)
General and administrative	8,522,000	12,289,000	(3,767,000)
Total operating expenses	20,665,000	142,600,000	121,935,000
Loss from operations	(17,875,000)	(142,374,000)	124,499,000
Change in fair value of warrant liability	26,567,000	—	26,567,000
Series A warrant and prefunded warrant expense	—	(24,438,000)	24,438,000
Other income, net	478,000	289,000	189,000
Net income (loss)	$ 9,170,000	$ (166,523,000)	$ 175,693,000

Revenues

Revenues were $2.8 million and $0.2 million for the years ended December 31, 2025 and 2024, respectively, related to the Company's license agreement with Symbio. The increase of $2.6 million is due to the immediate revenue recognition of the remaining deferred revenue of $2.7 million as a result of terminating the license agreement with Symbio on April 17, 2025. No further revenue will be recognized going forward in connection with this agreement.

Acquired in-process research and development

In connection with the acquisition of Trawsfynydd in the Merger, during year ended December 31, 2024, the Company recognized a non-cash in-process research and development expense of $117.5 million related to the acquired virology programs that had no alternative future use at the time of acquisition, which required immediate expense recognition.

Research and development expenses

The details of our research and development expenses are:

	Year ended December 31,	
	2025	2024
Virology	$ 9,513,000	$ 4,589,000
Oncology	654,000	5,290,000
Personnel related	1,852,000	2,787,000
Stock based compensation	124,000	181,000
	$ 12,143,000	$ 12,847,000

Research and development expenses decreased by $0.7 million, or (6%), to $12.1 million for the year ended December 31, 2025, from $12.8 million for the year ended December 31, 2024. The decrease was primarily driven by a $4.6 million decrease in oncology expenses as we continue to pursue strategic partnerships for our oncology assets, a $0.9 million decrease in personnel expenses, and a $0.1 million decrease in stock based compensation, partially offset by a $4.9 million increase in virology expenses due to our focus on initiating Phase 2 studies for both tivoxavir marboxil and TRX01.

General and administrative expenses

The details of our general and administrative expenses are:

	Year Ended December 31,	
	2025	2024
Professional & consulting fees	$ 3,474,000	$ 5,954,000
Stock based compensation	604,000	1,209,000
Personnel related	2,457,000	3,035,000
Public company costs	1,150,000	1,231,000
Insurance & other	837,000	860,000
	$ 8,522,000	$ 12,289,000

General and administrative expenses decreased by $3.8 million, or (31)%, to $8.5 million for the year ended December 31, 2025, from $12.3 million for the year ended December 31, 2024, primarily due to a decrease in professional and consulting fees as a result of a decrease in legal expenses related to oncology patent fees.

Change in fair value of warrant liability

Change in fair value of warrant liability of $26.6 million during the year ended December 31, 2025 represents the remeasurement of the warrant liability upon amendment of the pre-funded and Series A Warrants issued in the December 2024 Offering, the exercise of pre-funded warrants, and the remaining Series A Warrants as of December 31, 2025.

Series A warrant and prefunded warrant expense

Series A Warrant and pre-funded warrant expense of $24.4 million during the year ended December 31, 2024 represents the excess fair value of the warrant liabilities of $42.5 million over the $18.1 million in net proceeds in connection with the December 2024 Purchase Agreement.

Other income, net

Other income, net, increased by $0.2 million for the year ended December 31, 2025 compared to the year ended December 31, 2024. The change was caused by interest earned on our excess cash balances during the year.

Liquidity and Capital Resources

As of December 31, 2025, we had cash and cash equivalents of $3.8 million, an accumulated deficit of $640.0 million, and a working capital deficit of $3.2 million. Since inception, we have experienced negative cash flows from our operations and expect to continue to incur significant expenses in connection with our ongoing activities.

On April 15, 2026, we completed the April 2026 Financing, with funding expected April 16, 2026. The April 2026 Financing consisted of (i) $10.0 million of upfront gross proceeds at closing from the sale of shares of our common stock (or pre-funded warrants in lieu thereof), (ii) a milestone-based warrant with an aggregate exercise price of $10.0 million that becomes exercisable upon receipt of approval from the Medicines and Healthcare products Regulatory Agency ("MHRA") to conduct the human challenge trial in the UK, (iii) a second milestone-based warrant with an aggregate exercise price of $10.0 million that becomes exercisable upon shareholder approval and the announcement of data from the human challenge trial and (iv) common warrants, subject to shareholder approval, with a three-year term to purchase shares of our common stock, providing potential additional gross proceeds of $30.0 million if fully exercised.

The milestone-based warrants become exercisable only upon achievement of the applicable milestone conditions, and there can be no assurance that we will receive any additional proceeds from the exercise of the milestone-based warrants or the common warrants, or as to the timing thereof. If we do not receive additional proceeds from the exercise of the warrants or obtain capital from other sources, we will need to raise additional capital to fund our operations and to satisfy our obligations as they become due.

Based on our current projections, as of the date of this Annual Report, we believe that our existing cash and cash equivalents, together with the net proceeds received at closing from the April 2026 Financing, will not be sufficient to fund our operating requirements for at least the 12 months following the date that the consolidated financial statements included herein are issued. Accordingly, substantial doubt exists with respect to our ability to continue as a going concern within one year after the date that such financial statements are issued.

We will require substantial additional financing to fund our ongoing clinical trials and operations, and to continue to execute our strategy. There can be no assurance that we will be successful in obtaining such funding in sufficient amounts, on terms acceptable to us, or at all. The failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on our business, results of operations, and financial condition.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Cash Flows

The following table summarizes our cash flows for the year ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	**2024**
Net cash (used in) provided by:		
Operating activities	$ (18,185,000)	$ (29,792,000)
Investing activities	(2,585,000)	(3,648,000)
Financing activities	3,204,000	33,976,000
Effect of foreign currency translation	48,000	(19,000)
Net increase (decrease) in cash and cash equivalents	$ (17,518,000)	$ 517,000

Net cash used in operating activities

Net cash used in operating activities was $18.2 million for the year ended December 31, 2025 and consisted primarily of non-cash charges of $25.8 million primarily attributable to the change in fair value of warrant liability of $26.6 million and a $1.6 million change in operating assets and liabilities, partially offset by net income of $9.2 million. Significant changes in operating assets and liabilities included a decrease in deferred revenue of $2.8 million due to the recognition of revenue upon terminating our license agreement with Symbio and an increase in receivables of $2.0 million due to the timing of payment of our Australian tax incentive refund.

Net cash used in operating activities was $29.8 million for the year ended December 31, 2024 and consisted primarily of a net loss of $166.5 million and a $6.5 million change in operating assets and liabilities. Significant changes in operating assets and liabilities included a net decrease in accounts payable and accrued expenses of $4.5 million due to timing of invoices and payments to our vendors. These operating uses of cash were offset by $143.3 million in non-cash charges primarily attributable to the immediate expensing of in-process research and development acquired in connection with the Merger of $117.5 million, immediate expensing of the Series A warrant and pre-funded warrant expense of $24.4 million, and $1.4 million related to stock-based compensation expense.

Net cash used in investing activities

Net cash used in investing activities was $2.6 million for the year ended December 31, 2025 and was attributable to the purchase of intangible assets.

Net cash used in investing activities was $3.6 million for the year ended December 31, 2024 and primarily related to the transaction costs of $3.6 million in connection with the Merger.

Net cash provided by financing activities

Net cash provided by financing activities was $3.2 million for the year ended December 31, 2025 and was attributable to the proceeds received from the sale of shares of our common stock under the ATM and proceeds from exercised warrants, partially offset by the payment of offering costs.

Net cash provided by financing activities was $34.0 million for the year ended December 31, 2024 and primarily attributable to the net proceeds received from the sale of our preferred and common stock in connection with the securities offerings in April and December 2024.

Material Cash Requirements

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. We expect net cash expended in 2026 to be higher than 2025 due to clinical trials and increased headcount in our clinical and regulatory groups. We enter into contracts in the normal course of business with third-party contract organizations for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore we believe that, currently, our non-cancelable obligations under these agreements are not material. Based on current projections, we believe that we do not have sufficient cash and cash equivalents to support our operations for more than one year following the date that these financial statements from our Annual Report on Form 10-K are issued. These conditions raise substantial doubt about our ability to continue as a going concern through the one-year period after the date that the financial statements are issued.

We are exploring various sources of funding for continued development and any potential in-licensed compounds as well as our ongoing operations. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates, even if milestones under our license and collaboration agreements may be met. If we obtain regulatory approval for any of our product candidates, we expect to incur significant NDA preparation and commercialization expenses. We do not currently have a relationship with an organization for the sales, marketing and distribution of pharmaceutical products. In the future, we may rely on licensing and co-promotion agreements with strategic or collaborative partners for the commercialization of our products in the United States and other territories. If we choose to build a commercial infrastructure to support marketing in the United States for any of our product candidates that achieve regulatory approval, such commercial infrastructure could be expected to include a targeted, oncology sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to having any certainty about marketing approval. Furthermore, we have and expect to continue to incur additional costs associated with operating as a public company.

Please see “Risk Factors” for additional risks associated with our substantial capital requirements.

Pro Forma Impact of the April 2026 Financing

The following financial information has been developed by application of pro forma adjustments to the historical financial statements of the Company appearing elsewhere in this Annual Report. The unaudited pro forma information gives effect to the 2026 Private placement.

The unaudited pro forma financial information is presented for informational purposes only and does not purport to represent what the results of operations or financial position of the Company would have been had the transactions described above actually occurred on the dates indicated, nor do they purport to project the financial condition of the Company for any future period or as of any future date. The unaudited pro forma financial information should be read in conjunction with the Company’s financial statements and notes thereto included elsewhere in this Annual Report.

Unaudited Pro Forma Balance Sheet

	As of December 31, 2025		
	As Reported	Adjustments April 2026 Financing	Pro Forma As Adjusted
Assets			
Current assets:			
Cash and cash equivalents	$ 3,820,000	$ 9,400,000	$ 13,220,000
Tax incentive and other receivables	3,794,000	—	3,794,000
Prepaid expenses and other assets	365,000	—	365,000
Total current assets	7,979,000	9,400,000	17,379,000
Property and equipment, net	7,000	—	7,000
Intangible assets, net	2,527,000	—	2,527,000
Other assets	104,000	—	104,000
Total assets	$ 10,617,000	$ 9,400,000	$ 20,017,000
Liabilities and stockholders' (deficit) equity			
Current liabilities:			
Accounts payable	$ 5,653,000	$ —	$ 5,653,000
Accrued expenses and other liabilities	5,493,000	—	5,493,000
Total current liabilities	11,146,000	—	11,146,000
Warrant liabilities	100,000	—	100,000
Total liabilities	11,246,000	—	11,246,000
Stockholders' (deficit) equity:			
Series C Preferred stock, $0.01 par value, 5,000,000 shares authorized, 7,440 shares issued and 6,737 shares outstanding at December 31, 2025 and 7,440 shares issued and 7,398 outstanding at December 31, 2024	—	—	—
Common stock, $0.01 par value, 250,000,000 shares authorized, 9,067,774 and 3,650,731 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	90,000	—	90,000
Additional paid in capital	639,259,000	9,400,000	648,659,000
Accumulated deficit	(639,984,000)	—	(639,984,000)
Accumulated other comprehensive income	6,000	—	6,000
Total stockholders' (deficit) equity	(629,000)	9,400,000	8,771,000
Total liabilities and stockholders' (deficit) equity	$ 10,617,000	$ 9,400,000	$ 20,017,000

The unaudited pro forma balance sheet as of December 31, 2025 gives effect to an assumed $10.0 million gross equity financing completed after December 31, 2025. Offering costs are assumed to be $0.6 million (6% of gross proceeds) and are reflected as a reduction of additional paid-in capital in accordance with U.S. GAAP. No proceeds from warrant exercises are reflected.

Critical Accounting Policies and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with US generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and

liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

We believe the following accounting policies may involve a higher degree of judgment and complexity in their application than our other accounting policies and represent the most critical judgments and estimates used in the preparation of our consolidated financial statements. Our significant accounting policies are presented within Note 2 to our Financial Statements.

Clinical Trial Expense

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants and CROs and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by matching the appropriate expenses with the period in which services are provided and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models that take into account discussion with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on the facts and circumstances known to us at that time. Our clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements found in this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our consolidated financial statements.

ITEM 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*

As a smaller reporting company, the Company is not required to provide the information otherwise required by this Item.

ITEM 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

The financial statements and supplementary data required by this item are listed in Item 15 — "Exhibits and Financial Statement Schedules" of this Annual Report.

ITEM 9. *CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE*

None.

ITEM 9A. *CONTROLS AND PROCEDURES*

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer), has evaluated, as of the end of the period covered by this Annual Report,

the effectiveness of our "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, to allow timely decisions regarding required disclosure. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2025, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control Over Financial Reporting

As required by SEC rules and regulations implementing Section 404 of the Sarbanes-Oxley Act, our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our internal control over financial reporting was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with GAAP. Our internal control over financial reporting includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company,

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Management assessed our internal control over financial reporting as of December 31, 2025, the end of our fiscal year. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control — Integrated Framework (2013)." Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. Based on the results of its evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

As a result of the enactment of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the resulting amendment of Section 404 of the Sarbanes-Oxley Act of 2002, as a smaller reporting company, the Company is not required to provide an attestation report by our independent registered public accounting firm regarding internal control over financial reporting for the fiscal year ended December 31, 2025 or thereafter, until such time as we are no longer eligible for the exemption for smaller issuers set forth within the Sarbanes-Oxley Act.

Inherent Limitations on Effectiveness of Controls

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well-designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of the effectiveness of controls to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Control Over Financial Reporting

We remediated the material weakness related to our internal control over financial reporting, as described below. Except as otherwise described herein, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Remediation of Material Weakness in Internal Control over Financial Reporting

We strengthened our internal control over financial reporting by implementing a formal risk assessment process to identify and analyze risks of misstatement due to fraud and/or error, and by establishing appropriate segregation of duties over the preparation, review and posting of manual journal entries. Management believes that significant progress has been made in enhancing internal controls as of December 31, 2025 and has concluded that the enhanced controls are operating effectively. The material weakness described in Part II, Item 9A, "Controls and Procedures" in our Annual Report on Form 10-K for the year ended December 31, 2024 has been fully remediated.

ITEM 9B. *OTHER INFORMATION*

Securities Trading Plans of Directors and Executive Officers

During the three months ended December 31, 2025, none of our directors or officers entered into, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," in each case as defined in Item 408 of Regulation S-K.

ITEM 9C. *DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS*

Not applicable.

PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

Information with respect to this item will be set forth in the Proxy Statement for the 2026 Annual Meeting of Stockholders (the "Proxy Statement") under the headings "Election of Directors," "Executive Officers," "Section 16(a) Beneficial Ownership Reporting Compliance," "Code of Ethics" and "Corporate Governance" and is incorporated herein by reference.

ITEM 11. *EXECUTIVE COMPENSATION*

Information with respect to this item will be set forth in the Proxy Statement under the headings "Executive Compensation" and "Director Compensation," and is incorporated herein by reference.

ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS*

Information with respect to this item will be set forth in the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation," and is incorporated herein by reference.

ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE*

Information with respect to this item will be set forth in the Proxy Statement under the headings "Certain Relationships and Related Party Transactions" and "Corporate Governance" and is incorporated herein by reference.

ITEM 14. *PRINCIPAL ACCOUNTING FEES AND SERVICES*

Information with respect to this item will be set forth in the Proxy Statement under the heading "Ratification of the Selection of Independent Registered Public Accounting Firm," and is incorporated herein by reference.

PART IV

ITEM 15. *EXHIBITS AND FINANCIAL STATEMENT SCHEDULES*

(a) (1) Financial Statements: See Index to Consolidated Financial Statements on page F-1.

(3) Exhibits: See Exhibits Index on page 75

ITEM 16. *FORM 10-K SUMMARY*

Information with respect to this item is not required and has been omitted at the Company's option.

Exhibit Number	Exhibit Description
2.1	Agreement and Plan of Merger, dated April 1, 2024, by and among the Onconova Therapeutics, Inc., Traws Merger Sub I, Inc., Traws Merger Sub II, LLC, and Trawsfynydd Therapeutics, Inc *(Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on April 3, 2024)*.
3.1	Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc. *(Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 25, 2013).*
3.2	Certificate of Amendment to Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc. (*Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 31, 2016*).
3.3	Certificate of Amendment to Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc., as amended (*Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on March 22, 2018*).
3.4	Certificate of Amendment to Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc., as amended (*Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 8, 2018*).
3.5	Certificate of Amendment to Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc., as amended *(Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on September 25, 2018).*
3.6	Certificate of Designation of Series A Convertible Preferred Stock (*Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 8, 2018*).
3.7	Certificate of Designation of Series B Convertible Preferred Stock (*Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on April 30, 2018*).
3.8	Certificate of Amendment to the Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc., as amended (*Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 20, 2021*).
3.9	Certificate of Amendment to the Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc., as amended (*Incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on May 20, 2021*).
3.10	Certificate of Designation of Series C Non-Voting Convertible Preferred Stock of Onconova Therapeutics, Inc., dated April 1, 2024 *(Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on April 3, 2024)*.
3.11	Certificate of Amendment to Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc., as amended, dated April 2, 2024 *(Incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on April 3, 2024)*.
3.12	Certificate of Amendment to the Tenth Amended and Restated Certificate of Incorporation of Traws Pharma, Inc., as amended (the Reverse Stock Split Certificate of Amendment) (*Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on September 17, 2024)*.
3.13	Certificate of Amendment to the Tenth Amended and Restated Certificate of Incorporation of Traws Pharma, Inc., as amended (the Authorized Shares Increase Certificate of Amendment) (*Incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on September 17, 2024*).

Exhibit Number	Exhibit Description
3.14	Amended and Restated Bylaws of Onconova Therapeutics, Inc. *(Incorporated by reference to Exhibit 3.2 to Pre-Effective Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on July 11, 2013).*
3.15	Amendment to Amended and Restated Bylaws of Traws Pharma, Inc., effective as of June 26, 2024 (*Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 28, 2024*).
4.1	Form of Certificate of Common Stock *(Incorporated by reference to Exhibit 4.1 to Pre-Effective Amendment No. 1 the Company's Registration Statement on Form S-1 filed on July 11, 2013).*
4.2	Form of Pre-Funded Warrant, issued as of February 12, 2018 (*Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on February 8, 2018*).
4.3	Form of Pre-Funded Warrant, issued as of May 1, 2018 (*Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on April 30, 2018*).
4.4	Form of Series A Warrant, dated December 31, 2024 (*Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 31, 2024*).
4.5	Form of Pre-Funded Warrant, dated December 31, 2024 (*Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on December 31, 2024*).
4.6	Form of Amendment to Series A Common Stock Purchase Warrant, by and between Traws Pharma, Inc. and certain holders, dated February 18, 2025 (*Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 18, 2025*).
4.7	Form of Amendment to Pre-Funded Warrant, by and between Traws Pharma, Inc. and certain holders, dated March 27, 2025.(*Incorporated by reference to Exhibit 4.7 to the Company's Annual Report on Form 10-K filed on March 31, 2025*).
4.8	Description of the Company's Securities Registered under Section 12 of the Securities Exchange Act of 1934, as amended *(Incorporated by reference to Exhibit 4.8 to the Company's Annual Report on Form 10-K filed on March 31, 2025).*
10.1+	Onconova Therapeutics, Inc. 2007 Equity Compensation Plan, and forms of agreement thereunder *(Incorporated by reference to Exhibit 10.13 to Pre-Effective Amendment No. 1 the Company's Registration Statement on Form S-1 filed on July 11, 2013).*
10.2+	Consulting Agreement, effective as of January 1, 2012, by and between Onconova Therapeutics, Inc. and E. Premkumar Reddy, Ph.D., including Consultant Agreement Renewal, dated February 27, 2013 *(Incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.3+	Form of Indemnification Agreement entered into by and between Onconova Therapeutics, Inc. and each director and executive officer *(Incorporated by reference to Exhibit 10.24 to Pre-Effective Amendment No. 1 the Company's Registration Statement on Form S-1 filed on July 11, 2013).*
10.4+	Onconova Therapeutics, Inc. 2013 Equity Compensation Plan, and forms of agreement thereunder *(Incorporated by reference to Exhibit 10.25 to Pre-Effective Amendment No. 1 the Company's Registration Statement on Form S-1 filed on July 11, 2013).*
10.5+	Onconova Therapeutics, Inc. 2013 Performance Bonus Plan *(Incorporated by reference to Exhibit 10.26 to Pre-Effective Amendment No. 1 the Company's Registration Statement on Form S-1 filed on July 11, 2013).*
10.6*	License, Development and Commercialization Agreement, dated as of March 2, 2018, by and between Onconova Therapeutics, Inc. and Pint International SA (*Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 15, 2018*).
10.7+	Onconova Therapeutics, Inc. 2018 Omnibus Incentive Compensation Plan, as approved by the stockholders (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 29, 2018*).
10.8+	Form of Nonqualified Stock Option Award Agreement under the Onconova Therapeutics, Inc. 2018 Omnibus Incentive Compensation Plan (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 30, 2018*).
10.9	License and Collaboration Agreement, effective as of May 10, 2019, by and between Onconova Therapeutics, Inc. and HanX Biopharmaceuticals, Inc. (*Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2019*).

Exhibit Number	Exhibit Description
10.10	Securities Purchase Agreement, effective as of May 10, 2019, by and between Onconova Therapeutics, Inc. and HanX Biopharmaceuticals, Inc. (*Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2019*).
10.11**	Distribution, License and Supply Agreement, effective as of November 20, 2019, by and between Onconova Therapeutics, Inc. and Knight Therapeutics, Inc. (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 21, 2019*).
10.12**	Distribution, License and Supply Agreement, by and between Onconova Therapeutics, Inc. and Specialised Therapeutics Asia Pte. Ltd., effective as of December 18, 2019 (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 19, 2019*).
10.13+	Form of Stock Appreciation Right Award Agreement (for Employees) (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 10, 2020)*.
10.14+	Form of Stock Appreciation Right Award Agreement (for Non-Employee Directors) (*Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 16, 2020)*.
10.15+	Form of Performance Stock Unit Award Agreement (*Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 10, 2020)*.
10.16+	Form of Restricted Stock Unit Agreement *(Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 15, 2021*).
10.17+	Form of Non-Qualified Stock Option Agreement *(Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 15, 2021*).
10.18	Master Research and Development Agreement dated January 5, 2022, by and between Viriom, Inc and Trawsfynydd Therapeutics, Inc. (*Incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K filed on March 31, 2025*).
10.19	Master Research and Development Agreement dated September 23, 2022, by and between ChemDiv, Inc. and Trawsfynydd Therapeutics, Inc. (*Incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K filed on March 31, 2025*).
10.20	Master Research and Development Agreement dated September 1, 2022, by and between Expert Systems, Inc. and Trawsfynydd Therapeutics, Inc. (*Incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K filed on March 31, 2025*).
10.21+	Onconova Therapeutics, Inc. 2021 Incentive Compensation Plan *(Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2022)*.
10.22	License Agreement, dated January 20, 2023, by and between Trawsfynydd Therapeutics, Inc. and Viriom, Inc. (*Incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K filed on March 31, 2025*).
10.23+	Employment Agreement, dated as of October 2, 2023, by and between Onconova Therapeutics, Inc. and Victor Mandia Moyo, MBChB (*Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2023*).
10.24**	Securities Purchase Agreement, dated April 1, 2024, by and among the Onconova Therapeutics, Inc., OrbiMed and TorreyPines (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 3, 2024*).
10.25+	Employment Agreement, dated April 1, 2024, by and between Onconova Therpeutics, Inc. and Werner Cautreels (*Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on April 3, 2024*).
10.26+	Form of Offer Letter for Ian Dukes and Nikolay Savchuck, dated April 1, 2024 (*Incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on April 3, 2024*).
10.27	Form of Securities Purchase Agreement, dated December 31, 2024 (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 31, 2024*).
10.28+	Separation Agreement and Release of all Claims, by and between Traws Pharma, Inc. and Mark Guerin, dated February 5, 2025 (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 7, 2025*).
10.29+	Offer Letter, by and between Traws Pharma, Inc. and Nora Brennan, dated February 5, 2025 (*Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on February 7, 2025*).

Exhibit Number	Exhibit Description
10.30	At the Market Offering Agreement, by and between Traws Pharma, Inc. and Citizens JMP Securities, LLC *(Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 10, 2025)*.
10.31+	Separation Agreement and Release of all Claims, by and between Traws Pharma, Inc. and Werner Cautreels, dated March 31, 2025 (*Incorporated by reference to Exhibit 10.46 to the Company's Annual Report on Form 10-K filed on March 31, 2025*).
10.32+	Consulting Services Agreement, by and between Traws Pharma, Inc. and Werner Cautreels, dated March 31, 2025. (*Incorporated by reference to Exhibit 10.47 to the Company's Annual Report on Form 10-K filed on March 31, 2025*).
10.33+	Employment Agreement, effective April 1, 2025, by and between Traws Pharma, Inc. and Iain Dukes (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 18, 2025*).
10.34**	Asset Purchase Agreement, dated September 9, 2025, by and between Traws Pharma, Inc. and Viriom, Inc. (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 12, 2025*).
10.35+#	Form of Incentive Stock Option Agreement.
19.1#	Insider Trading Policy.
21.1	Subsidiaries of Traws Pharma, Inc. (*Incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed on March 31, 2025*).
23.1#	Consent of KPMG LLP
31.1#	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2#	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1##	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2##	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Compensation Recoupment Policy of Onconova Therapeutics, Inc., dated as of December 1, 2023 *(Incorporated by reference to Exhibit 97 to the Company's Annual Report on Form 10-K filed on April 1, 2024)*.
101.INS †	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH†	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents.
104 †	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101 attachments)

EXHIBITS INDEX

+ Indicates management contract or compensatory plan.

* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

** Certain annexes, schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant agrees to furnish supplementally a copy of any omitted attachment to the SEC on a confidential basis upon request.

Filed herewith.

Furnished herewith.

† The XBRL related information in Exhibit 101 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability of that section and shall not be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing or document.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: April 15, 2026

Traws Pharma, Inc.

By: /s/ Iain Dukes, D. Phil
Iain Dukes, D. Phil
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Iain Dukes, D. Phil Iain Dukes, D. Phil	Chief Executive Officer and Director (Principal Executive Officer)	April 15, 2026
/s/ Charles Parker Charles Parker	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 15, 2026
/s/ Jack E. Stover Jack E. Stover	Executive Chairman, Board of Directors	April 15, 2026
/s/ Nikolay Savchuk, PH.D. Nikolay Savchuk, Ph.D.	Director	April 15, 2026
/s/ Trafford Clarke, PH.D. Trafford Clarke, Ph.D.	Director	April 15, 2026
/s/ Mary Teresa Shoemaker Mary Teresa Shoemaker	Director	April 15, 2026
/s/ John Leaman, MD John Leaman, MD	Director	April 15, 2026
/s/ Werner Cautreels, Ph.D. Werner Cautreels, Ph.D.	Director	April 15, 2026

TRAWS PHARMA, INC.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors
Traws Pharma, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Traws Pharma, Inc. and subsidiaries (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations since inception that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Evaluation of accrued research and development expenses

As discussed in Note 4 to the consolidated financial statements, the Company has $4.3 million of accrued research and development expenses as of December 31, 2025. As discussed in Note 2, research and development costs are charged to expense as incurred and consist primarily of expenses incurred under agreements with contract research organizations (CRO) and investigative sites that conduct clinical trials and preclinical studies. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued expense.

We identified the evaluation of accrued research and development expenses for a certain CRO as a critical audit matter. Specifically, evaluating the sufficiency of audit evidence obtained over associated costs incurred for the services provided by the selected CRO required especially subjective auditor judgment due to the nature of evidence available regarding progress towards completion of underlying phases within the statements of work.

The following are the primary procedures we performed to address this critical audit matter. For the selected CRO, we inspected the statements of work and a selection of invoices, and compared them to the Company's schedule of costs incurred as of year-end. We also confirmed the status of underlying phases within the statements of work directly with the selected CRO. We assessed the sufficiency of audit evidence obtained related to accrued research and development expenses with the CRO by evaluating the cumulative results of the audit procedures.

/s/ KPMG LLP

We have served as the Company's auditor since 2025.

Philadelphia, Pennsylvania
April 15, 2026

TRAWS PHARMA, INC.

Consolidated Balance Sheets

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 3,820,000	$ 21,338,000
Tax incentive and other receivables	3,794,000	1,765,000
Prepaid expenses and other assets	365,000	1,848,000
Total current assets	7,979,000	24,951,000
Property and equipment, net	7,000	10,000
Intangible assets, net	2,527,000	—
Other assets	104,000	1,000
Total assets	$ 10,617,000	$ 24,962,000
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 5,653,000	$ 8,186,000
Accrued expenses and other liabilities	5,493,000	3,121,000
Deferred revenue	—	226,000
Total current liabilities	11,146,000	11,533,000
Deferred revenue, non-current	—	2,565,000
Warrant liabilities	100,000	42,494,000
Total liabilities	11,246,000	56,592,000
Commitments and contingencies (Note 6)		
Stockholders' deficit:		
Series C Preferred stock, $0.01 par value, 5,000,000 shares authorized, 7,440 shares issued and 6,737 shares outstanding at December 31, 2025 and 7,440 shares issued and 7,398 outstanding at December 31, 2024	—	—
Common stock, $0.01 par value, 250,000,000 shares authorized, 9,067,774 and 3,650,731 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	90,000	36,000
Additional paid in capital	639,259,000	617,530,000
Accumulated deficit	(639,984,000)	(649,154,000)
Accumulated other comprehensive income (loss)	6,000	(42,000)
Total stockholders' deficit	(629,000)	(31,630,000)
Total liabilities and stockholders' deficit	$ 10,617,000	$ 24,962,000

See accompanying notes to consolidated financial statements.

TRAWS PHARMA, INC.

Consolidated Statements of Operations

	Years ended December 31,	
	2025	2024
Revenue	$ 2,790,000	$ 226,000
Operating expenses:		
Acquired in-process research and development	—	117,464,000
Research and development	12,143,000	12,847,000
General and administrative	8,522,000	12,289,000
Total operating expenses	20,665,000	142,600,000
Loss from operations	(17,875,000)	(142,374,000)
Change in fair value of warrant liability	26,567,000	—
Series A warrant and pre-funded warrant expense	—	(24,438,000)
Other income, net	478,000	289,000
Net income (loss)	$ 9,170,000	$ (166,523,000)
Net income (loss) attributable to common stockholders, basic and diluted	$ 6,865,000	$ (54,674,000)
Weighted-average shares of common stock outstanding, basic	8,228,169	1,552,685
Net income (loss) per share of common stock, basic	$ 0.83	$ (35.21)
Weighted-average shares of common stock outstanding, diluted	8,376,380	1,552,685
Net income (loss) per share of common stock, diluted	$ 0.82	$ (35.21)
Net income (loss) attributable to Series C Preferred stockholders, basic and diluted	$ 2,305,000	$ (111,849,000)
Weighted-average shares of Series C Preferred outstanding, basic and diluted	6,906	7,941
Net income (loss) per share of Series C Preferred, basic and diluted	$ 333.77	$ (14,085.00)

See accompanying notes to consolidated financial statements.

TRAWS PHARMA, INC.

Consolidated Statements of Comprehensive Income (Loss)

	Years ended December 31,	
	2025	2024
Net income (loss)	$ 9,170,000	$ (166,523,000)
Other comprehensive income (loss)		
Foreign currency translation adjustments	48,000	(19,000)
Other comprehensive income (loss)	48,000	(19,000)
Comprehensive income (loss)	$ 9,218,000	$ (166,542,000)

See accompanying notes to consolidated financial statements.

TRAWS PHARMA, INC.

Consolidated Statements of Stockholders' Equity (Deficit)

	Stockholders' Equity (Deficit)									
	Redeemable Convertible Preferred Stock		Preferred Stock		Common Stock		Additional Paid in	Accumulated	Accumulated other comprehensive	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	deficit	income (loss)	Total
Balance at December 31, 2023	—	$ —	—	$ —	840,251	$ 9,000	$ 493,317,000	$ (482,631,000)	$ (23,000)	$ 10,672,000
Issuance of stock in connection with the asset acquisition of Trawsfynydd	10,359	93,232,000	—	—	141,982	1,000	3,549,000	—	—	3,550,000
Transaction costs paid through the issuance of stock	535	4,815,000	—	—	6,747	—	169,000	—	—	169,000
Issuance of stock in connection with the private placement, net of expenses	1,578	13,572,000	—	—	19,879	—	427,000	—	—	427,000
Exchange of Trawsfynydd stock options for options of the Company	—	—	—	—	—	—	7,085,000	—	—	7,085,000
Conversion of redeemable convertible preferred stock upon stockholder approval	(12,472)	(111,619,000)	7,440	—	2,029,953	20,000	111,599,000	—	—	111,619,000
Issuance of common stock in connection with the Securities Purchase Agreement	—	—	(42)	—	608,197	6,000	(6,000)	—	—	—
Stock-based compensation	—	—	—	—	—	—	1,390,000	—	—	1,390,000
Shares issued for vested restricted stock units	—	—	—	—	3,722	—	—	—	—	—
Other comprehensive loss	—	—	—	—	—	—	—	—	(19,000)	(19,000)
Net loss	—	—	—	—	—	—	—	(166,523,000)	—	(166,523,000)
Balance at December 31, 2024	—	$ —	7,398	$ —	3,650,731	$ 36,000	$ 617,530,000	$ (649,154,000)	$ (42,000)	$ (31,630,000)
Stock-based compensation	—	—	—	—	—	—	728,000	—	—	728,000
Shares issued for vested restricted stock units	—	—	—	—	6,509	—	—	—	—	—
Issuance of common stock, net of offering costs	—	—	—	—	2,517,270	25,000	5,177,000	—	—	5,202,000
Reclassification of warrant liability upon exercise of prefunded warrants and amended warrant agreements	—	—	—	—	—	—	15,827,000	—	—	15,827,000
Exercise of prefunded warrants	—	—	—	—	2,628,962	26,000	—	—	—	26,000
Conversion of Series C Preferred shares into common stock	—	—	(661)	—	264,302	3,000	(3,000)	—	—	—
Other comprehensive income	—	—	—	—	—	—	—	—	48,000	48,000
Net income	—	—	—	—	—	—	—	9,170,000	—	9,170,000
Balance at December 31, 2025	—	$ —	6,737	$ —	9,067,774	$ 90,000	$ 639,259,000	$ (639,984,000)	$ 6,000	$ (629,000)

See accompanying notes to consolidated financial statements.

TRAWS PHARMA, INC.

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2025	2024
Operating activities:		
Net income (loss)	$ 9,170,000	$ (166,523,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	—	117,464,000
Change in fair value of warrant liability	(26,567,000)	—
Series A warrant and pre-funded warrant expense	—	24,438,000
Depreciation and amortization	61,000	12,000
Stock-based compensation	728,000	1,390,000
Changes in assets and liabilities:		
Receivables	(2,029,000)	(1,747,000)
Prepaid expenses and other current assets	1,483,000	(27,000)
Accounts payable	(612,000)	646,000
Accrued expenses and other current liabilities	2,372,000	(5,219,000)
Deferred revenue	(2,791,000)	(226,000)
Net cash used in operating activities	(18,185,000)	(29,792,000)
Investing activities:		
Purchase of intangible assets	(2,585,000)	—
Cash paid for acquisition, net of cash acquired	—	(3,648,000)
Net cash used in investing activities	(2,585,000)	(3,648,000)
Financing activities:		
Proceeds from sale of common and preferred stock in connection with the private placement, net of expenses	—	13,999,000
Proceeds from sale of common stock in connection with the Securities Purchase Agreement, net of expenses	—	19,977,000
Proceeds from sale of common stock pursuant to the ATM	5,582,000	—
Payment of offering costs	(2,404,000)	—
Proceeds from exercised prefunded warrants	26,000	—
Net cash provided by financing activities	3,204,000	33,976,000
Effect of foreign currency translation on cash	48,000	(19,000)
Net (decrease) increase in cash and cash equivalents	(17,518,000)	517,000
Cash and cash equivalents at beginning of period	21,338,000	20,821,000
Cash and cash equivalents at end of period	$ 3,820,000	$ 21,338,000
Supplemental disclosure of cash flow information:		
Reclassification of warrant liability upon exercise of prefunded warrants and amended warrant agreements	$ 15,827,000	$ —
Preferred stock issued in connection with the reclassification and conversion of redeemable convertible preferred stock	$ —	$ 111,619,000
Common stock issued in connection with acquisition of Trawsfynydd	$ —	$ 3,719,000
Preferred stock issued in connection with acquisition of Trawsfynydd	$ —	$ 98,047,000
Offering costs included in other assets	$ 104,000	$ —
Offering costs included in accounts payable	$ —	$ 1,921,000

See accompanying notes to consolidated financial statements.

TRAWS PHARMA, INC.

Notes to Consolidated Financial Statements

1. Nature of Business

The Company

Traws Pharma, Inc. ("Traws Pharma" or the "Company"), formerly known as Onconova Therapeutics, Inc., was incorporated in the State of Delaware on December 22, 1998 and commenced operations on January 1, 1999. The Company's headquarters are located in Newtown, Pennsylvania. On April 1, 2024, the Company acquired Trawsfynydd Therapeutics, Inc., a Delaware corporation ("Trawsfynydd"), through a merger (the "Merger") and the name change to Traws Pharma was effected. The Company accounted for the transaction as an asset acquisition as substantially all of the fair value of the gross assets acquired was concentrated in two programs that were grouped as a single identifiable in-process research and development ("IPR&D") asset. Traws Pharma is a clinical stage biopharmaceutical company dedicated to developing novel therapies to target critical threats to human health in respiratory viral diseases. Following the Merger, the Company has four clinical programs: (i) tivoxavir marboxil, an investigational oral, small molecule CAP-dependent endonuclease inhibitor designed to be administered as a single-dose for the treatment of bird flu and seasonal influenza; (ii) ratutrelvir, an inhibitor of the main protease (also known as 3CL protease) of the SAR-CoV-2 virus, the causative agent in COVID-19; (iii) narazaciclib (ON 123300), a multi-targeted kinase inhibitor in solid tumors and hematological malignancies as a single agent or in combination with other anti-cancer therapies; and (iv) rigosertib, administered alone or in combination for investigation in various cancers. The Company's primary focus is the development of tivoxavir marboxil and ratutrelvir, and its strategic objective for narazaciclib and rigosertib is to establish additional partnerships for further development of the compounds.

Liquidity

The Company has incurred recurring operating losses since inception. As of December 31, 2025, the Company had generated an accumulated deficit of $639,984,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, strategic alliances and its administrative organization. At December 31, 2025, the Company had cash and cash equivalents of $3,820,000. Based on current projections, the Company believes that it does not have sufficient cash and cash equivalents to support its operations for more than one year following the date that these financial statements are issued. As a result of these conditions, substantial doubt exists about the Company's ability to continue as a going concern.

The Company will require substantial additional financing to fund its ongoing clinical trials and operations, and to continue to execute its strategy. Management plans to explore various dilutive and non-dilutive sources of funding, including equity financings, strategic alliances, business development and other sources. The future success of the Company is dependent upon its ability to obtain additional funding. The failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on the Company's business, results of operations and financial condition. There can be no assurance, however, that the Company will be successful in obtaining such funding in sufficient amounts, on terms acceptable to the Company, or at all.

Due to the inherent uncertainty involved in making estimates and the risks associated with the research, development, and commercialization of biotechnology products, the Company may have based this estimate on assumptions that may prove to be wrong, and the Company's operating plan may change as a result of many factors currently unknown to the Company.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States ("GAAP"). The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Trawsfynydd Therapeutics LLC, Trawsfynydd Therapeutics AU Ltd, Throxavir Therapeutics AU Pty Ltd, and Onconova Europe GmbH. All significant intercompany transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets, liabilities, and equity and the amount of revenues and expenses. Actual results could differ significantly from those estimates. The most significant estimates and assumptions that management considers in the preparation of the Company's financial statements relate to prepaid and accrued research and development costs; the valuation of consideration transferred in acquiring the assets of Trawsfynydd; and inputs used in the Black-Scholes model for stock-based compensation expense and Series A Warrant (as defined below) liability.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources in assessing performance. The Company has one operating segment. The Company's chief operating decision maker ("CODM") is the chief executive officer. The Company's CODM manages the Company's operations on a consolidated basis for the purpose of allocating resources. All the Company's long-lived assets are held in the United States.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. The Company maintains a portion of its cash and cash equivalent balances in the form of money market accounts with financial institutions that management believes are creditworthy. The Company has no financial instruments with off-balance sheet risk of loss.

At December 31, 2025 the Company had $2,927,000 of its cash and cash equivalents in money market funds that invest in a portfolio of liquid, high-quality debt securities issued by the U.S. government.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original or remaining maturity from the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include bank demand deposits, marketable securities with maturities of three months or less at purchase, and money market funds that invest primarily in certificates of deposit, commercial paper and U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value. During the years ended December 31, 2025 and 2024, the Company received $455,000 and $510,000, respectively, of interest income primarily from a money market mutual fund that invests primarily in U.S. government obligations. The interest income is included in Other income, net in the Statement of Operations.

Deferred Financing Costs

The Company capitalizes costs that are directly associated with in-process equity and debt financing until such financings are consummated, at which time such costs are recorded against the gross proceeds from the applicable financing. If a financing is abandoned, deferred financing costs are expensed.

Asset Acquisitions

Acquisitions of assets or a group of assets that do not meet the definition of a business are accounted for as asset acquisitions, with a cost accumulation model used to determine the cost of the acquisition. Common stock issued as consideration in an acquisition of assets is generally measured based on the acquisition date fair value of the equity interests issued. Direct transaction costs are recognized as part of the cost of an acquisition of assets. Intangible assets that are acquired in an asset acquisition for use in research and development activities that have an alternative future use are capitalized as in-process research and development, or IPR&D. Acquired IPR&D that has no alternative future use is expensed immediately in the consolidated statements of operations and comprehensive loss.

Tax Incentive Receivable

The Company is eligible to receive a cash refund from the Australian Taxation Office for eligible research and development ("R&D") expenditures under the Australian Research and Development Tax Incentive Program (the "Australian Tax Incentive"). The Australian Tax Incentive is recognized as a reduction to R&D expense when the relevant expenditure has been incurred, the amount can be reliably measured and that the Australian Tax Incentive will be received. The Company's Australian subsidiaries began operations in the second quarter of 2024, and the Company has recognized reductions to R&D expenses of $2,031,000 and $1,543,000 for the year ended December 31, 2025 and 2024, respectively. In February 2026, the Company received $2,558,000 in Australian Tax Incentive refunds.

Impairment of Definite Lived Intangible Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If the carrying amount of the asset exceeds its estimated undiscounted net cash flows, before interest, the Company will recognize an impairment loss equal to the difference between its carrying amount and its estimated fair value. If impairment is recognized, the reduced carrying amount of the asset will be accounted for as its new cost. Generally, fair values are estimated using discounted cash flow, replacement cost or market comparison analyses. The process of evaluating impairment requires estimates as to future events and conditions, which are subject to varying market and economic factors. Therefore, it is reasonably possible that a change in an estimate resulting from judgements as to future events could occur which would affect the recorded amounts of the asset. No impairment losses were recorded for the years ended December 31, 2025 or 2024.

Intangible Assets

Intangible assets consist entirely of patents. Costs related to patents, which include legal and application fees, are capitalized and amortized over the estimated useful lives using the straight-line method. Patent amortization commences once final approval of the patent has been obtained. For patents purchased in an asset acquisition, the useful life is determined largely by valuation estimates of remaining economic life. The Company's patent, purchased in connection with the Purchased Assets from Viriom, Inc. ("Viriom") (Note 3), has a useful life of 15 years.

Fair Value of Financial Instruments

The Company accounts for financial instruments under ASC 820, *Fair Value Measurements* ("ASC 820"). This statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. To increase consistency and comparability in fair value measurements, ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels as follows:

Level 1 — quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 — observable inputs other than Level 1, quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, and model-derived prices whose inputs are observable or whose significant value drivers are observable; and

Level 3 — assets and liabilities whose significant value drivers are unobservable.

The carrying amounts reported in the accompanying consolidated financial statements for cash and cash equivalents, tax incentive and other receivables, accounts payable, and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts.

The following fair value hierarchy table presents information about the Company's assets and liabilities measured at fair value on a recurring basis:

	Fair value measurement at reporting date using		
December 31, 2025	**(Level 1)**	**(Level 2)**	**(Level 3)**
Assets:			
Cash and cash equivalents - money market funds	$ 2,927,000	$ -	$ -
Liabilities:			
Warrant liabilities - Series A Warrants	$ -	$ -	$ 100,000
December 31, 2024			
Assets:			
Cash and cash equivalents - money market funds	$ 20,508,000	$ -	$ -
Liabilities:			
Warrant liabilities - Series A Warrants	$ -	$ -	$ 13,125,000
Warrant liabilities - Pre-funded Warrants	-	29,369,000	-

On December 29, 2024, the Company entered into a Securities Purchase Agreement with several investors (the "December 2024 Purchase Agreement") for the sale of (i) up to 3,630,205 Class A Units ("Class A Units"), each Class A Unit consisting of (a) one share of common stock or one pre-funded warrant to initially purchase one share of common stock, and (b) one Series A Warrant to purchase one share of common stock ("Series A Warrants") and (ii) 289,044 Class B Units", and together, with the Class A Units, the "Units"), each Class B Unit consisting of one pre-funded warrant and one Series A Warrant. The fair value of the pre-funded warrants was the intrinsic value of the pre-funded warrants due to their nominal exercise price. The fair value of the Series A Warrants was calculated using the Black-Scholes option pricing model and is revalued to fair value at the end of each reporting period until the earlier of the exercise or expiration of the Series A Warrants. The fair value of the Series A Warrant liability was estimated using the Black-Scholes option pricing model using the following assumptions:

	December 31, 2025	**February 18, 2025 (Amendment date)**	**December 31, 2024 (Issuance date)**
Expected term of warrants (years)	2 years	0.9 years	1 year
Risk-free interest rate	3.5%	4.3%	4.2%
Expected volatility	121.8%	137.3%	126.9%
Dividend yield	$ -	$ -	$ -

The warrant liabilities were initially measured at fair value at the day of issuance and on a recurring basis. The changes in fair value of warrant liabilities will be recognized as part of the consolidated statements of operations. A summary of warrant liability activity for the year ended December 31, 2025, is as follows:

Balance, December 31, 2024	$	42,494,000
Reclassification of warrant liability upon exercise of pre-funded warrants		(6,694,000)
Reclassification of warrant liability upon amendment of Series A Warrant agreements		(9,133,000)
Change in fair value of Series A Warrants		(26,567,000)
Balance, December 31, 2025	$	100,000

On February 18, 2025, the Company and certain of the purchasers entered into amendments to the Series A Warrants, pursuant to which the Series A Warrant liability attributable to the Series A Warrants held by such purchasers was reclassified to permanent equity. The change in fair value of the warrant liability related to the Series A Warrants was measured using the fair value of the amended Series A Warrants immediately prior to February 18, 2025.

During the first quarter of 2025, certain purchasers exercised their pre-funded warrants for an aggregate of 1,382,559 shares of the Company's common stock. On March 27, 2025, the Company and those purchasers holding all pre-funded warrants outstanding as of such date entered into amendments to the pre-funded warrants, pursuant to which the pre-funded warrant liability was reclassified to permanent equity.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the useful life of the asset or the lease term, whichever is shorter. Maintenance and repairs are expensed as incurred. The following estimated useful lives were used to depreciate the Company's assets:

	Estimated Useful Life
Lab equipment	5-6 years
Software	3 years
Computer and office equipment	5-6 years
Leasehold improvements	Shorter of the lease term or estimated useful life

Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized.

The Company reviews long-lived assets for impairment when events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceeds their fair value, which is measured based on the projected discounted future net cash flows generated from the assets. No impairment losses have been recorded through December 31, 2025.

Warrant Accounting

The Company evaluates all of its financial instruments, including issued share purchase warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives, pursuant to ASC Topic 480, Distinguishing Liabilities from Equity, ASC Topic 505, Equity, and ASC Topic 815, Derivatives and Hedging ("ASC 815"). The Series A Warrants and pre-funded warrants issued in connection with the December 2024 Offering (defined below) did not meet the scope exception under ASC 815 and, therefore were classified as liabilities as of December 31, 2024. Certain outstanding Series A Warrants and all pre-funded warrants issued in connection with the December 2024 Offering subsequently met the scope exception under ASC 815, as a result of amending the terms of such warrants and, therefore, were reclassified to permanent equity. The remaining liability classified Series A Warrants are subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in the Company's consolidated statements of operations. The change in fair value of warrant liability during the year ended December 31, 2025 was $26,567,000. There was no change in fair value of warrant liability during the year ended December 31, 2024.

Foreign Currency

The reporting currency of the Company and its U.S. subsidiaries is the U.S. dollar. The functional currency of the Company's Australian subsidiary is the U.S. dollar. Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than the U.S. dollar are included in operations in the period in which the transaction occurs and reported within the other income, net in the consolidated statements of operations. The functional currency for the Company's German subsidiary is the euro. Translation adjustments are included as a component of accumulated other comprehensive income and gains and losses resulting from exchange rate changes on such transactions are reflected within other income, net, in the Company's statements of comprehensive loss.

Revenue Recognition

The Company derives revenue from its collaboration and licensing agreements.

The Company recognizes revenue in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The Company applies ASC 606 to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. In accordance with ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods and services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract that falls under the scope of ASC 606, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

License, Collaboration and Other Revenues

The Company enters into licensing and collaboration agreements, under which it licenses certain of its product candidates' rights to third parties. The Company recognizes revenue related to these agreements in accordance with ASC 606. The terms of these arrangements typically include payment from third parties of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; and royalties on net sales of the licensed product.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligation under each of its agreements, the Company performs the five steps described above. As part of the accounting for these arrangements, the

Company must develop assumptions that require judgment to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement of personnel costs, discount rates and probabilities of technical and regulatory success.

Licensing of Intellectual Property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other performance obligations, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front-fees. The Company evaluates the measure of progress each reporting period, and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensees, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in their period of adjustment.

Manufacturing supply service: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered as options. The Company assesses if these options provide material rights to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the customer exercises these options, any additional payments are recorded when the customer obtains control of the goods, which is upon shipment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some of all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue from its license agreements.

Effective April 17, 2025, the Company and Symbio Pharmaceuticals Limited ("Symbio") mutually terminated the license agreement originally entered into by and between the parties in 2011. No payments, compensation, reimbursements or settlements shall be due or owed by either party in connection with the termination of the license agreement. As a result, the Company recognized the remaining $2,733,000 of deferred revenue as revenue in April 2025.

	Year ended December 31,	
	2025	2024
Symbio		
Upfront license fee recognition	$ 2,790,000	$ 226,000

Deferred revenue is as follows:

	Symbio Upfront Payment
Deferred balance at December 31, 2024	$ 2,790,000
Recognition to revenue	(2,790,000)
Deferred balance at December 31, 2025	$ —

Research and Development Expenses

R&D costs are charged to expense as incurred. These costs include, but are not limited to, license fees related to the acquisition of in-licensed products; employee-related expenses, including salaries, benefits and travel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the cost of acquiring, developing and manufacturing clinical trial materials; facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and costs associated with preclinical activities and regulatory operations.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued R&D expense, as the case may be.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. The deferred tax asset primarily includes net operating loss and tax credit carry forwards, accrued expenses not currently deductible and the cumulative temporary differences related to certain research and patent costs, which have been charged to expense in the accompanying statements of operations but have been recorded as assets for income tax purposes. The portion of any deferred tax asset for which it is more likely than not that a tax benefit will not be realized must then be offset by recording a valuation allowance. A full valuation allowance has been established against all of the deferred tax assets (Note 11), as it is more likely than not that these assets will not be realized given the Company's history of operating losses. The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not to be sustained upon examination based on the technical merits of the position. The amount for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that the Company believes is more likely than not to be realized upon ultimate settlement of the position.

Stock-Based Compensation Expense

The Company applies the provisions of ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and non-employees, including employee stock options, stock appreciation rights, performance stock units and restricted stock units.

Share-based payment transactions with employees are recognized as compensation expense over the requisite service period based on their estimated fair values. The Company accounts for forfeitures in the period in which they occur. ASC 718 also requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility over the term and expected lives, to estimate the grant date fair value of equity-based compensation and requires the recognition of the fair value of stock compensation in the statement of operations.

Clinical Trial Expense Accruals

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate trial expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2025 and 2024, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Net Income (Loss) Per Share

For purposes of net income (loss) per share, the Company's Series C Preferred shares have the same characteristics as common stock and have no liquidation or other material preferential rights over common stock and accordingly, have been considered as a second class of common stock in the computation of income (loss) per share regardless of their legal form. Income (losses) are allocated between the common shares and the Series C Preferred on a pro rata basis, as they share equally in (losses) income and residual net assets on an as-converted basis.

Basic income (loss) per share of common stock is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during each period, including pre-funded warrants. The pre-funded warrants to purchase common stock with an exercise price of $0.01 per share are included in the calculation of basic and diluted net income (loss) per share as the exercise price is non-substantive and is virtually assured.

Diluted income (loss) per share of common stock includes the effect from the potential exercise or conversion of securities, such as stock options, unvested restricted stock units, and common stock warrants, which would result in the issuance of incremental shares of common stock, using the treasury stock method, and the potential shares of converted common stock associated with the Series C Preferred using the if-converted method. Potential common shares are excluded from the diluted per share calculation when their effect is anti-dilutive, including in periods of net loss or when inclusion does not result in a decrease in earnings per share.

For the years ended December 31, 2025 and 2024, the components of basic and diluted net income (loss) per share were as follows:

(in thousands except per share amounts)	Year Ended December 31, 2025	2024
Numerator:		
Net income (loss)	$ 9,170,000	$ (166,523,000)
Net income (loss) attributable to common stockholders	$ 6,865,000	$ (54,674,000)
Net income (loss) attributable to Series C Preferred stockholders	$ 2,305,000	$ (111,849,000)
Denominator:		
Weighted-average shares of common stock outstanding, basic	8,228,169	1,552,685
Restricted stock units	6,794	-
Stock options	141,417	-
Weighted-average shares of common stock outstanding, diluted	8,376,380	1,552,685
Net income (loss) per share of common stock, basic	$ 0.83	$ (35.21)
Net income (loss) per share of common stock, diluted	$ 0.82	$ (35.21)
Weighted-average shares of Series C Preferred outstanding, basic and diluted	6,906	7,941
Net income (loss) per share of Series C Preferred, basic and diluted	$ 333.77	$ (14,085.00)

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:

	December 31, 2025	2024
Warrants	3,919,249	3,919,249
Stock Options	324,525	423,107
Unvested restricted stock units	15,912	22,421
Series C Preferred (assumed conversion to common stock)	2,694,757	—
	4,259,686	4,364,777

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures (ASU 2023-09)*, which expands the disclosure required for income taxes. This ASU is effective for fiscal years beginning after December 16, 2024, with early adoption permitted. The Company adopted *ASU 2023-09* on a prospective basis effective January 1, 2025. Accordingly, the enhanced income tax disclosures are presented in the income taxes footnote (Note 11) beginning in fiscal year 2025, and prior period disclosures have not been recast.

Recently Issued but not yet Adopted Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures* (Subtopic 220-40): *Disaggregation of Income Statement Expenses*, which is intended to provide more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation and amortization) included in certain expense captions presented on the consolidated statement of operations. The guidance in this ASU is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the consolidated financial statements. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on its consolidated financial statements and disclosures.

3. Asset Acquisition

Viriom

On September 9, 2025, the Company and Viriom, a related party (Note 12), entered into an Asset Purchase Agreement (the "Purchase Agreement"), pursuant to which the Company purchased a patent from Viriom in exchange for $2,350,000 in cash. The patent includes certain intellectual property and other assets related to a pyrrolidine antiviral compound.

The Company concluded that the acquisition of the Purchased Assets was not a business combination as the purchased assets did not meet the definition of a business under ASC 805, *Business Combinations*. Therefore, the Company accounted for the Purchase Agreement under the authoritative guidance for asset acquisitions, and allocated the costs of the acquisition of $2,350,000 and legal costs incurred in consummating the Purchase Agreement of $235,000 to the acquired patent. The patent has a useful life of 15 years and will be amortized on a straight-line basis over this period, as the economic benefits are expected to be realized evenly over the patent's useful life.

Trawsfynydd

On April 1, 2024, the Company acquired Trawsfynydd, in accordance with the terms of an Agreement and Plan of Merger, dated April 1, 2024 (the "Merger Agreement"), pursuant to which the Company acquired Trawsfynydd's tivoxavir marboxil and TRX01 programs and assumed certain liabilities associated with the acquired assets (the "Merger"). The upfront consideration included (i) the issuance of 141,982 shares of common stock of the Company at an aggregate fair value of $3,550,000, (ii) the issuance of 10,359 shares of Series C Convertible Preferred Stock ("Series C Preferred") at an aggregate fair value of $93,232,000, and (iii) the assumption of all Trawsfynydd stock options (the "assumed options") immediately outstanding prior to the transaction at an aggregated fair value of $7,085,000.

Each share of Series C Preferred converts into 400 shares of common stock, subject to the Beneficial Ownership Limitation (defined below). The fair value of the shares issued to Trawsfynydd and options assumed was based on the closing stock price of the Company's common stock on April 1, 2024 of $1.00, less a discount 10.0% related to unregistered share restrictions of the preferred shares.

The Company accounted for the transaction as an asset acquisition as the Company acquired inputs and no substantive processes or outputs. The assets acquired in the transaction were measured based on the estimated fair value of the consideration paid of $112,543,000, which included direct transactions costs of $8,676,000. Tungsten Partners LLC ("Tungsten") acted as financial advisor to the Company in connection with the Merger. As partial compensation for services rendered by Tungsten, the Company issued to Tungsten and its affiliates and designees an aggregate of 6,747 shares of common stock and 535 shares of Series C Preferred.

The consideration paid and the relative fair values of the assets acquired and liabilities assumed were as follows:

Consideration transferred:		
Common stock	$	3,550,000
Series C Preferred		93,232,000
Assumed options		7,085,000
Company transaction costs settled in equity		4,984,000
Company transaction costs paid in cash		3,692,000
Total consideration transferred	$	112,543,000
Assets acquired:		
Cash and cash equivalents	$	44,000
Total assets acquired	$	44,000
Liabilities assumed:		
Accrued expenses and other current liabilities	$	4,965,000
Total liabilities assumed		4,965,000
Net assets acquired		(4,921,000)
In-process research and development		117,464,000
Net assets acquired	$	112,543,000

The Company elected to follow the asset acquisition approach and the Trawsfynydd IPR&D assets acquired have no alternative future use to the Company. As a result, the Company charged $117,464,000 to expense within its consolidated statement of operations for the year ended December 31, 2024.

The Company's board of directors ("Board") approved the Merger Agreement and the related transactions, and the consummation of the Merger was not subject to approval of Company stockholders. In accordance with the Merger Agreement, three directors were appointed to the Board, and there were several changes to management, each effective as of the Closing.

Concurrently with the Closing of the Merger, the Company entered into a contingent value rights agreement (the "CVR Agreement") with a rights agent (the "Rights Agent"), pursuant to which each holder of common stock as of the applicable record date (April 15, 2024), including those holders receiving shares of common stock in connection with the Merger, is entitled to one contractual contingent value right (each, a "CVR") entitling the holder to certain distributions of net proceeds and net sales of Traws Pharma's two leading cancer candidates, subject to, and in accordance with, the terms and conditions of the CVR Agreement, for each share of common stock held by such holder as of the applicable record time.

The distributions in respect of the CVRs will be made on a quarterly basis, and will be subject to a number of deductions, subject to certain exceptions or limitations, including but not limited to for certain taxes and certain out-of-pocket expenses incurred by Traws Pharma. At the time of Merger and again at December 31, 2025, the value ascribed to the CVR liability was de minimis given the uncertainty related to the success of the underlying oncology programs.

4. Balance Sheet Detail

Prepaid expenses and other current assets:

	December 31,	
	2025	2024
Research and development	$ 42,000	$ 1,514,000
Insurance	234,000	156,000
Other	89,000	178,000
	$ 365,000	$ 1,848,000

Property and Equipment:

	December 31,	
	2025	2024
Computer and office equipment	$ 84,000	$ 84,000
Less accumulated depreciation	(77,000)	(74,000)
	$ 7,000	$ 10,000

Depreciation and amortization expense was $3,000 and $12,000 for the years ended December 31, 2025 and 2024, respectively.

Accrued expenses and other current liabilities:

	December 31,	
	2025	2024
Research and development	$ 4,271,000	$ 2,331,000
Employee compensation	936,000	265,000
Professional fees	158,000	525,000
Other	128,000	—
	$ 5,493,000	$ 3,121,000

5. Intangible Assets

The following table summarized intangible assets included on the balance sheet:

	December 31, 2025		
	Gross	Accumulated Amortization	Net
Patent	$ 2,585,000	$ (58,000)	$ 2,527,000

Total amortization expense for the patent was $58,000 for the year ended December 31, 2025. There was no amortization expense for the year ended December 31, 2024. The Company's patent has a remaining useful life of 14.8 years.

Future amortization of intangible assets are estimated to be as follows:

Years Ending December 31:	
2026	$ 172,000
2027	172,000
2028	172,000
2029	172,000
2030	172,000
Thereafter	1,667,000
	$ 2,527,000

6. Commitments and Contingencies

Litigation

In the normal course of business, the Company from time to time is named as a party to legal claims and actions. The Company records a loss contingency reserve for a legal proceeding when the potential loss is considered probable and can be reasonably estimated. The Company has not recorded any amounts for loss contingencies as of December 31, 2025.

On June 17, 2024, Steven M. Fruchtman informed the Board of his intent to resign from his positions of President and Chief Scientific Officer, Oncology and indicated to the Company that Dr. Fruchtman believes his resignation to be for "good reason" under the terms of his employment agreement and his expectation of compensation commensurate therewith and in connection with a change in control. The Board accepted Dr. Fruchtman's resignation effective immediately but disagrees with the characterization of the events set forth in the letter. The Company believes that no severance payments are due to Dr. Fruchtman under the terms of his employment agreement as it pertains to termination for good reason events. The claims have been submitted to arbitration for resolution, and arbitration proceedings with the American Arbitration Association are currently scheduled to commence on June 1, 2026. At December 31, 2025, the Company determined a range of possible losses associated with Dr. Fruchtman's claim to be zero to $1,500,000. While the Company intends to defend itself against these claims, and believes it has strong arguments to prevail in the litigation, there can be no assurance that the Company will prevail on its claims.

Contingent Value Rights

The Company issued CVRs to common stockholders as of April 15, 2024 and may be obligated to make future distributions to such CVR holders in connection with entering into strategic arrangements related to its oncology programs and/or future royalty payments related to the successful commercialization of such programs. Refer to discussion of Contingent Value Rights within Note 3.

7. Convertible Preferred Stock and Stockholders' (Deficit) Equity

In connection with the acquisition of Trawsfynydd and the concurrent private placement of securities in April 2024 (Note 3), the Company issued shares of Series C Preferred to various individuals. Except in limited circumstances, Series C Preferred shares have no voting rights. At December 31, 2025, there were 6,737 shares of Series C Preferred outstanding. Certain material provisions of the Series C Preferred are as follows:

Conversion: Each share of Series C Preferred is convertible into 400 shares of Company common stock, subject to the Beneficial Ownership Limitation.

Dividends: Shares of series C Preferred participate in any dividends with common stockholders on an as-converted basis.

Liquidation: In the event of the liquidation, dissolution, or winding up of the affairs of the Company, whether voluntary or involuntary, the holders of Series C Preferred shall rank on parity with common stockholders as to the distribution of assets.

Beneficial Ownership Limitation: A holder of Series C Preferred is prohibited from converting shares of Series C Preferred into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 19.9% of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion (the "Beneficial Ownership Limitation")

At the Market Offering Agreement

On March 10, 2025, the Company entered into an At the Market Offering Agreement (the "ATM Agreement") with Citizens JMP Securities, LLC ("Citizens"), pursuant to which the Company may offer and sell shares of its common stock, having an aggregate sales price of up to $50,000,000 (subject to certain limitations set forth in the ATM Agreement), from time to time, to or through Citizens, acting as sales agent and/or principal. During the year ended December 31, 2025, the Company sold and issued an aggregate of 2,517,270 shares of its common stock under the ATM Agreement for net proceeds of $5,202,000.

Amendment of Series A Warrants and Pre-funded Warrants

On February 18, 2025, the Company and certain of the purchasers of Units in the equity offering that closed on December 31, 2024 (the "December 2024 Offering") entered into amendments to the Series A Warrants (the "Series A Warrant Amendment"), pursuant to which the Series A Warrants issued to such purchasers were amended to (i) increase the threshold for a change of control, for purposes of determining whether a Fundamental Transaction (as defined in the Series A Warrants) has occurred, from 50% of the outstanding common stock of the Company to greater than 50% of the outstanding common stock of the Company, (ii) revise the expected volatility rate to be applied for purposes of determining the Black Scholes Value of the Series A Warrants to be utilized for calculating consideration payable to the holders of the Series A Warrants in connection with a Fundamental Transaction that is not within the Company's control, and (iii) remove Section 3(h) of the Series A Warrants, which, under certain circumstances, provided for adjustments to the exercise price of the Series A Warrants in the event of a reverse stock split, stock consolidation, or a recapitalization or similar event involving the Company's common stock based on the volume weighted average price of the Company's common stock over the eleven trading day period commencing five trading days immediately preceding such event and the five trading days immediately following such event. The Series A Warrant Amendment resulted in the reclassification of $4,196,000 in warrant liability into permanent equity during the year ended December 31, 2025.

During the first quarter of 2025, certain purchasers of Units in the December 2024 Offering exercised their pre-funded warrants for an aggregate of 1,382,559 shares of the Company's common stock. On March 27, 2025, the Company and those purchasers holding all pre-funded warrants outstanding as of such date entered into amendments to the pre-funded warrants (the "PFW Amendment"), pursuant to which the pre-funded warrants issued to such purchasers were amended to increase the threshold for a change of control, for purposes of determining whether a Fundamental Transaction (as defined in the pre-funded warrants) has occurred, from 50% of the outstanding common stock of the Company to greater than 50% of the outstanding common stock of the Company. The PFW Amendment and exercises of pre-funded warrants resulted in the reclassification of $11,631,000 in warrant liability into permanent equity during the year ended December 31, 2025.

8. Warrants

The Series A Warrants and pre-funded warrants issued in connection with the December 2024 Offering did not meet the scope exception under ASC 815 and, therefore, were classified as liabilities as of December 31, 2024. However, as a result of the Series A Amendment and PFW Amendment, 3,375,457 outstanding Series A Warrants and 1,928,493 outstanding pre-funded warrants met the scope exception under ASC 815 and, therefore, were reclassified to permanent equity during the year ended December 31, 2025.

Warrants outstanding and warrant activity (reflects the number of common shares as if the warrants were converted to common stock) for the year ended December 31, 2025 is as follows:

Description	Classification	Exercise Price	Expiration Date	Balance December 31, 2024	Warrants Exercised	Balance December 31, 2025
Non-tradable pre-funded warrants	Equity	$ 56.25	none	141	—	141
Non-tradable pre-funded warrants	Equity	$ 56.25	none	199	—	199
Non-tradable pre-funded warrants	Equity	$ 0.01	none	3,311,052	(2,628,962)	682,090
Series A Warrants	Liability	$ 13.42	Variable	543,792	—	543,792
Series A Warrants	Equity	$ 13.42	Variable	3,375,457	—	3,375,457
				7,230,641	(2,628,962)	4,601,679

9. Stock-Based Compensation

In 2021, the Company adopted its 2021 Incentive Compensation Plan, which was subsequently amended and restated in each of 2022 and 2024 (as amended and restated, the "2021 Plan"). Upon adopting the 2021 Plan, no further awards have been or will be made under the Company's 2018 Omnibus Incentive Compensation Plan (the "2018 Plan"). Under the 2021 Plan, the Company may grant incentive stock options, non-qualified stock options, stock awards, stock units, stock appreciation rights and other stock-based awards to employees, non-employee directors, consultants, and advisors. On November 21, 2025, the Company's stockholders approved an amendment and restatement of the Company's Amended and Restated 2021 Incentive Compensation Plan (as so amended and restated, the "Amended Plan"), to increase the number of shares of common stock reserved and authorized for issuance thereunder by 1,500,000 shares and extend the term of the Amended Plan until November 20, 2035. At December 31, 2025, there were 827,840 shares available for future issuance with respect to new awards and outstanding awards.

Stock-based compensation expense includes stock options granted to employees and non-employees and has been reported in the Company's consolidated statements of operations and comprehensive loss in either R&D expenses or general and administrative expenses depending on the function performed by the optionee. No net tax benefits related to the stock-based compensation costs have been recognized since the Company's inception. The Company recognized stock-based compensation expense related to stock options and restricted stock units ("RSUs") as follows for the year ended December 31, 2025, and 2024:

	Year ended December 31,	
	2025	2024
Research and development	$ 124,000	$ 181,000
General and administrative	604,000	1,209,000
Total stock-based compensation expense	$ 728,000	$ 1,390,000

A summary of stock option activity for the twelve months ended December 31, 2025 is as follows:

	Options Outstanding			
	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance, December 31, 2024	423,107	$ 11.89	8.75	$ 2,698,000
Granted	924,650	$ 2.57		
Forfeitures and expirations	(24,391)	$ 113.45		
Balance, December 31, 2025	1,323,366	$ 3.55	9.11	$ 85,000
Exercisable at December 31, 2025	456,900	$ 5.58	7.71	$ 67,000
Vested and expected to vest at December 31, 2025	1,323,366	$ 3.55	9.11	$ 85,000

The Company accounts for all stock-based payments made to employees, non-employees and directors using an option pricing model for estimating fair value. Accordingly, stock-based compensation expense is measured based on the estimated fair value of the awards on the date of grant. Compensation expense is recognized for the portion that is ultimately expected to vest over the period during which the recipient renders the required services to the Company using the straight-line single option method.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes model requires the Company to make certain estimates and assumptions, assumptions related to the expected price volatility of the common stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company's stock.

As of December 31, 2025, there was $1,592,000 of unrecognized compensation expense related to the unvested stock options which is expected to be recognized over a weighted-average period of approximately 0.92 years.

The weighted-average assumptions underlying the Black-Scholes calculation of grant date fair value include the following:

	Year ended December 31,	
	2025	2024
Risk-free interest rate	3.82 %	3.46 %
Expected volatility	122.0 %	117.9 %
Expected term	5.47 years	6.00 years
Expected dividend yield	— %	— %
Weighted average grant date fair value	$ 2.21	$ 7.36

The weighted-average valuation assumptions were determined as follows:

- Risk-free interest rate: The Company based the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.
- Expected term of options: Due to its lack of sufficient historical data, the Company estimates the expected term of its employee stock options using the "simplified" method, as prescribed in Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option.
- Expected stock price volatility: Expected volatility is based on the historical volatility of the Company's common stock.
- Expected annual dividend yield: The Company has never paid, and does not expect to pay, dividends in the foreseeable future. Accordingly, the Company assumed an expected dividend yield of 0.0%.

The Company grants RSUs to employees under the 2021 Plan, which typically have a vesting term of 33% on each of the first and second anniversaries, and 34% on the third anniversary of the date of grant. In April 2024, the

compensation committee of the Board approved RSU grants as inducement awards ("Inducement RSUs") to certain of the Company's employees who joined the Company in connection with the Merger. The inducement RSUs vest 25% on each of the first four anniversaries of the date of grant. The Inducement RSUs were granted outside of the Company's incentive plans in accordance with Nasdaq Listing Rule 5635(c)(4). During the year ended December 31, 2025, the Company granted 140,651 RSUs with a weighted average grant date fair value of $2.70 per RSU.

A summary of RSU activity for the year ended December 31, 2025 is as follows:

	Number of Units	Weighted average grant date fair value
Outstanding and unvested December 31, 2024	22,421	$ 25.12
Granted	140,651	$ 2.70
Vested	(6,509)	$ 25.44
Outstanding and unvested December 31, 2025	156,563	$ 4.97

At December 31, 2025, the unrecognized compensation cost related to unvested service-based RSUs was $628,000, which will be recognized over the remaining service period of 1.58 years.

Grants of PSUs and SARs

During 2020 and 2021, the compensation committee of the Board and the Board approved a cash bonus program of cash-settled stock appreciation right ("SAR") awards to the Company's employees and non-employee directors, and cash-settled performance stock unit ("PSU") awards to the Company's employees. These awards were granted outside of the Amended 2018 Plan and the 2021 Plan. As the Company's stock price has decreased since these awards were issued, their impact on the results of operations and balance sheet of the Company was not material during 2025 or 2024.

10. Segment Information

The Company has one operating segment. The Company's chief operating decision maker ("CODM") is the chief executive officer. The Company's CODM manages the Company's operations on a consolidated basis for the purpose of allocating resources. All the Company's long-lived assets are held in the United States.

The accounting policies of its segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for its segment based on net loss, which is reported on the consolidated statements of operations and comprehensive loss. The measure of segment assets is reported on the balance sheet as total assets. The CODM uses cash forecast models in deciding how to invest into the segment. The CODM analyzes the Company's net loss and monitors budget versus actual results to assess the performance of the Company.

The table below summarizes the significant expense categories regularly reviewed by the CODM for the years ended December 31, 2025 and 2024:

	Years ended December 31,	
	2025	2024
Revenue	$ 2,790,000	$ 226,000
Less:		
Acquired in-process research and development	—	117,464,000
Research and development expenses:		
Preclinical & clinical development	9,456,000	7,441,000
Personnel related	1,852,000	2,787,000
Other research and development (a)	835,000	2,619,000
Total research and development expenses	12,143,000	12,847,000
General and administrative expenses:		
Professional & consulting fees	3,474,000	5,954,000
Personnel related	2,457,000	3,035,000
Other general and administrative (b)	2,591,000	3,300,000
Total general and administrative	8,522,000	12,289,000
Change in fair value of warrant liability	(26,567,000)	
Series A warrant and pre-funded warrant expense	—	24,438,000
Other income, net (c)	(478,000)	(289,000)
Net income (loss)	$ 9,170,000	$ (166,523,000)

(a) Other research and development expenses include stock based compensation, manufacturing, formulation, development, and consulting fees.

(b) Other general and administrative expenses include stock based compensation, public company costs, and insurance.

(c) Other income, net included interest income.

11. Income Taxes

The Company accounts for income taxes under FASB ASC 740 ("ASC 740"). Deferred income tax assets and liabilities are determined based upon differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

Income taxes have been based on the following income (loss) before income tax expense:

	December 31,	
	2025	2024
Domestic	$ 15,660,000	$ (161,830,000)
Foreign	(6,490,000)	(4,696,000)
	$ 9,170,000	$ (166,526,000)

As of December 31, 2025, the Company had federal net operating loss ("NOL") carry forwards of $132,839,000 state NOL carry forwards of $39,718,000, foreign NOL of $1,610,000 and federal research and development tax credit carry forwards of $0, which may be available to reduce future taxable income. The federal NOL, that was generated before the 2025 tax year, and the tax credit carry forwards will begin to expire at various dates starting in 2026. The state NOL carry forwards will begin to expire at various dates starting in 2026. In accordance with Section 382 of the Internal Revenue Code of 1986, as amended, a change in equity ownership of greater than 50% within a three-year period results in an annual limitation on the Company's ability to utilize its NOL carryforwards created during the tax periods prior to the change in ownership. The Company has determined that they have gone through an ownership change during 2024 and completed an ownership change analysis pursuant to Section 382. As a result, the utilization of a portion of the Company's

NOL carryforwards is subject to an annual limitation under Section 382. The limitation may cause certain NOLs to expire unused before being fully utilized. Because the Company has incurred cumulative net operating losses since inception, all tax years remain open to examination by U.S. federal and state income tax authorities.

The Company's reserves related to taxes are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized. The Company recognized no material adjustment for unrecognized income tax benefits. Through December 31, 2025, the Company had no unrecognized tax benefits or related interest and penalties accrued.

The principal components of the Company's deferred tax assets are as follows:

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryovers	$ 29,865,000	$ 28,324,000
Non-qualified stock options	2,544,000	2,509,000
Deferred revenue	—	696,000
Fixed assets	—	2,000
Accrued expenses	686,000	459,000
Capitalized research and development costs	6,671,000	4,839,000
Healthcare withholding - SARs	—	11,000
Deferred tax assets	39,766,000	36,840,000
Less valuation allowance	(39,766,000)	(36,840,000)
Net deferred tax assets	$ —	$ —

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded a full valuation allowance against its deferred tax assets at December 31, 2025. The Company experienced a net change in valuation allowance of $2,926,000 and $(137,452,000) for the years ended December 31, 2025 and 2024, respectively.

A reconciliation of the provision for income to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes after the adoption of ASU 2023-09 as follows:

	Year Ended December 31, 2025	
		Percent
Federal statutory income tax	$ 1,927,000	21.00 %
State and Local Income Taxes, Net of Federal Income Tax Effect [(a)]		—
Foreign Tax Effect		
Australia		
Statutory tax rate differential	(260,000)	(2.83)
Research and development costs	1,626,000	17.72
Other foreign jurisdictions	(3,000)	(0.03)
Change in Valuation Allowance	2,162,000	23.56
Nontaxable or Nondeductible Items		
Warrants	(5,579,000)	(60.81)
Other	23,000	0.26
Other Reconciling Items		
Stock options expired or cancelled	104,000	1.13
Effective income tax rate	$ —	— %

[(a)] The Company did not record state income tax expense or benefit for the period; therefore, no state-related reconciling item is included in the effective tax rate reconciliation.

The Company did not pay income taxes during the year ended December 31, 2025. Income tax payments were not required during the period as a result of generating net operating losses. Accordingly, no disaggregation of income taxes paid by jurisdiction has been provided.

As previously disclosed for the years ended December 31, 2024 prior to the adoption of ASU 2023-09, the following is a reconciliation of the difference between the effective income tax rate and federal statutory rate:

	December 31, 2024
Federal income tax expense at statutory rate	21.0 %
Permanent items	(17.9)
Foreign permanent items	(0.7)
Foreign rate differential	0.1
State income tax, net of federal benefit	0.5
State expirations	—
Tax credits	—
Change in valuation allowance	83.6
Deferred tax adjustment	(1.0)
State tax rate changes	—
Sec 382 expirations	(84.0)
Other	(1.6)
Effective income tax rate	— %

On July 4, 2025, the One Big Beautiful Bill Act, or OBBBA, was signed into law in the United States. This comprehensive tax legislation contains a broad range of tax reforms, including provisions that allow for the immediate expensing of domestic research and development expenses, restore and make permanent 100% bonus depreciation for qualifying assets, and ease limitations on the deductibility of interest expense. The legislation has multiple effective dates, with certain provisions taking effect in 2025 and others being implemented through various future years. The Company has accounted for the provisions of the OBBBA in its consolidated financial statements. The changes did not impact income taxes due to its cumulative tax loss and tax effect of a full valuation allowance against those balances.

12. Research and Development Arrangements and Related Party Transactions

Research and development arrangements with unrelated parties

The Company has entered into various licensing and right-to-sublicense agreements with educational institutions for the exclusive use of patents and patent applications, as well as any patents that may develop from research being conducted by such educational institutions in the field of anticancer therapy, genes and proteins. Results from this research have been licensed to the Company pursuant to these agreements. Under one of these agreements with Temple University ("Temple"), the Company is required to make annual maintenance payments to Temple and royalty payments based upon a percentage of sales generated from any products covered by the licensed patents, with minimum specified royalty payments.

Research and development arrangements with related parties

Prior to consummation of the Merger, Trawsfynydd entered into a Master Research and Development Agreement with ChemDiv, Inc. ("ChemDiv"). Pursuant to the Master Research and Development Agreement, ChemDiv provided services related to preclinical drug discovery to Trawsfynydd prior to the Merger and continues to provide services to the Company post-Merger. Dr. Nikolay Savchuk, COO of the Company and a director on the Board, is a stockholder of

ChemDiv and a member of its board of directors. During the years ended December 31, 2025 and 2024, the Company incurred R&D expense of $2,425,000 and $460,000 in the Company's consolidated statements of operations related to ChemDiv's services. As of December 31, 2025, the Company owed ChemDiv $63,000 which was included in accounts payable in the Company's consolidated balance sheets.

Prior to consummation of the Merger, Trawsfynydd entered into a Master Research and Development Agreement with Viriom, Inc. ("Viriom"). Pursuant to the Master Research and Development Agreement, Viriom provided services related to virology to Trawsfynydd prior to the Merger and continues to provide services to the Company post-Merger. Nikolay Savchuk, COO of the Company, serves as President of Viriom and as a member of its board of directors. Dr. Savchuk indirectly holds a significant number of its shares of common stock through a limited liability company of which Dr. Savchuk is the managing member and equity holder. Dr. Robert R. Redfield, M.D., our Chief Medical Officer, serves as a strategic advisor and member of Viriom's board of directors. Additionally, Dr. C. David Pauza Ph.D., our Chief Science Officer, served as the Chief Science Officer of Viriom until April 1, 2024, after which time he resigned from any position with Viriom; and Iain Dukes, Executive Chairman of the Company, served as CEO of Viriom and as a member of its board of directors. On September 9, 2025, the Company and Viriom entered into the Purchase Agreement, pursuant to which the Company purchased certain assets from Viriom in exchange for $2,350,000 cash (Note 3). Effective December 2025, Viriom was sold to an unrelated third-party and is no longer a related party to the Company. During the period from January 1, 2025 through December 2025 and the year ended December 31, 2024, the Company incurred R&D expense of $244,000 and $128,000, respectively, in the Company's consolidated statements of operations related to Viriom's services. As of December 31, 2025, the Company owed Viriom $15,000, which was included in accounts payable in the Company's consolidated balance sheets.

Prior to consummation of the Merger, Trawsfynydd entered into a Master Research and Development Agreement with Expert Systems, Inc. ("Expert"). Pursuant to the Master Research and Development Agreement, Expert provided drug development and consulting services to Trawsfynydd prior to the Merger and continues to provide services to the Company post-Merger. An immediate family member of Dr. Savchuk had a significant ownership interest in Expert. Effective April 1, 2025, Dr. Savchuk's family member divested his ownership interests in Expert Systems and Expert Systems is no longer a related party. During the period from January 1, 2025 through April 1, 2025, the Company incurred immaterial expenses to Expert Systems. As of December 31, 2025, the Company did not owe Expert Systems for services provided while being a related party. During the year ended December 31, 2024, $149,000 was expensed as R&D in the Company's consolidated statements of operations related to Expert Systems services.

License Agreement with related party

In addition, prior to consummation of the Merger, Trawsfynydd entered into a License Agreement (the "Viriom License Agreement") with Viriom, pursuant to which Trawsfynydd obtained an exclusive, royalty-free, sublicensable, world-wide license to certain Viriom patents, applications, and technical information (collectively, the "Viriom Licensed IP") to make, have made, use, sell, offer for sale and import several classes of novel compounds related to the treatment and prevention of viral diseases, specifically for use of the Viriom Licensed IP in the development of treatment and methods to prevent viral disease in Canada, China, the European Union, Hong Kong, Japan, the United States and all areas covered by PCT applications for the Viriom Licensed IP. No annual license fees, royalties, or milestone payments are required. Additionally, pursuant to the Viriom License Agreement, Trawsfynydd obtained the right to control prosecution, defense of infringement and enforcement. As a result of the Merger, the rights and obligations of Trawsfynydd under the Viriom License Agreement were transferred to the Company (through its subsidiaries).

Unless terminated earlier pursuant to the agreement, the Viriom License Agreement shall remain in force and effect for the life of the last-to-expire patent included in the Viriom Licensed IP or last-to-be abandoned patent application licensed under the agreement, whichever is later. The Viriom License Agreement can be terminated by either party due to the material breach of either party (subject to a cure period).

13. License and Collaboration Agreements

SymBio Agreement

In July 2011, the Company entered into a license agreement with SymBio Pharmaceuticals Limited ("SymBio"), which has been subsequently amended, granting SymBio an exclusive, royalty-bearing license for the development and commercialization of rigosertib in Japan and Korea. Under the SymBio license agreement, SymBio is obligated to use commercially reasonable efforts to develop and obtain market approval for rigosertib inside the licensed territory and the Company has similar obligations outside of the licensed territory. The Company has also entered into an agreement with SymBio providing for it to supply SymBio with development-stage product. Under the SymBio license agreement, the Company also agreed to supply commercial product to SymBio under specified terms that will be included in a commercial supply agreement to be negotiated prior to the first commercial sale of rigosertib. The supply of development-stage product and the supply of commercial product will be at the Company's cost plus a defined profit margin. Sales of development-stage product have been de minimis. The Company has additionally granted SymBio a right of first negotiation to license or obtain the rights to develop and commercialize compounds having a chemical structure similar to rigosertib in the licensed territory.

Under the terms of the SymBio license agreement, the Company received an upfront payment of $7,500,000 in 2011. The Company assessed the SymBio arrangement in accordance with ASC 606 and determined that its performance obligations under the SymBio agreement include the exclusive, royalty-bearing, sublicensable license to rigosertib, the research and development services to be provided by the Company and its obligation to serve on a joint committee. The Company concluded that the license was not distinct since it was of no benefit to SymBio without the ongoing research and development services and that, as such, the license and the research and development services should be bundled as a single performance obligation. Since the provision of the license and research and development services are considered a single performance obligation, the $7,500,000 upfront payment was being recognized as revenue ratably through the expected period over which the Company expected the research and development services to be performed. Effective April 17, 2025, the Company and Symbio mutually terminated the license agreement originally entered into by and between the parties in 2011. No payments, compensation, reimbursements or settlements shall be due or owed by either party in connection with the termination of the license agreement. As a result, the Company recognized the $2,733,000 of deferred revenue as revenue on April 17, 2025.

HanX Narazaciclib (ON 123300) Agreement

In December 2017, the Company entered into a license and collaboration agreement with HanX Biopharmaceuticals, Inc. ("HanX"), a company focused on development of novel oncology products, for the further development, registration and commercialization of narazaciclib in Greater China. Narazaciclib is a preclinical compound which the Company believes has the potential to overcome the limitations of current generation CDK 4/6 inhibitors. The key feature of the collaboration was that HanX provided all funding required for the Chinese IND enabling studies necessary in order to seek IND approval by the National Medical Products Administration ("Chinese FDA"). The Chinese IND was approved in January 2020. The Company and HanX also intended for these studies underlying the Chinese IND approval, to meet the US FDA standards for IND approval. Accordingly, such studies were used by the Company for an IND filing with the US FDA in November 2020. In September 2020, a Phase 1 Study with narazaciclib in cancer patients was initiated in China. The Company maintains global rights to the study and study data outside of China. The US FDA Study May Proceed letter was issued in December 2020. Enrollment into the US phase 1 study ("Study 19-01") commenced in May 2021.

If the compound receives regulatory approval and is commercialized, the Company would receive regulatory and commercial milestone payments, as well as royalties on sales in the Greater China territory.

Pint Agreement

On March 2, 2018, the Company entered into a License, Development and Commercialization Agreement (the "Pint License Agreement") and a Securities Purchase Agreement (the "Pint Securities Purchase Agreement") with Pint International SA (which, together with its affiliate Pint Pharma GmbH, are collectively referred to as "Pint").

Under the terms of the Pint License Agreement, the Company granted Pint an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product (the "Pint Licensed Product") containing rigosertib in all uses of rigosertib in humans in Latin American countries (the "Pint Territory", including Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, French Guiana, British Guiana, Suriname, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela).

Pint agreed to make an upfront equity investment in the Company's common stock. In addition, the Company could receive additional regulatory, development and sales-based milestone payments, an additional equity investment, as well as tiered, double digit royalties based on net aggregate net sales in the Pint Territory. Pint and the Company have also agreed to enter into a supply agreement providing for Pint purchasing rigosertib and the Pint Licensed Product from the Company within 90 days of FDA approval of an NDA for the Pint Licensed Product.

Pint may terminate the Pint License Agreement in whole (but not in part) at any time upon 45 days' prior written notice. The Pint License Agreement also contains certain provisions for termination by either party in the event of breach of the Pint License Agreement by the other party, subject to a cure period, or bankruptcy of the other party.

In addition, under the Pint Securities Purchase Agreement, if the FDA approves the NDA for the Pint Licensed Product, Pint will reimburse the Company for certain research and development expenses. Half of the reimbursement amount will be paid in cash, the other half of the amount will be by an equity investment at a premium to the average of the volume weighted average price of common stock for the ten consecutive trading days ended on the day the FDA approves the NDA.

Knight Agreement

In November 2019, the Company entered into a Distribution, License and Supply Agreement (the "Knight License Agreement") with Knight Therapeutics Inc. ("Knight"). Under the terms of the Knight License Agreement, the Company granted Knight (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and manufacture any product (the "Knight Licensed Product") containing rigosertib for Canada (and Israel should Knight exercise its option) (the "Knight Territory") and in human uses (the "Knight Licensed Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to commercialize the Knight Licensed Product in the Knight Territory and in the Knight Licensed Field.

Knight has also agreed to obtain from the Company all of Knight's requirements of the Knight Licensed Products for the Knight Territory, and the Company has agreed to supply Knight with all of its requirements of the Knight Licensed Products. The Company may, at its discretion, use the services of a contract manufacturer to manufacture and package the Knight Licensed Products.

In addition, the Company has granted Knight an exclusive right of first refusal with respect to all or any part of the Knight Territory, to store, market, promote, sell, offer for sale and/or distribute any ROFR Products. As used in the Knight License Agreement, "ROFR Products" means all products other than the Knight Licensed Product that are owned, licensed, or controlled by the Company as of the effective date and all improvements thereto.

The Company is eligible to receive clinical, regulatory and sales-based milestone payments. The Company is also eligible to receive tiered double-digit royalties based on net sales in the Knight Territory.

The Knight License Agreement is for a term of 15 years from the launch on a country-by-country basis in the Knight Territory and contains customary provisions for termination by either party in the event of breach of the Knight License Agreement by the other party (subject to a cure period), bankruptcy of the other party, or challenges to the patents by any sublicensee or assignee.

Specialised Therapeutics Asia Pte. Ltd. Agreement

On December 18, 2019, the Company entered into a Distribution, License and Supply Agreement (the "STA License Agreement") with Specialised Therapeutics Asia Pte. Ltd. ("STA"). Under the terms of the STA License Agreement, the Company granted STA (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and manufacture any product (the "STA Licensed Product") containing rigosertib for Australia and New Zealand (the "STA Territory") and in human uses (the "Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to commercialize the STA Licensed Product in the STA Territory and in the Field.

STA has also agreed to obtain from the Company all of STA's requirements of the STA Licensed Products for the STA Territory, and the Company has agreed to supply STA with all of its requirements of the STA Licensed Products. The Company may, at its discretion, use the services of a contract manufacturer to manufacture and package the STA Licensed Products.

The Company may be entitled to receive clinical, regulatory and sale-based milestone payments. The Company may also be entitled to receive tiered double-digit royalties based on net sales in the Territory.

The License Agreement is for a term of 15 years from the launch on a country-by-country basis in the Territory and contains customary provisions for termination by either party in the event of breach of the License Agreement by the other party (subject to a cure period), bankruptcy of the other party, or challenges to the patents by any sublicensee or assignee.

14. Subsequent Events

On April 15, 2026, the Company completed the April 2026 Financing, with funding expected April 16, 2026, for aggregate gross proceeds of up to $60.0 million. The April 2026 Financing consisted of (i) $10.0 million of upfront gross proceeds at closing from the sale of 5,982,919 shares of the Company's common stock (including pre-funded warrants in lieu thereof), (ii) the issuance of milestone-based warrants with an aggregate exercise price of $10.0 million that becomes exercisable upon receipt of approval from the Medicines and Healthcare products Regulatory Agency ("MHRA") to conduct the human challenge trial, (iii) the issuance of additional milestone-based warrants with an aggregate exercise price of $10.0 million that becomes exercisable upon shareholder approval and the announcement of data from the human challenge trial and (iv) the issuance of common warrants, subject to shareholder approval, with a three-year term to purchase shares of the Company's common stock providing potential additional gross proceeds of $30.0 million if fully exercised. The milestone-based warrants and the common warrants each have an exercise price equal to the per share purchase price in the April 2026 Financing. The common warrants are subject to a forced exercise provision if the trading price of the Company's common stock equals or exceeds 200% of the applicable exercise price for 30 consecutive trading days. The milestone-based warrants become exercisable only upon achievement of the applicable milestone conditions, and there can be no assurance that we will receive any additional proceeds from the exercise of the milestone-based warrants or the common warrants, or as to the timing thereof.

The Company incurred placement agent fees and other offering costs in connection with the April 2026 Financing, including a cash success fee equal to 6% of the upfront gross proceeds.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K/A
(Amendment No. 1)

(Mark one)

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

For the fiscal year ended December 31, 2025

Or

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

For the transition period from to

Commission file number 001-36020

Traws Pharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**22-3627252**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
12 Penns Trail, Newtown, PA	**18940**
(Address of principal executive offices)	(Zip Code)

(267) 759-3680
(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer,", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's voting stock held by non-affiliates was approximately $9.8 million, based on the last reported sale price of the registrant's common stock on the Nasdaq Capital Market.

There were 15,150,669 shares of common stock outstanding as of April 24, 2026.

DOCUMENTS INCORPORATED BY REFERENCE

EXPLANATORY NOTE

Traws Pharma, Inc. (the "Company") is filing this Amendment No. 1 on Form 10-K/A (this "Amendment") to its Annual Report on Form 10-K for the fiscal year ended December 31, 2025, as filed with the Securities and Exchange Commission on April 15, 2026 (the "Original Form 10-K"), to include the information required by Part III of Form 10-K. The Part III information was previously omitted from the Original Form 10-K in reliance on General Instruction G(3) to Form 10-K, which permits the information required by Part III to be incorporated by reference from our definitive proxy statement if such statement is filed no later than 120 days after our fiscal year-end. We are filing this Amendment to provide information required in Part III of Form 10-K because a definitive proxy statement containing such information will not be filed by the Company within 120 days after the end of the fiscal year covered by the Original Form10-K.

In accordance with, among other things, Rule 12b-15 under the Securities Exchange Act of 1934, as amended, this Amendment is accompanied by a currently dated certifications on Exhibits 31.3 and 31.4 by the Company's current Principal Executive Officer and Principal Financial Officer (because no financial statements have been included in this Amendment, and this Amendment does not contain or amend any disclosure with respect to Items 307 and 308 of Regulation S-K, paragraphs 3, 4 and 5 of the certification have been omitted). This Amendment is being filed to: (i) delete the reference on the cover of the Original Form 10-K to the incorporation by reference information from the Company's definitive proxy statement, (ii) amend and restate Part III, Items 10 through 14 of the Original Form 10-K in their entirety to include information previously omitted from the Original Form 10-K, and (iii) amend the Exhibit Index of the Original Form 10-K to include the filing of new certifications.

Except as expressly noted above, this Amendment does not modify or update in any way the disclosures made in the Original Form 10-K and no attempt has been made in this Amendment to modify or update the other disclosures presented in the Original Form 10-K. The Amendment does not reflect events occurring after the filing of the Original Form 10-K or modify or update those disclosures that may be affected by subsequent events, other than as expressly indicated in this Amendment. Accordingly, this Amendment should be read in conjunction with the Original Form 10-K and the Company's other filings with the Securities and Exchange Commission.

TRAWS PHARMA, INC.
INDEX TO REPORT ON AMENDMENT NO.1 ON FORM 10-K/A

PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.*

Directors

All of our directors bring to our Board of Directors executive leadership experience from their service as executives and/or directors of our Company and/or other entities. The biography of each of our current directors, below, contains information regarding the person's business experience, director positions held currently or at any time during the last five years, and the experience, qualifications, attributes and skills that caused the Nominating and Corporate Governance Committee and our Board of Directors to determine that the person should serve as a director, given our business and structure.

Name	Age	Position(s) with Traws Pharma, Inc.	Served as Director From
Iain Dukes, D. Phil.	67	Director, Chief Executive Officer and Secretary	2024
Jack E. Stover	73	Chairman	2016
Werner Cautreels, Ph.D.	73	Director	2024
Nikolay Savchuk, Ph.D.	57	Director and Chief Operating Officer	2024
Trafford Clarke, Ph.D.	68	Director	2022
M. Teresa Shoemaker	65	Director	2020
John Leaman, M.D.	53	Director	2025

Iain Dukes, D. Phil. Dr. Dukes has served as a member of our Board of Directors since April 1, 2024, and previously served as Executive Chairman of the Company from April 1, 2024 to April 15, 2025. Dr. Dukes has served as our Chief Executive Officer since October 1, 2025, prior to which he served as our Interim Chief Executive Officer commencing as of April 1, 2025. Dr. Dukes is a Venture Partner at OrbiMed Advisors LLC, a global investment firm, which he joined in August 2016. He has also served in a consulting role as Chief Executive Officer and as Chairman of Lomond Therapeutics Holdings, Inc. ("Lomond") since November 1, 2024 (prior to which, commencing in January 2020, he served as Chairman of Lomond Therapeutics, Inc., which became a wholly owned subsidiary of Lomond through a merger on November 1, 2024), as the Executive Chair of Angiex Inc. since February 2020, the Chief Executive Officer and Chairman of Eilean Therapeutics LLC since July 2022 and President of Dinas Therapeutics, Inc. since March 2022. In September 2017, Dr. Dukes co-founded Kartos Therapeutics, Inc., and he currently serves as its President and as a member of its board of directors. Dr. Dukes also co-founded Telios Pharmaceuticals, Inc., where he serves as President. From February 2019 to December 2024, Dr. Dukes served as the Chief Executive Officer of Viriom Inc. He also served on the board of directors of Ikena Oncology, Inc. from November 2016 until July 2025. In June 2018, Dr. Dukes co-founded Theseus Pharmaceuticals, Inc., where he served as chairman and director until its acquisition by Concentra Biosciences, LLC in April 2024. Dr. Dukes previously served as Senior Vice President and Head of Business Development and Licensing for Merck Research Laboratories. Prior to joining Merck, Dr. Dukes was Vice President of External Research & Development at Amgen, Inc. He has also served as President and Chief Executive Officer, as well as a member of the Board of Directors of Essentialis Therapeutics, a clinical stage biotechnology company focused on the treatment of rare metabolic diseases. Previously, Dr. Dukes was Vice President of Scientific and Technology Licensing at GlaxoSmithKline, and he held various positions at Glaxo Wellcome, including Head of Exploratory Development for Metabolic and Urogenital Diseases and Head of Ion Channel Drug Discovery Group. From October 2017 to July 2020, Dr. Dukes was a board member and Chairman of KaNDy Therapeutics, which was acquired by Bayer AG in September 2020. From January 2020 to June 2020, Dr. Dukes served as supervisory board member of Themis BioScience GmbH, until it was acquired by Merck & Co. Dr. Dukes currently serves on the boards of directors of NeRRe Therapeutics, Rathlin Therapeutics Limited, Clywedog Therapeutics, Inc. and ENYO Therapeutics. Since August 2016, Dr. Dukes has also served as chairman of the board of directors of Iovance Biotherapeutics Inc. (NASDAQ: IOVA). He previously served on the board of directors of ReViral Limited until its acquisition by Pfizer Inc. in June 2022. Dr. Dukes holds Master of Jurisprudence and Doctor of Philosophy degrees from the University of Oxford, a Master of Science degree in Cardiovascular Studies from the University of Leeds and a Bachelor of Science degree in Pharmacology from the University of Bath.

Our Board of Directors believes that Dr. Dukes' experience holding an executive role at the Company and senior leadership positions in the pharmaceutical industry, as well as his specific skills, developing, financing and managing organizations in the pharmaceutical industry, provide him with the qualifications and skills to serve as a director of the Company.

Jack E. Stover. Mr. Stover has served as a member of our Board of Directors since May 2016, and as Chairman of our Board of Directors since April 15, 2025. From May 2016 to March 2024, he served as a member of the Board of Directors, Chairman of the Audit Committee and a member of the Compensation Committee of Onconova Therapeutics, Inc. (formerly Nasdaq: ONTX) which merged with Trawsfynydd Therapeutics, Inc., to become Traws in March 2024. From March 2021 until July 2025, Mr. Stover served as Chief Executive Officer and as a director of NorthView Acquisition Corp. ("NVAC") (NASDAQ: NVAC), a special purpose acquisition company, and NorthView Sponsor I LLC, and in July 2025 NVAC merged into Profusa, Inc. (NASDAQ: PFSA) ("Profusa"), a digital health company developing tissue integrated biosensors. Since July 2025, he has served as a member of the Board of Directors of Profusa.. From June 2022 until November 2022, when he resigned, Mr. Stover served as a director and Chairman of the Audit Committee of PharmaCyte Biotech (NASDAQ: PMCB) a biotech company developing cell-based therapies for cancer and diabetes. Mr. Stover has also been a member of the Board of Directors of Stero Therapeutics, Inc., a privately-held small molecule biopharma development company since February 2024. From December 2015 until June 2016, Mr. Stover served as Interim President and Chief Executive Officer of Interpace Diagnostics Group, Inc. ("Interpace") (OTC: IDXG)), a molecular diagnostics company focused principally on pancreatic and thyroid cancer and served on the Board of Directors of Interpace and as Chairman of Interpace's Audit Committee from August 2005 until December 2015. From June 2016 until December 2020, Mr. Stover served as President, Chief Executive Officer and Director of Interpace, which changed its name to Interpace Biosciences, Inc. in 2019. From 2004 to 2008, Mr. Stover served as Chief Executive Officer, President and as a director of Antares Pharma, Inc., a publicly held specialty pharmaceutical and device company then listed on the American Stock Exchange and subsequently Nasdaq. In addition to other relevant experience, Mr. Stover has previously served as Chief Operating Officer and Chief Financial Officer of various public and private companies and was also formerly a partner with PricewaterhouseCoopers (then Coopers and Lybrand), working in the bioscience industry division in New Jersey. Mr. Stover received his B.A. in Accounting from Lehigh University and is a Certified Public Accountant.

Our Board of Directors believes that Mr. Stover's experience holding senior leadership positions in the life sciences industry, his specific experience and skills in the areas of general operations, and financial operations and administration, and his extensive experience in accounting and as an audit committee member and chair of various public companies in the life sciences industry, provide him with the qualifications and skills to serve as a director of the Company.

Werner Cautreels, Ph.D. Dr. Cautreels has served as a member of our Board of Directors since April 1, 2024 and served as Chief Executive Officer of the Company from April 1, 2024 to March 31, 2025. Dr. Cautreels is a highly accomplished biopharmaceutical executive with a core emphasis in research and development in various therapeutic areas, who brings a deep understanding of clinical and regulatory strategy. During his 40-year plus career, his work has touched on cardiovascular, autoimmune, oncology, rare disease, and vaccines. Dr. Cautreels served as President and Chief Executive Officer of Selecta Biosciences from July 2010 until 2018. Prior to Selecta Biosciences, Dr. Cautreels served as Global Chief Executive Officer of Solvay Pharmaceuticals until it was acquired by Abbott Laboratories in 2010. Prior to joining Solvay, he worked at Sanofi, Sterling Winthrop and Nycomed-Amersham in a variety of research and development management positions in Europe and the United States. Dr. Cautreels also served as a Director of Innogenetics NV (Gent, Belgium) and of Arqule Inc. (Woburn, Massachusetts). Until April 2019, Dr. Cautreels served as a Director and as Chair of the Audit Committee of Galapagos NV (Mechelen, Belgium). Dr. Cautreels currently serves on the board of directors of Third Pole Therapeutics, a privately held company developing critical life-sustaining therapies for people living with cardiopulmonary and infectious diseases, and on the advisory board of Thuja Capital, an early-stage venture capital firm. Dr. Cautreels also currently serves as Chief Executive Officer of Cristal Therapeutics (Maastricht, The Netherlands) and Chairman of MRM Health (Gent, Belgium). Dr. Cautreels has a Ph.D. in chemistry from the University of Antwerp, Belgium, and an Executive M.B.A. from Harvard Business School.

Our Board of Directors believes that Dr. Cautreels' experience holding senior leadership positions in the pharmaceutical industry, and his specifically as the Company's prior Chief Executive Officer and as a prior Chief Executive Officer for other companies in the pharmaceutical industry, provide him with the qualifications and skills to serve as a director of the Company.

Nikolay Savchuk, Ph.D. Dr. Savchuk has served as a director and Chief Operating Officer of the Company since April 1, 2024. He also currently serves as President and Chief Operating Officer and as a member of the board of directors of Lomond, roles he assumed on November 1, 2024. Prior to that, beginning in January 2020, Dr. Savchuk served as director of Lomond Therapeutics, Inc., which became a wholly owned subsidiary of Lomond through a merger completed on November 1, 2024. Dr. Savchuk has been a Managing Director and Founder at Torrey Pines Investment LLC, an investment firm, since November 2002. Since March 2019, he has been a Member at i2020 Accelerator, which is an accelerator program backed by Torrey Pines Investment. He has also served as the Chief Executive Officer and director of Clywedog Therapeutics, Inc. since December 2020. Dr. Savchuk has served as Chief Operating Officer and President of Eilean Therapeutics, LLC since September 2022, as President and Chief Executive Officer of Eil Therapeutics, Inc. since February 2020, as President and Chief Executive Officer of Bala Therapeutics, Inc. since June 2018, as and Chief Executive Officer of Dinas Therapeutics, Inc. since March 2022. In addition, since October 2018, he has been a Founder and Managing General Partner at Teal Ventures, a venture capital fund. Since November 2015, he has been the Chairman of the board of directors of Viriom Inc., a private biotechnology company. He has been the Chairman of the board of directors at ChemDiv, Inc. since November 2013, and he served as Chief Executive Officer at such company from April 2008 to January 2022. Dr. Savchuk holds a Masters of Science degree in Physics and a Ph.D. in Applied Mathematics, each from the Moscow Institute of Physics and Technology.

Our Board of Directors believes that Dr. Savchuk's experience in biotech investments, drug development and operations provide him with the qualifications and skills to serve as a director of the Company.

Trafford Clarke, Ph.D. Dr. Clarke was appointed to serve as a member of our Board of Directors in December 2022. Dr. Clarke held roles of increasing responsibility in drug development and management at Eli Lilly for 31 years from 1986 until May 2017. Most recently, he served as a Managing Director and UK Research and Development Site Head. While at Eli Lilly, he served as a board member for Eli Lilly and Company Ltd. UK and on the Innovation Board of the Association of the British Pharmaceutical Industry and the European Federation of Pharmaceutical Industries Research Directors group. Dr. Clarke currently serves on the board of the non-profit Barrier Islands Free Medical Clinic. Dr. Clarke has a Ph.D. in organic chemistry from Imperial College, London and a Bachelor of Science in organic chemistry from University of Liverpool.

Our Board of Directors believes that Dr. Clarke's experience holding senior leadership positions in the pharmaceutical industry and his specific skills, developing and managing organizations in the pharmaceutical industry, provide him with the qualifications and skills to serve as a director of the Company.

M. Teresa Shoemaker. Ms. Shoemaker has served as a member of our Board of Directors since April 2020. Ms. Shoemaker served as the President and Chief Executive Officer of Medexus Pharmaceuticals, Inc. ("Medexus") from October 2018 to May 2020. Prior to joining Medexus, she served as President and Chief Executive Officer and as a board member of Medac Pharma, Inc. from its inception in June 2012 until its acquisition by Medexus in October 2018. Ms. Shoemaker led the development and regulatory approval of a product candidate for the treatment of rheumatoid arthritis and developed the commercial strategy that enabled a successful U.S. launch. Previously, Ms. Shoemaker served as Principal and Co-Founder of BioPharm Strategic Solutions from 2010 to 2012. From October 2009 to July 2010, she served as Vice President of Sales at InterMune, Inc., where she built and led the commercial organization, recruiting and scaling a national sales team and establishing foundational go-to-market strategies. From 2002 to 2008, Ms. Shoemaker served as National Sales Director and then Sr. Director US Commercial Operations for Pharmion Corporation ("Pharmion"). Ms. Shoemaker led the U.S. launch of a first-in-class therapy for the treatment of myelodysplastic syndromes (MDS). In 2008, when Celgene Corporation acquired Pharmion, Ms. Shoemaker remained as Executive Director of Strategic Commercial Operations working as part of the executive transition team until 2009. Ms. Shoemaker began her career at DuPont Pharmaceuticals, which was acquired by Bristol Myers Squibb in 2000, where she held a number of sales and marketing leadership positions. Ms. Shoemaker holds B.S. degrees in Communication Science and Psychology from Missouri State University, and a M.S. degree in Communication Science and Disorders from University of Central Missouri.

Our Board of Directors believes that Ms. Shoemaker's experience holding senior leadership positions in the life sciences industry and her specific skills, developing and managing commercial organizations in the life sciences industry, provide her with the qualifications and skills to serve as a director of the Company.

John Leaman, MD. Dr. Leaman was appointed as an independent director of our Board on October 1, 2025, and also serves as a member of our audit committee and compensation committee. Dr. Leaman currently serves as Chief Financial Officer of Cellarity, Inc., a role he has held since March 2023. During his time at Cellarity, he has helped oversee the close of a large pharma partnership, as well as led the company's Series D crossover financing. Prior to joining Cellarity, from June 2019 to February 2023, Dr. Leaman served as Chief Financial & Business Officer of Impel Pharmaceuticals, where he helped lead its IPO in April 2021. From October 2017 to March 2019, Dr. Leaman served as the Chief Financial & Business Officer and Head of Corporate Development at Selecta Biosciences Inc. From June 2016 to September 2017, he served as Head of Corporate Development at InfaCare Pharmaceutical Corp., a specialty pharmaceutical company, until it was acquired by Mallinckrodt plc. in September 2017. From August 2014 to March 2016, Dr. Leaman was the Chief Financial & Business Officer of Medgenics Inc. He also previously held senior roles at Shire plc. and Devon Park Bioventures, a venture capital fund targeting investments in therapeutics companies, and began his career serving a range of life sciences companies as an Associate Principal at McKinsey & Company. He received an M.D. from the Perelman School of Medicine at the University of Pennsylvania, an M.B.A. from the Wharton School at the University of Pennsylvania, a B.A. in psychology, philosophy and physiology from Oriel College, University of Oxford while completing a Rhodes Scholarship, and a B.S. in biology from Elizabethtown College.

Our Board believes that Dr. Leaman's experience holding senior leadership positions in public and private companies in the life sciences and biopharmaceutical industry, as well as his experience with capital raising transactions and partnering with large pharmaceutical companies, provide him with the qualifications and skills to serve as an independent director of the Company.

Executive Officers

The following table sets forth certain information regarding our current executive officers.

Name	Age	Position(s) with Traws Pharma, Inc.
Iain Dukes, D. Phil.	67	Chief Executive Officer, Secretary and Director
Charles Parker	45	Chief Financial Officer
Nikolay Savchuk, Ph.D.	57	Chief Operating Officer and Director
C. David Pauza, Ph.D.	72	Chief Science Officer, Virology
Robert Redfield, M.D.	74	Chief Medical Officer
Victor Moyo, M.D.	58	Chief Medical Officer, Oncology

Iain Dukes, D. Phil. Please see Dr. Dukes' biography under the section entitled "Directors," above.

Charles Parker. Mr. Parker has served as Chief Financial Officer of the Company, on a consulting basis, since October 1, 2025, prior to which he served as our Interim Chief Financial Officer, also on a consulting basis, from July 3, 2025 to September 30, 2025. Mr. Parker is an experienced finance executive with over two decades of experience working with publicly traded biopharma companies and private equity organizations. In May 2025, Mr. Parker began serving as a Director at Stout Risius Ross, LLC, a global advisory firm specializing in corporate finance and accounting services, which has provided supporting finance and accounting related services to the Company since 2024 and through which he provides Chief Financial Officer services to us. Prior to joining Stout, from November 2021 to May 2025, Mr. Parker worked as a consultant for LS Associates, where he provided consulting chief financial officer and other finance and accounting related services to various companies on an interim basis, including without limitation, to Pristine Surgical, LLC, ROM Technologies, Inc., Cantana Bio, and Zogenix, Inc. (Nasdaq: ZGNX). From January 2021 to November 2021, he served as Controller of Dascena, Inc. Mr. Parker has significant experience in public accounting, having worked at BDO USA, LLP for five years and at Parker, Parker and Associates, PLC for five and a half years. Over the course of his career, he has worked with domestic and international small and mid-cap public and private organizations on numerous IPOs, mergers and acquisitions and financings, including more than $700 million in capital raises and multi-million dollar debt restructurings. Mr. Parker holds a B.S. in Accounting from the Lipscomb University.

Nikolay Savchuk, Ph.D. Please see Dr. Savchuk's biography under the section entitled "Directors," above.

C. David Pauza, Ph.D. Dr. Pauza has served as Chief Science Officer, Virology of the Company since April 1, 2024. From 2021 to 2024, Dr. Pauza served as Chief Science Officer of both Trawsfynydd Therapeutics, Inc. ("Trawsfynydd") and Viriom, Inc. Dr. Pauza previously served as Chief Science Officer of American Gene Technologies International, Inc. from 2016 to 2021, where he led development of a cell and gene therapy for HIV disease and developed a robust intellectual property portfolio in cancer and infectious diseases. Before joining the biotechnology industry, Dr. Pauza had a 35-year career in academic research at the University of Maryland, Baltimore. Dr. Pauza obtained his B.A. from San Jose State University, his Ph.D. from University of California, Berkeley and his Post Doctorate from the Medical Research Counsel, United Kingdom.

Robert Redfield, M.D. Dr. Redfield has served as Chief Medical Officer of the Company since April 1, 2024. From 2021 to 2023, Dr. Redfield served as Senior Public Health Advisor to Governor Hogan and the State of Maryland. Dr. Redfield previously served as Director of the U.S. Centers for Disease Control and Prevention from 2018 to 2021 and Senior Strategic Advisor at Pasaca Capital Inc. from 2021 to 2022. Currently, Dr. Redfield is the President and Chief Executive Officer of R3 Enterprises and Consulting, a role he has held since 2021; the Co-Founder and President of Prevention, Diagnosis, Treatment Inc. (PDTi), a role he has held since 2021; and a practicing physician with Greater Baltimore Medical Center (GBMC) Health Partners, a role he has held since 2022. Dr. Redfield is also a director and strategic advisor at Viriom, Inc.

Dr. Redfield has been a public health leader actively engaged in clinical research and clinical care of chronic human viral infections and infectious diseases, especially HIV, for more than 30 years. He served as the founding director of the Department of Retroviral Research within the U.S. Military's HIV Research Program, and retired after 20 years of service in the U.S. Army Medical Corps. Following his military service, he co-founded the University of Maryland's Institute of Human Virology and served as the Chief of Infectious Diseases and Vice Chair of Medicine at the University of Maryland School of Medicine. Dr. Redfield obtained his B.S. and M.D. from Georgetown University.

Victor Moyo, M.D. Dr. Moyo has served as the Company's Chief Medical Officer, Oncology since April 12, 2024. Dr. Moyo joined the Company in June 2023 as Consulting Chief Medical Officer and transitioned to Chief Medical Officer in October 2023. Dr. Moyo is a highly experienced physician researcher and drug developer, with approximately 30 years of clinical research experience, including 19 years in the pharmaceutical industry. He has held a variety of senior leadership positions with responsibility for a number of clinical development plans, IND filings, NDA filings, post-market development plans, notably including his work on Onivyde® for metastatic pancreatic cancer, epoetin alpha trial in myelodysplastic syndrome. He is also a named inventor on numerous granted patents and patent applications. From May 2022 to October 2023, Dr. Moyo served as Chief Medical Officer of OncoPep, Inc. From January 2019 to May 2022, he served as Executive Vice-President, Chief Medical Officer and Head of R&D at L.E.A.F. Pharmaceuticals, where he served as Senior Vice President R&D and Chief Medical Officer from January 2016 to January 2019. Prior to that, he held various leadership roles as a Vice President Clinical Investigations or Medical Director at Merrimack Pharmaceuticals and the Centocor Ortho Biotech Services, LLC division of Johnson & Johnson. Dr. Moyo earned his M.D. from the University of Zimbabwe. Following his move to the U.S., he went on to complete his internship and residency in Internal Medicine at the George Washington School of Medicine and Health Sciences and his fellowship in Hematology and Oncology at the Johns Hopkins University School of Medicine.

Family Relationships

There are no family relationships between or among our directors or executive officers.

Arrangements and Understandings with our Officers and Directors

On April 1, 2024, we completed the acquisition of Trawsfynydd in accordance with the terms of an Agreement and Plan of Merger, dated April 1, 2024 (the "Merger Agreement"), by and among the Company, Traws Merger Sub I, Inc., Traws Merger Sub II, LLC, and Trawsfynydd. Pursuant to the Merger Agreement, on April 1, 2024, effective immediately upon closing of the acquisition, our Board of Directors, upon the recommendation of the Nominating and Corporate Governance

Committee, (i) accepted the resignations of Dr. Steven M. Fruchtman, Peter Atadja, Jerome Groopman and Viren Mehta from the Board of Directors; (ii) accepted the resignations of Dr. Steven M. Fruchtman and Mark Guerin from their roles of Chief Executive Officer of the Company and Chief Operating Officer of the Company, respectively; (iii) appointed Iain Dukes as a director and Executive Chairman of the Company, Nikolay Savchuk as a director of the Company, and Werner Cautreels as a director of the Company; and (iv) appointed Werner Cautreels as the Company's Chief Executive Officer and Nikolay Savchuk as the Company's Chief Operating Officer. Dr. Steven M. Fruchtman remained as the President of the Company and was appointed Chief Scientific Officer, Oncology and Mark Guerin remained as the Chief Financial Officer of the Company.

Except as discussed above, there are no arrangements or understandings between any two or more of our directors or executive officers or between any of our directors or executive officers and any other person pursuant to which any director or officer was or is to be selected as a director or officer, and to our knowledge there is no arrangement, plan or understanding as to whether non-management stockholders will exercise their voting rights to continue to elect the current members of our Board of Directors. To our knowledge, there are also no arrangements, agreements or understandings between non-management stockholders that may directly or indirectly participate in or influence the management of our affairs.

Legal Proceedings

To the best of our knowledge, during the past ten years, none of the following occurred with respect to a present or former director, executive officer, or employee: (i) any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time; (ii) any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses); (iii) being subject to any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his or her involvement in any type of business, securities or banking activities; and (iv) being found by a court of competent jurisdiction (in a civil action), the Securities and Exchange Commission ("SEC") or the Commodities Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacated.

Corporate Governance

Board Composition and Independence

Our Board of Directors currently consists of seven (7) members. Our Board of Directors has undertaken a review of the independence of our directors and has determined that all directors, except Werner Cautreels, Iain Dukes, and Nikolay Savchuk, are independent within the meaning of Section 5605(a)(2) of the NASDAQ Stock Market listing rules and Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our Tenth Amended and Restated Certificate of Incorporation, as amended, provides that our Board of Directors will consist of not less than three nor more than eleven (11) directors, as such number may be fixed by our Board of Directors from time to time. Each director shall be elected to the Board of Directors to hold office until the next annual meeting of stockholders and until his or her successor is elected and qualified, subject to earlier death, resignation or removal.

Board Leadership Structure and Role in Risk Oversight

Our Board of Directors recognizes the time, effort and energy that our Chief Executive officer is required to devote to his position in the current business environment, as well as the commitment required to serve as Chairman of our Board of Directors, particularly as the Company continues to undergo changes to its business and management team and as the Board of Directors' oversight responsibilities continue to grow. We believe that, at present, separating these positions allows our Chief Executive officer to focus on our day-to-day business, while allowing our Chairman to lead the Board of Directors in its fundamental role of providing advice to, and independent oversight of, management. Our Board of Directors also believes that this structure ensures a greater role for the independent directors in the oversight of our company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our Board of Directors.

While our bylaws do not require that our Chairman and Chief Executive Officer positions be separate, our Board of Directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including but not limited to risks relating to limited cash resources, economic uncertainty, volatility of the capital markets, need to raise additional funds, product candidate development, technological uncertainty, dependence on collaborative partners and other third parties, uncertainty regarding patents and proprietary rights, comprehensive government regulations, regulatory uncertainty, having no commercial manufacturing experience, marketing or sales capability or experience and dependence on key personnel. Management is responsible for the day-to-day management of risks we face, while our Board of Directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our Board of Directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed. The Board of Directors periodically consults with management regarding the Company's risks.

Our Board of Directors is actively involved in oversight of risks that could affect us. This oversight is conducted primarily through the Audit Committee of our Board of Directors, but the full Board of Directors has retained responsibility for general oversight of risks.

Board Committees

Our Board of Directors has established three standing committees: the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee. The current members of our Audit Committee are M. Teresa Shoemaker, Trafford Clarke, Jack E. Stover and John Leaman, with Jack E. Stover serving as chairperson. The current members of our Compensation Committee are M. Teresa Shoemaker, Trafford Clarke and Jack E. Stover, with M. Teresa Shoemaker serving as chairperson. The current members of our Nominating and Corporate Governance committee are M. Teresa Shoemaker, Trafford Clarke and Jack E. Stover, with Trafford Clarke serving as chairperson.

Our Board of Directors has determined that each of Jack E. Stover, John Leaman, Trafford Clarke and M. Teresa Shoemaker meet the additional test for independence for audit committee members imposed by SEC regulations and Section 5605(c)(2)(A) of the NASDAQ Stock Market listing rules and that Jack E. Stover, John Leaman, Trafford Clarke and M. Teresa Shoemaker meet the additional test for independence for compensation committee members imposed by Section 5605(d)(2)(A) of the NASDAQ Stock Market listing rules.

Audit Committee

The primary purpose of our Audit Committee is to assist the Board of Directors in the oversight of the integrity of our accounting and financial reporting process, the audits of our consolidated financial statements, and our compliance with legal and regulatory requirements. Our Audit Committee held 8 formal meetings, several informal meetings and various actions were approved by unanimous written consent of the committee during fiscal year 2025. The functions of our Audit Committee include, among other things:

- engaging the independent registered public accounting firm to conduct the annual audit of our consolidated financial statements and monitoring its independence and performance;
- reviewing and approving the planned scope of the annual audit and the results of the annual audit;
- pre-approving all audit services and permissible non-audit services provided by our independent registered public accounting firm;
- reviewing the significant accounting and reporting principles to understand their impact on our consolidated financial statements;
- reviewing our internal financial, operating and accounting controls with management, our independent registered

public accounting firm and our internal audit provider;

- reviewing with management and our independent registered public accounting firm, as appropriate, our financial reports, earnings announcements and our compliance with legal and regulatory requirements;
- periodically reviewing and discussing with management the effectiveness and adequacy of our system of internal controls;
- in consultation with management and the independent auditors, reviewing the integrity of our financial reporting process and adequacy of disclosure controls;
- periodically reviewing potential conflicts of interest under and violations of our code of conduct and overseeing the administration of the Company's code of conduct;
- periodically reviewing financial and accounting personnel succession planning within the Company;
- establishing procedures for the treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters and confidential submissions by our employees of concerns regarding questionable accounting or auditing matters;
- providing oversight for all matters related to the security of and risks related to information technology systems and procedures;
- reviewing and approving related-party transactions; and
- reviewing and evaluating, at least annually, our Audit Committee's charter.

With respect to reviewing and approving related-party transactions, our Audit Committee reviews related-party transactions for potential conflicts of interests or other improprieties. Under SEC rules, as a smaller reporting company, related-party transactions are those transactions to which we are or may be a party in which the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors or executive officers or any other related person had or will have a direct or indirect material interest, excluding, among other things, compensation arrangements with respect to employment and Board of Directors membership. Our Audit Committee could approve a related-party transaction if it determines that the transaction is in our best interests. Our directors are required to disclose to our Audit Committee or the full Board of Directors any potential conflict of interest, or personal interest in a transaction that our Board of Directors is considering.

Our executive officers are required to disclose any related-party transaction to the Audit Committee. We also poll our directors on an annual basis with respect to related-party transactions and their service as an officer or director of other entities. Any director involved in a related-party transaction that is being reviewed or approved must recuse himself or herself from participation in any related deliberation or decision. Whenever possible, the transaction should be approved in advance and if not approved in advance, must be submitted for ratification as promptly as practical.

The financial literacy requirements of the SEC require that each member of our Audit Committee be able to read and understand fundamental financial statements. In addition, at least one member of our Audit Committee must qualify as an Audit Committee financial expert, as defined in Item 407(d)(5) of Regulation S-K promulgated under the Securities Act, and have financial sophistication in accordance with the NASDAQ Stock Market listing rules. Our Board of Directors has determined that Jack E. Stover qualifies as an audit committee financial expert.

Both our independent registered public accounting firm and management periodically will meet privately with our Audit Committee.

The Board of Directors has adopted a charter for the Audit Committee, which is available in the corporate governance section of our website at *https://www.trawspharma.com/corporate-governance.*

Compensation Committee

The primary purpose of our Compensation Committee is to assist our Board of Directors in exercising its responsibilities relating to compensation of our executive officers and employees and to administer our equity compensation and other benefit plans. In carrying out these responsibilities, this committee reviews all components of executive officer and employee compensation for consistency with its compensation philosophy, as in effect from time to time. Our Compensation Committee held 10 formal meetings, several informal meetings and various actions were approved by unanimous written consent of the committee during fiscal year 2025. The functions of our Compensation Committee include, among other things:

- designing and implementing competitive compensation, retention and severance policies to attract and retain key personnel;
- reviewing and formulating policy and determining the compensation of our Chief Executive Officer, other executive officers and employees;
- reviewing and recommending to our Board of Directors the compensation of our non-employee directors;
- reviewing and evaluating our compensation risk policies and procedures;
- administering our equity incentive plans and granting equity awards to our employees and consultants;
- administering our performance bonus plans and granting bonus opportunities to our employees, consultants and non-employee directors under these plans;
- if required from time to time, preparing the analysis or reports on executive officer compensation required to be included in our annual proxy statement;
- engaging compensation consultants or other advisors it deems appropriate to assist with its duties and evaluating whether any consultants retained have any conflicts of interest; and
- reviewing and evaluating, at least annually, our Compensation Committee's charter.

The Board of Directors has adopted a charter for the Compensation Committee, which is available in the corporate governance section of our website at *https://www.trawspharma.com/corporate-governance.*

The Compensation Committee has utilized Radford ("Radford"), an Aon Hewitt company, as its executive compensation consultant. Radford reports directly to the Compensation Committee. The Compensation Committee may replace Radford or hire additional consultants at any time. Upon request by the Compensation Committee or its chair, a representative of Radford attends meetings of the Compensation Committee and is available to discuss compensation issues in between meetings.

In connection with its work for the Compensation Committee, Radford has provided various executive compensation services to the Compensation Committee pursuant to a written consulting agreement. Generally, these services included advising the Compensation Committee on the principal aspects of our executive and non-employee director compensation programs and evolving industry practices and providing market information and analysis regarding the competitiveness of our programs design and our award values in relation to performance.

The Compensation Committee retains sole authority to hire any compensation consultant, approve such consultant's compensation, determine the nature and scope of its services, evaluate its performance, and terminate its engagement. We assessed the independence of Radford pursuant to SEC rules and determined that no known conflict of interest existed that would prevent Radford from serving as an independent consultant to the Compensation Committee.

The Compensation Committee has reviewed our compensation policies and practices for all employees, including our named executive officers, as they relate to risk management practices and risk-taking incentives, and has determined that there are no risks arising from these policies and practices that are reasonably likely to have a material adverse effect on us.

Nominating and Corporate Governance Committee

The primary purpose of our Nominating and Corporate Governance Committee is to assist our Board of Directors in promoting the best interest of our company and our stockholders through the implementation of sound corporate governance principles and practices. Our Nominating and Corporate Governance Committee held 2 formal meetings, several informal meetings and various actions were approved by unanimous written consent of the committee during fiscal 2025. The functions of our Nominating and Corporate Governance Committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our Board of Directors;
- determining the minimum qualifications for service on our Board of Directors;
- developing and recommending to our Board of Directors an annual self-evaluation process for our Board of Directors and overseeing the annual self-evaluation process;
- developing, as appropriate, a set of corporate governance principles, and reviewing and recommending to our Board of Directors any changes to such principles; and
- periodically reviewing and evaluating our Nominating and Corporate Governance Committee's charter.

The Board of Directors has adopted a charter for the Nominating and Corporate Governance Committee, which is available in the corporate governance section of our website at *https://www.trawspharma.com/corporate-governance.*

Meetings of the Board of Directors

The Board of Directors held 4 formal meetings, several informal meetings and various actions were approved by unanimous written consent of the Board of Directors during fiscal 2025. During fiscal 2025, each director attended at least 75 percent of the aggregate of the total number of meetings of the Board of Directors and the committees on which such director served.

Directors are encouraged, but not required, to attend our annual meetings of stockholders. All of our directors attended the 2025 Annual Meeting of Stockholders.

Director Nomination Process

The process followed by our Nominating and Corporate Governance Committee to identify and evaluate director candidates includes requests to members of our Board of Directors and others for recommendations, meetings from time to time to evaluate biographical information and background material relating to potential candidates and interviews of selected candidates by members of the Nominating and Corporate Governance Committee and the Board of Directors.

In determining whether to recommend any particular candidate for inclusion in the Board of Directors' slate of recommended director nominees, our Nominating and Corporate Governance Committee considers the composition of the Board of Directors with respect to depth of experience, balance of professional interests, required expertise and other factors. The Nominating and Corporate Governance Committee considers the value of diversity when recommending candidates. The committee views diversity broadly to include diversity of experience, skills and viewpoint. The Nominating and Corporate Governance Committee does not assign specific weights to particular criteria and no particular criterion is a prerequisite for each prospective nominee. Our Board of Directors believes that the backgrounds and qualifications of its directors, considered as a group, should provide a composite mix of experience, knowledge and abilities that will allow it to fulfill its responsibilities.

Stockholders may recommend individuals to our Nominating and Corporate Governance Committee for consideration as potential director candidates. The Nominating and Corporate Governance Committee will evaluate stockholder-recommended candidates by following the same process and applying the same criteria as it follows for candidates submitted by others.

Stockholders may directly nominate a person for election to our Board of Directors by complying with the procedures set forth in Section 2.2(A) of our bylaws and with the rules and regulations of the SEC. Under our bylaws, only persons nominated in accordance with the procedures set forth in the bylaws will be eligible to be elected to serve as directors. In order to nominate a candidate for service as a director, you must be a stockholder at the time you give the Board of Directors notice of your nomination, and you must be entitled to vote for the election of directors at the meeting at which your nominee will be considered. In addition, the stockholder must have given timely notice in writing to our Secretary. To be timely, a stockholder's notice must be delivered to the Secretary at our principal executive offices not later than the 90th day, nor earlier than the 120th day, prior to the first anniversary of the prior year's annual meeting of stockholders (provided, however, that in the event that the date of the annual meeting is more than 30 days before or 60 days after such anniversary date, notice by the stockholder must be delivered no earlier than the 120th day prior to the annual meeting and no later than the later of the 90th day prior to such annual meeting or the 10th day following the day on which public announcement of the date of such annual meeting is first made by us).

A stockholder's notice must set forth (i) the name, age, business address and, if known, residence address of the nominee, (ii) the principal occupation or employment of the nominee, (iii) the class and number of shares of stock of the Company directly or indirectly, owned beneficially or of record by the nominee, (iv) a description of all arrangements or understandings between you and the nominee and any other person or persons (naming such person or persons) pursuant to which the nomination is to be made by you, and (v) all other information relating to the nominee that is required to be disclosed in solicitations of proxies for the election of directors in an election contest, or is otherwise required, in each case, pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder. Nominations for director must be accompanied by the nominee's written consent to being named in the proxy statement as a nominee and to serving as a director if elected.

Stockholder Communications with the Board of Directors

You can contact our Board of Directors to provide comments, to report concerns, or to ask a question, at the following address.

Chief Executive Officer
Traws Pharma, Inc.
12 Penns Trail
Newtown, PA 18940
United States

You may submit your concern anonymously or confidentially by postal mail. You may also indicate whether you are a stockholder, customer, supplier, or other interested party.

Communications are distributed to our Board of Directors or to any individual directors, as appropriate, depending on the facts and circumstances outlined in the communication.

Code of Conduct for Employees, Executive Officers and Directors

We have adopted a code of conduct (the "Code") applicable to all of our employees, executive officers and directors. If we make any substantive amendments to, or grant any waivers from, the Code for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a Current Report on Form 8-K. The Code is available in the corporate governance section of our website at *https://www.trawspharma.com/corporate-governance.* The inclusion of our website address in this filing does not include or incorporate by reference the information on our website into this filing.

The Audit Committee of our Board of Directors is responsible for overseeing the code of conduct and must approve any waivers of the code of conduct for employees, executive officers or directors.

Insider Trading Policy

We have adopted an Insider Trading Policy governing the purchase, sale, and other dispositions of our securities by our directors, officers, employees and other individuals associated with us, as well as by the Companu itself, that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to us. A copy of our Insider Trading Policy was filed as Exhibit 19.1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

Delinquent Section 16(a) Reports

Pursuant to Section 16(a) of the Exchange Act and the rules issued thereunder, our executive officers, directors and beneficial owners of more than ten percent of our common stock are required to file with the SEC reports of holdings of and transactions in our securities. Copies of such reports are required to be furnished to us. Based solely on a review of the copies of such reports furnished to us, or written representations that no other reports were required, we believe that all required reports were filed in fiscal 2025 in a timely manner, except that (i) Charles Parker, the Company's Chief Financial Officer, failed to timely file his Form 3; (ii) Nikolay Savchuk, the Company's Chief Operating Officer and a director of our Board of Directors, and TPAV, LLC, a 10% stockholder of the Company, each inadvertently failed to timely file one transaction on Form 4 relating to transactions in our securities, and (iii) John Leaman, a director of our Board of Directors failed to timely file one transaction on Form 4 relating to transactions in our securities.

ITEM 11. *EXECUTIVE COMPENSATION.*

Overview of Executive Compensation

The Compensation Committee of our Board of Directors is responsible for overseeing the compensation of all of our executive officers. In this capacity, our Compensation Committee annually reviews and approves the compensation of our (interim) chief executive officer and other executive officers, including such goals and objectives relevant to the executive officers' compensation that the committee, in its discretion, determines are appropriate, evaluates their performance in light of those goals and objectives, and sets their compensation based on this evaluation.

2025 Summary Compensation Table

The following table sets forth information for the fiscal years ended December 31, 2025 and 2024 concerning compensation of (i) each individual who served as our principal executive officer during 2025, and (ii) the two most highly compensated executive officers other than our principal executive officers during 2025 that were serving as executive officers of the Company as of December 31, 2025. We refer to these executive officers as our "named executive officers." The following table shows compensation awarded to or earned by each of our named executive officers for each of the last two or fewer fiscal years during which such individuals were determined to be NEOs.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Stock Awards ($)(2)	Option Awards ($)(3)	All Other Compensation ($)(4)	Total ($)
Iain Dukes, D. Phil. (5)	2025	539,000	237,375	86,077	539,472	—	1,401,924
Chief Executive Officer							
Werner Cautreels, Ph.D. (6)	2025	166,577	—	11,356	118,801	57,163	353,897
Former Chief Executive Officer	2024	445,769	—	200,000	—	1,813	647,582
Charles Pauza (7)	2025	500,000	180,000	43,037	269,696	21,307	1,014,040
Chief Science Officer							
Nikolay Savchuk, Ph.D. (8)	2025	350,000	126,000	38,256	220,554	—	734,810
Chief Operating Officer							

(1) Represents discretionary annual bonus amounts earned in the year reported herein.

(2) The amounts shown for 2025 and 2024 represent the aggregate grant date fair value related to the grant of restricted stock units ("RSUs") to our named executive officers in fiscal 2025 and 2024. Aggregate grant date fair value is calculated in accordance with FASB ASC Topic 718 (excluding the effect of any estimate of future forfeitures). Additional information concerning our financial reporting of RSUs is presented in Note 8 to our Consolidated Financial Statements set forth in our Annual Report on Form 10-K for the year ended December 31, 2025. See the "Outstanding Equity Awards at 2025 Fiscal Year-End" table below for additional details regarding the RSUs that were granted to our named executive officers in fiscal 2025.

(3) The amounts shown for 2025 and 2024 represent the aggregate grant date fair value related to the grant of non-qualified stock options and/or incentive stock options to our named executive officers in fiscal 2025 and 2024. Aggregate grant date fair value is calculated in accordance with FASB ASC Topic 718 (excluding the effect of any estimate of future forfeitures). Additional information concerning our financial reporting of stock options is presented in Note 8 to our Consolidated Financial Statements set forth in our Annual Report on Form 10-K for the year ended December 31, 2025. See the "Outstanding Equity Awards at 2025 Fiscal Year-End" table below for additional details regarding the non-qualified stock options that were granted to our named executive officers in fiscal 2025.

(4) For Dr. Cautreels in 2025, also includes $10,000 payable pursuant to the Separation Agreement and Release of All Claims entered into in connection with his retirement, $45,000 for service as a director of the Board of Directors of the Company, and $2,163 payable as "gross-ups" or other amounts reimbursed during the fiscal year for the payment of taxes. For Mr. Pauza in 2025, this amount includes $13,570 payable for medical insurance expenses and $7,737 payable for "gross-ups" or other amounts reimbursed during the fiscal year for the payment of taxes.

(5) Dr. Dukes has served as a member of our Board of Directors since April 1, 2024, as Executive Chairman of the Company from April 1, 2024 to April 15, 2025, as Interim Chief Executive Officer of the Company from March 31, 2025 to October 1, 2025 and Chief Executive Officer since October 1, 2025. Dr. Dukes' 2025 salary reflects his compensation as Executive Chairman (January through March 2025 at an annualized rate of $350,000) and as Chief Executive Officer (April through December 2025 at an annualized rate of $610,000). In 2025 Dr. Dukes was awarded nonqualified stock options with an average grant value of $439,474, incentive stock options with a grant value of $99,998 and RSUs with a grant value of $86,077.

(6) Dr. Cautreels was appointed as Chief Executive Officer of the Company on April 1, 2024 in connection with closing of our acquisition of Trawsfynydd. Subsequent to the end of fiscal 2024, effective March 31, 2025, he retired and resigned from his role as Chief Executive Officer of the Company. He continues to serve as a member of our Board of Directors. In 2025 Dr. Cautreels, while serving as a non-employee director of the Board of Directors of the Company, was awarded nonqualified stock options with an average grant value of $118,081, RSUs with a grant value of $11,357, as well as $45,000 in cash compensation for service as a director.

(7) Mr. Pauza has served as Chief Science Officer, Virology of the Company since April 1, 2024. In 2025 Mr. Pauza was awarded nonqualified stock options with an average grant value of $169,699, incentive stock options with an average grant value of $99,998 and RSUs with an grant value of $43,037.

(8) Dr. Savchuk has served as Chief Operating Officer and a director of the Company since April 1, 2024. In 2025 Dr. Savchuk was awarded nonqualified stock options with an average grant value of $120,557, incentive stock options with an average grant value of $99,998 and RSUs with an grant value of $38,256.

Employment Agreements

We have entered into employment agreements with each of our named executive officers, and the compensation of our named executive officers is determined, in large part, by the terms of those employment agreements. A summary of the material terms of each named executive officer's employment agreement is set forth below.

Iain Dukes, D. Phil.

Dr. Dukes has served as a member of our Board of Directors since April 1, 2024 and as Executive Chairman of the Company from April 1, 2024 to April 15, 2025. Effective March 31, 2025, Dr. Dukes was appointed as Interim Chief Executive Officer of the Company. Effective October 1, 2025, Dr. Dukes was appointed Chief Executive Officer of the Company.

We entered into an employment agreement with Dr. Dukes on April 16, 2025 (the "Dukes Employment Agreement"), effective April 1, 2025. The Dukes Employment Agreement has an initial term of one year, unless terminated sooner by Dr. Dukes or the Company, and the term automatically renews for additional one-year periods, unless either party provides written notice of termination at least 90 days prior to the end of the applicable term. The Company's failure to renew the agreement does not, by itself, constitute termination without Cause or Good Reason.

The Dukes Employment Agreement provides for an initial base salary at an annualized rate of $610,000, subject to annual review and adjustment by the Compensation Committee or the Board. Subject to the Board's or Compensation Committee's sole discretion, Dr. Dukes is eligible to receive a discretionary annual bonus with a target of 50% of his base salary, evaluated on the basis of pre-set annual bonus goals. Any annual bonus may be paid in the form of cash, stock options, shares of Common Stock, or a combination thereof, at the Board's or Compensation Committee's discretion.

Dr. Dukes is entitled to participate in any employee benefit plans or programs made generally available to similarly situated employees, including health insurance, a flexible spending account, and 401(k) participation. Dr. Dukes is entitled to four weeks of vacation each year. The Company reimburses Dr. Dukes for all reasonable business expenses incurred in connection with his employment. The Dukes Employment Agreement contains confidentiality and intellectual property assignment provisions. Dr. Dukes' position is a full-time position, and Dr. Dukes has agreed to devote his full-time effort, attention, and energies to his duties, subject to pre-approved outside activities set forth in the agreement.

Pursuant to the Dukes Employment Agreement, if Dr. Dukes' employment is terminated for any reason, including death, disability or for Cause, we are obligated to pay to Dr. Dukes or his spouse or estate, as applicable, the balance of his accrued and unpaid base salary, unreimbursed expenses, and unused accrued vacation time through the termination date.

Additionally, pursuant to the Dukes Employment Agreement, if Dr. Dukes' employment is terminated by us without "Cause" or by Dr. Dukes for "Good Reason" on or prior to the first anniversary of the effective date (April 1, 2026), other than during the Change in Control Protection Period, Dr. Dukes would be entitled to receive only the accrued amounts

described above. If such termination occurs after the first anniversary of the effective date and outside the Change in Control Protection Period, Dr. Dukes would be entitled to receive, for each full month of service rendered after the first anniversary of the effective date (up to a maximum of 12 months), one month of severance payments equal to one-twelfth of the sum of (i) his then-current base salary and (ii) his target bonus, payable in installments during the applicable severance period in accordance with the Company's usual payroll practices. If such termination occurs during the Change in Control Protection Period (the 12-month period following a Change in Control), Dr. Dukes would be entitled to receive one and one-half times the sum of (i) his then-current base salary and (ii) target bonus, payable in a lump sum.

In addition, for each full month of service rendered after the first anniversary of the effective date (up to a maximum of 12 months), one-twelfth of any outstanding unvested time-based equity awards previously awarded to Dr. Dukes would become fully vested as of the date of termination, and any then-approved, accrued and unpaid annual bonus for the fiscal year ended immediately prior to the termination date would be paid. The Company would also pay Dr. Dukes' COBRA premiums for a corresponding number of months (up to a maximum of 12 months) following a qualifying termination, or for 18 months following a qualifying termination during the Change in Control Protection Period. As a condition to receive the foregoing severance benefits, Dr. Dukes must deliver to the Company an effective release and waiver of claims and continue to comply with the confidentiality and intellectual property covenants set forth in the Dukes Employment Agreement.

The Dukes Employment Agreement also provides that in the event of a change in ownership or control under Section 280G of the Internal Revenue Code, if any payment to Dr. Dukes would constitute an "excess parachute payment," the aggregate present value of the payments shall be reduced (but not below zero) to the amount that maximizes Dr. Dukes' net after-tax benefit, but only if such reduction would provide a greater net after-tax benefit than no reduction.

Werner Cautreels, Ph.D.

We entered into an employment agreement with Dr. Cautreels on April 1, 2024 (the "Cautreels Employment Agreement") in connection with our acquisition of Trawsfynydd. The Cautreels Employment Agreement had an initial term of one year, unless terminated sooner by Dr. Cautreels or the Company, and the term was to renew for additional one year periods, unless either party provided written notice of termination at least 90 days prior to the end of the applicable term.

The Cautreels Employment Agreement provided for an initial base salary of $610,000, subject to adjustment upon annual review. Subject to the Board of Directors' or Compensation Committee's sole discretion, Dr. Cautreels was eligible for an annual bonus, with a target amount equal to 50% of his base salary (i.e., target bonus), based on the performance of Dr. Cautreels and the Company. The annual bonus may be paid in the form of cash, stock options, shares of our common stock, or a combination thereof, at our Board of Directors' or Compensation Committee's discretion. Additionally, the Cautreels Employment Agreement provided for the grant of 8,000 RSUs as an inducement for Dr. Cautreels to join the Company, which RSUs will vest as to 25% on the first anniversary of the grant date and the remainder will vest in substantially equal annual installments for three years thereafter, subject to his continued service to the Company. The RSUs were granted as inducement awards under Rule 5635(c)(4) of the Nasdaq Stock Market Listing Rules and were granted outside of the Company's 2021 Incentive Compensation Plan (as amended, the "2021 Plan").

Dr. Cautreels was entitled to participate in all of our employee benefit plans and programs that are made generally available from time to time to our executive officers and was entitled to up to four weeks of vacation each year. The Cautreels Employment Agreement contains non-solicitation, non-competition, confidentiality and inventions assignment provisions that, among other things, prevent him from competing with us during the term of his employment and for a specified time thereafter. The Company was also obligated to reimburse Dr. Cautreels for reasonable business expenses, including certain travel and cell phone expenses.

Pursuant to the Cautreels Employment Agreement, if Dr. Cautreels' employment was terminated for any reason, we were obligated to pay to Dr. Cautreels or his spouse or estate, as applicable, the balance of his accrued and unpaid salary, unreimbursed expenses, and unused accrued vacation time through the termination date.

Additionally, pursuant to the Cautreels Employment Agreement, if Dr. Cautreels' employment was terminated by us without "cause" or by Dr. Cautreels for "good reason," other than during the 12-month period following a change in control

of the Company, Dr. Cautreels would be entitled to receive the sum of (i) his current base salary and (ii) target bonus, payable in installments over 12 months. If the termination was during the 12-month period following a change in control of the Company, Dr. Cautreels would be entitled to receive one and one-half times the sum of (i) his current base salary and (ii) target bonus, payable in a lump sum. The Company would also be obligated to reimburse Dr. Cautreels for the employer's portion of his medical insurance costs under COBRA for 12 months if Dr. Cautreels' termination occurred other than during the 12-month period following a change in control of the Company or for 18 months if Dr. Cautreels' termination occurs during the 12 month-period following a change in control of the Company. In addition, all of Dr. Cautreels' outstanding unvested equity awards as of the date of such termination would fully vest as of the date of termination and any accrued, approved and unpaid annual bonus for the year prior to the termination date would be paid. As a condition to receive the forgoing severance benefits, Dr. Cautreels was obligated to deliver to the Company an effective release and waiver of claims and continue to comply with the non-solicitation, non-competition, confidentiality and inventions assignment covenants set forth in the Cautreels Employment Agreement.

Dr. Cautreels retired and resigned from his position as Chief Executive Officer on March 31, 2025. In connection with his retirement, on March 31, 2025, the Company and Dr. Cautreels entered into a Separation Agreement and Release of all Claims, pursuant to which the Company agreed to pay Dr. Cautreels $10,000 (less standard deductions and withholdings), payable in a single lump sum, which amount includes all amounts due and payable to Mr. Cautreels through the termination date. In exchange for such payment, Dr. Cautreels provided the Company with a general release and waiver of claims, and agreed to be bound by certain restrictive covenants, including those relating to non-disparagement and confidentiality.

Additionally, on March 31, 2025, the Company and Dr. Cautreels entered into a Consulting Services Agreement (the "Consulting Agreement"), pursuant to which Dr. Cautreels agreed to provide certain consultancy services to the Company for the period from April 1, 2025 to December 31, 2025, subject to earlier termination or extension pursuant to the Consulting Agreement. Pursuant to the Consulting Agreement, the Company shall pay Dr. Cautreels $10,000 per month as compensation for services to be rendered during the term of the Consulting Agreement.

Charles Pauza

Mr. Pauza has served as Chief Science Officer of the Company since April 1, 2024 on an at-will basis pursuant to an employee offer letter. Mr. Pauza's 2025 base salary was $500,000. Subject to the Compensation Committee's sole discretion, Mr. Pauza is eligible for an annual bonus, of up to 40% of his base salary (i.e., target bonus), based on the performance of Mr. Pauza and the Company. Mr. Pauza earned a bonus of $180,000 for fiscal year 2025.

Nikolay Savchuk, Ph.D.

Dr. Savchuk has served as Chief Operating Officer and a director of the Company since April 1, 2024 on an at-will basis pursuant to an employee offer letter. Dr. Savchuk's 2025 base salary was $350,000. Subject to the Compensation Committee's sole discretion, Dr. Savchuk is eligible for an annual bonus, of up to 40% of his base salary (i.e., target bonus), based on the performance of Dr. Savchuk and the Company. Dr. Savchuk earned a bonus of $126,000 for fiscal year 2025.

Outstanding Equity Awards at 2025 Fiscal Year-End

The following table contains certain information regarding equity awards held by the named executive officers as of December 31, 2025:

	Option Awards(1)				Stock Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Iain Dukes								
	152,116 (4)	—	1.75	11/1/2033				
					2,025 (2)	2,288		
	—	33,222	3.01	10/12/2035				
	—	31,617	3.01	10/12/2035				
	—	147,771	2.33	12/12/2035				
					36,943	41,476		
Werner Cautreels								
					6,000 (2)	6,780		
	—	23,000	1.65	6/19/2035				
	—	11,530	3.01	10/12/2035				
	—	19,496	2.33	12/12/2035				
					4,874	5,508		
Charles Pauza								
	20,130 (3)	—	0.25	12/13/2031				
	13,326 (3)	—	1.75	11/1/2033				
					2,925 (2)	3,305		
	—	32,406	3.01	10/12/2035				
	—	1,054	2.33	12/12/2035				
	—	72,832	2.33	12/12/2035				
					18,471	20,872		
Nikolay Savchuk								
	152,116 (4)	—	1.75	11/1/2033				
					2,025 (2)	2,288		
	—	22,435	3.01	10/12/2035				
	—	13,935	2.33	12/12/2035				
	—	51,741	2.33	12/12/2035				
					16,419	18,553		

(1) Unless otherwise noted, all unvested option awards vest 100% on the first year anniversary of the grant date.

(2) These are RSUs issued as inducement grants outside of the Company's incentive plans in accordance with Nasdaq Listing Rules that vest over four years: 25% on the first anniversary; 25% on the second anniversary; 25% on the third anniversary; and 25% on the further anniversary.

(3) Options vested in 24 equal monthly installments.

(4) Options vested 100% on grant date.

Potential Payments Upon Termination of Employment or Change in Control

As discussed under the section of this filing entitled "Employment Agreements" above, we have agreements with our named executive officers pursuant to which they will receive severance payments upon certain termination events. The information below describes certain compensation that would be available under our existing plans and arrangements if (i) the named executive officer was terminated as of December 31, 2025 or (ii) if a Change in Control, as defined in the applicable employment agreement or plan, occurred on December 31, 2025 and the named executive officer's employment had been subsequently terminated on the same date.

Acceleration of Equity Awards in connection with a Change in Control

Pursuant to the terms of each named executive officer's option agreements reflecting options granted under the Company's 2018 Omnibus Incentive Compensation Plan, as previously amended (the "2018 Plan"), applicable award agreements reflecting options and RSUs granted under the 2021 Plan and the applicable award agreement reflecting cash-settled stock appreciation rights and cash-settled PSUs, in the event of a "Change in Control" in which the Company is not the surviving corporation (or survives only as a subsidiary of another corporation) and the awards are assumed by, or replaced with awards with comparable terms by, the surviving corporation (or parent or subsidiary of the surviving corporation) and the named executive officer's employment or service is terminated without "Cause" or the named executive officer terminates his employment for "Good Reason" (as such terms are defined in the applicable award agreement), all such awards shall fully vest and, if applicable, become exercisable, upon termination of employment or service. In the event that the surviving corporation (or a parent or subsidiary of the surviving corporation) does not assume or replace the awards with grants that have comparable terms, and named executive officer is employed by, or providing services to, the Company and its subsidiaries on the date of the Change in Control, all awards granted pursuant to such award agreements shall fully vest and, if applicable, become exercisable.

Termination Other than for Cause, Death or Disability; Resignation for Good Reason

The outstanding options, RSUs and stock appreciation rights held by our named executive officers will vest and, if applicable, become exercisable in the event that the named executive officer's employment or service is terminated without "Cause" or the named executive officer terminates his employment for "Good Reason" (as such terms are defined in the applicable award agreement).

Director Compensation

The following table summarizes compensation paid to our non-employee directors in fiscal 2025.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($) (1) (2)	Option Awards ($) (1) (2)	All Other Compensation ($)	Total ($)
Jack E. Stover (3)	196,500	14,346	130,041	—	340,887
M. Teresa Shoemaker	71,500	14,346	130,041	—	215,887
Trafford Clarke, Ph.D.	69,500	14,346	130,041	—	213,887
Werner Cautreels, Ph.D. (4) . .	45,000	11,356	118,081	—	174,437
John Leaman, MD (5)	13,125	9,455	65,153	—	87,733

(1) The amounts shown represent the aggregate grant date fair value related to the grant of non-qualified stock options and/or RSUs to our non-employee directors during fiscal 2025, calculated in accordance with FASB ASC Topic 718. These stock options and RSUs vest on the first anniversary of the grant, and the stock options expire ten years after the grant date and are subject to the director's continued service. Additional information concerning our financial reporting of stock options is presented in Note 8 to our Consolidated Financial Statements set forth in our Annual Report on Form 10-K for the year ended December 31, 2025.

(2) As of December 31, 2025, the aggregate number of outstanding stock option awards held by each non-employee director was: Mr. Stover—94,214; Dr. Clarke—81,598; Ms. Shoemaker—80,777; and Dr. Cautreels—54,026. As of December 31, 2025, the aggregate number of stock appreciation rights held by each non-employee director was: Ms. Shoemaker—334; and Mr. Stover—334. As of December 31, 2025, the aggregate number of RSUs held by each non-employee director was: Dr. Clarke—6,157; Ms. Shoemaker—6,157; Dr. Cautreels—10,874; and Mr. Stover—6,157.

(3) Mr. Stover was appointed as Chairman of the Board of Directors on April 15, 2025. In connection with his appointment as Chairman, the Board approved the payment of an aggregate of $120,000 in cash for services to be rendered as Chairman during the period from April 15, 2025 through December 31, 2025.

(4) Dr. Cautreels retired and resigned from his role as Chief Executive Officer of the Company effective March 31, 2025. He has continued to serve as a non-employee member of our Board of Directors since that date. Amounts shown in this table reflect only compensation earned by Dr. Cautreels for his service as a non-employee director. Compensation

earned by Dr. Cautreels as Chief Executive Officer during January through March 2025 is reported in the Summary Compensation Table above.

(5) Dr. Leaman was appointed as a non-employee director on October 1, 2025.

In June 2013, our Board of Directors approved a non-employee director compensation policy, which became effective for all non-employee directors in July 2013 and has been amended from time to time since the adoption of such policy. In September 2024, our Board of Directors revised its non-employee director compensation policy to change the equity award value members of our Board of Directors would receive, based on a benchmarking study comparing our director compensation to a group of comparable peer companies; cash stipend amounts remain unchanged. Under the new policy, each non-employee director is entitled to receive an annual equity award with a grant date value of $28,400 for the applicable fiscal year, which is to be awarded at the first Board of Directors meeting after the Company's annual meeting of stockholders for that year; provided, however, that for the first Board meeting following the Company's 2024 Annual Meeting, each non-employee director received stock options with a grant date value of $59,000 (options to purchase 15,780 shares of Company common stock). Additionally, pursuant to the new policy, each new non-employee director receives an option with a grant date value of $59,000 on the date service commences.

In accordance with this policy, each non-employee director is entitled to receive an annual base retainer of $45,000. In addition to the equity compensation discussed above, our non-employee directors are entitled to receive the following cash compensation for board services, as applicable:

- the chair of our Board of Directors, when the chair is not an employee, receives an additional annual retainer of $30,000;

- each member of our Audit, Compensation and Nominating and Corporate Governance Committees received an additional retainer of $7,500, $5,000 and $4,000, respectively; and

- each chairperson of our Audit, Compensation and Nominating and Corporate Governance Committees received an additional annual retainer of $15,000, $10,000 and $8,000, respectively, in addition to the retainer received for service as a member of such committee.

Notwithstanding the foregoing, on April 15, 2025, in connection with Mr. Stover's appointment as Chairman, our Board of Directors approved the payment of an aggregate of $120,000 in cash to Mr. Stover for services to be rendered by Mr. Stover as Chairman of the Board of Directors during the period commencing April 15, 2025 through December 31, 2025, after which the Chairman retainer is expected to revert back to the typical annual retainer of $30,000.

All amounts are paid in quarterly installments. To the extent that an individual serves as a non-employee director for less than a full year, he or she shall be entitled to receive a pro-rata portion of the above amounts based on the percentage of the year for which he or she serves in such role.

All of our directors are eligible to receive additional discretionary awards under the 2021 Plan, subject to the annual limit set forth in the 2021 Plan.

We reimburse each non-employee director for out-of-pocket expenses incurred in connection with attending our Board of Directors and committee meetings. Compensation for our directors, including cash and equity compensation, is determined, and remains subject to adjustment, by our Board of Directors.

Equity Award Grant Timing

We do not have a written policy in place regarding the timing of the grant and issuance of stock options in relation to the release of material non-public information. Historically, we have typically granted option awards in the first quarter of the year, to the extent that options are awarded as a component of annual bonuses, shortly after the completion of our annual meeting of shareholders, and as may otherwise be deemed appropriate by our Board of Directors or Compensation

Committee from time to time based on the facts and circumstances, as applicable. We have not intentionally timed the grant of stock options in anticipation of the release of material nonpublic information, nor have we intentionally timed the release of material nonpublic information based on stock option grant dates.

The date on which an equity award is granted is the date specified in the resolutions of the Board of Directors or Compensation Committee, as applicable, authorizing the grant. The grant date must fall on or after the date on which the resolutions are adopted by the Board of Directors or Compensation Committee. For stock options, the exercise price is the closing sale price of the Company's common stock on the grant date, as reported by the Nasdaq Capital Market, or as otherwise required or permitted by the applicable equity plan under which the option is granted. Under our equity plans, the per share exercise price of an option cannot be less than the fair market value of a share of our common stock on the date of grant.

During fiscal year 2025, we did not grant stock options (or similar awards) to any of our named executive officers during the period beginning four business days before and ending one business day after the filing of any Company periodic report on Form 10-Q or Form 10-K, or the filing or furnishing of any Company Form 8-K that disclosed any material non-public information.

ITEM 12. ***SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.***

The following table sets forth certain information regarding the beneficial ownership of our common stock as of April 24, 2026 by (a) each person known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock, (b) each of our named executive officers identified under the heading, "2025 Summary Compensation Table," (c) each of our directors, and (d) all of our executive officers and directors as a group.

The percentage of common stock outstanding is based on 15,150,669 shares of common stock outstanding on April 24, 20256. For purposes of the table below, and in accordance with the rules of the SEC, we deem shares of common stock subject to warrants and options that are currently exercisable or exercisable within sixty days of April 24, 2026 to be outstanding and to be beneficially owned by the person holding the warrants and options for the purpose of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. Except as otherwise noted, we believe that each of the persons or entities in this table has sole voting and investing power with respect to all of the shares of common stock beneficially owned by him, her or it, subject to community property laws, where applicable. Except as otherwise noted below, the street address of each beneficial owner is c/o Traws Pharma, Inc., 12 Penns Trail, Newtown, PA 18940.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or greater stockholders:		
Silv Fund Ltd. (1)	1,995,883	12.69 %
OrbiMed Advisors LLC (2)	1,203,260	7.94 %
Perceptive Advisors LLC (3)	886,887	5.85 %
Ally Bridge Medalpha Master Fund L.P. (4)	1,197,918	7.70 %
Ikarian Healthcare Master Fund, L.P.(5)	812,524	5.32 %
Directors, Director Nominees and Named Executive Officers:		
Iain Dukes, D. Phil. (6)	233,983	1.53 %
Charles Pauza (7)	35,406	*
Werner Cautreels, Ph.D. (8)	123,348	*
Trafford Clarke, Ph.D. (9)	45,439	*
Nikolay Savchuk, Ph.D. (10)	659,969	4.24 %
M. Teresa Shoemaker (11)	44,618	*
Jack E. Stover (12)	58,055	*
John Leaman, MD	—	—
All current executive officers and directors as a group (11 persons) (13)	1,206,102	7.57 %

* Represents a beneficial ownership of less than one percent of our outstanding shares of common stock.

(1) Based on our records. Includes (i) 1,388,527 shares directly held by Silv Fund Ltd., (ii) 565,792 shares issuable upon exercise of pre-funded warrants issued to Silv Fund Ltd., which are currently exercisable subject to certain beneficial ownership limitation terms set forth within such pre-funded warrants, (iii) 29,531 shares directly held by Manatee Access Fund LP, which may be viewed as an affiliate of Silv Fund Ltd., and (iv) 12,033 shares issuable upon exercise of pre-funded warrants issued to Manatee Access Fund LP, which are currently exercisable subject to certain beneficial ownership limitation terms set forth within such pre-funded warrants. The address of both entities is 1674 Meridian Avenue, Suite 320 Miami Beach, FL 33139.

(2) Based on our records and a Form 4 filed by OrbiMed on April 28, 2026 with the SEC. These shares are held of record by OPI VIII. OrbiMed Capital GP VIII LLC ("GP VIII"), is the general partner of OPI VIII. OrbiMed Advisors is the managing member of GP VIII. By virtue of such relationships, OrbiMed Advisors and GP VIII may be deemed to have voting power and investment power over the securities held by OPI VIII and, as a result, may be deemed to have beneficial ownership over such securities. OrbiMed Advisors exercises voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter

Neild, each of whom disclaims beneficial ownership of the securities held by OPI VIII. The address of OrbiMed Advisors is 601 Lexington Avenue, 54th Floor, New York, NY 10022.

(3) Based on our records and a Schedule 13G/A filed by Perceptive Advisors LLC ("Perceptive Advisors") with the SEC on November 14, 2026. Perceptive Advisors shares voting and dispositive power over the shares of common stock with Perceptive Life Sciences Master Fund, Ltd and Joseph Edelman. Mr. Edelman serves as the Managing Member of Perceptive Advisors. The address of Perceptive Advisors is 51 Astor Place, 10th Floor, New York, NY 10003.

(4) Based on our records. Includes (i) 393,118 shares directly held by Ally Bridge Medalpha Master Fund L.P., (ii) 205,841 shares issuable upon exercise of pre-funded warrants issued to Ally Bridge Medalpha Master Fund L.P., which are currently exercisable subject to certain beneficial ownership limitation terms set forth within such pre-funded warrants, (iii) 393,118 shares directly held by Ally Bridge Medalpha Long Opportunities Fund L.P., which may be viewed as an affiliate of Ally Bridge Medalpha Master Fund L.P., and (iv) 205,841 shares issuable upon exercise of pre-funded warrants issued to Ally Bridge Medalpha Long Opportunities Fund L.P., which are currently exercisable subject to certain beneficial ownership limitation terms set forth within such pre-funded warrants. The address of both entities is c/o Ally Bridge Group (NY) LLC 430 Park Avenue, 12th Floor New York, NY 10022.

(5) Includes 134,382 shares of common stock issuable upon exercise of outstanding warrants that are currently exercisable or exercisable or exercisable within sixty days of February 17, 2026. Based on a Schedule 13G/A filed by Ikarian Capital, LLC ("Ikarian") and Neil Shahrestani on February 17, 2026 with the SEC. Ikarian is an investment adviser registered under the Investment Advisers Act of 1940, as amended, and serves as investment manager to Ikarian Healthcare Master Fund, L.P. (the "Fund") and as sub-adviser to the managed accounts, and may be deemed to have beneficial ownership of the securities through the investment discretion it has over the Fund and the managed accounts. Ikarian is ultimately controlled, indirectly, by Mr. Shahrestani. Accordingly, Mr. Shahrestani may be deemed to indirectly beneficially own securities beneficially owned by Ikarian. The Fund disclaims beneficial ownership of the shares held by the managed accounts. The managed accounts disclaim beneficial ownership of the shares held by the Fund. The address of Ikarian is c/o Ikarian Capital, LLC, 100 Crescent Court, Suite 1620, Dallas, Texas 75201.

(6) Includes 80,517 shares of common stock, 1,350 RSUs that have vested or are scheduled to vest within sixty days of April 24, 2026, and 152,116 shares of common stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of April 24, 2026.

(7) Includes 33,456 shares of common stock issuable upon the exercise of options that are exercisable within sixty days of April 24, 2026 and 1,950 RSUs that have vested or are scheduled to vest within sixty days of April 24, 2026.

(8) Includes 96,348 shares of common stock, 23,000 shares of common stock issuable upon the exercise of options that are exercisable within sixty days of April 24, 2026 and 4,000 RSUs that have vested or are scheduled to vest within sixty days of April 24, 2026.

(9) Includes 45,439 shares of common stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of April 24, 2026.

(10) Includes 251,227 shares of common stock, 255,276 shares of common stock issuable upon conversion of outstanding shares of Series C Non-Voting Convertible Preferred Stock that are currently convertible, 1,350 RSUs that are scheduled to vest within sixty days of April 24, 2026, and 152,116 shares of common stock issuable upon the exercise options that are currently exercisable or exercisable within sixty days of April 24, 2026. Does not include shares of common stock owned by Viriom, Inc. or TPAV, LLC, for which Mr. Savchuk disclaims beneficial ownership.

(11) Includes 44,618 shares of common stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of April 24, 2026.

(12) Includes 58,055 shares of common stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of April 24, 2026.

(13) Includes shares beneficially owned by Victor Moyo, who serves as the Company's Chief Medical Officer, Oncology, Charles Parker, who serves as the Company's Chief Financial Officer, and Robert Redfield, M.D., who serves as the Company's Chief Medical Officer, as well as Iain Dukes, Charles Pauza, Werner Cautreels, Nikolay Savchuk, Trafford Clarke, M. Teresa Shoemaker, Jack E. Stover, and John Leaman.

Equity Compensation Plan Information

The following table summarizes the total number of outstanding awards and shares available for other future issuances of options under our equity compensation plans as of December 31, 2025.

Plan Category	Number of Shares to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Shares Remaining Available for Future Issuance Under the Equity Compensation Plan (Excluding Shares in First Column)
Equity compensation plans approved by stockholders.	1,479,929(1)	$ 8.67 (2)	827,845(3)
Equity compensation plans not approved by stockholders. . . .	386,747(4)	$ 1.24 (2)	—
Total.	1,866,676		827,845

(1) Consists of stock options and RSUs granted under our 2013 Equity Compensation Plan, 2018 Plan and the 2021 Plan (collectively, the "Plans").

(2) The weighted average exercise price is calculated based solely on the outstanding stock options. It does not take into account the shares issuable upon vesting of outstanding RSU awards, which have no exercise price.

(3) Consists of shares remaining available for issuance under our 2021 Plan.

(4) Consists of (i) 21,200 shares of common stock underlying outstanding RSUs issued as inducement awards outside of the Plans in April 2024 in accordance with Nasdaq Listing Rules, and (ii) stock options to purchase 365,547 shares of common stock that were assumed by the Company in connection with our acquisition of Trawsfynydd. No additional awards may be granted under the Trawsfynydd Therapeutics, Inc. 2021 Stock Plan, pursuant to which such assumed stock options were initially granted.

ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.*

Review and Approval of Related Person Transactions

The Audit Committee of our Board of Directors is charged with the responsibility of reviewing and approving all related person transactions (as defined in SEC regulations) and periodically reassessing any related person transaction that we enter to ensure continued appropriateness. This responsibility is set forth in our Audit Committee charter. A related party transaction will only be approved if the Audit Committee determines that the transaction is in the best interests of the Company. If a director is involved in the transaction, he or she will recuse himself or herself from all decisions regarding the transaction.

After our acquisition of Trawsfynydd on April 1, 2024, the Company had the following related party transactions, all of which have been approved by the Board and the Audit Committee as deemed necessary:

Prior to our acquisition of Trawsfynydd, on January 5, 2022, Trawsfynydd entered into a Master Research and Development Agreement with Viriom, Inc. ("Viriom"), pursuant to which Viriom provided services related to virology to Trawsfynydd prior to the Merger and continues to provide services to the Company. Nikolay Savchuk, Chief Operating Officer of the Company and a member of our Board of Directors, serves as President of Viriom and as a member of its board of directors, and Iain Dukes, Chief Executive Officer of the Company and a member of our Board of Directors, served as Chief Executive Officer of Viriom until December 2024. Dr. Savchuk has investment control of Viriom and indirectly holds a significant number of its shares of common stock through AAAn LLC, a limited liability company of which Dr. Savchuk is the managing member and equity holder. Dr. Robert R. Redfield, M.D., our Chief Medical Officer, serves as a strategic advisor and member of Viriom's board of directors. Additionally, Dr. C. David Pauza Ph.D., our Chief Science Officer, served as the Chief Science Officer of Viriom until April 1, 2024, after which time he resigned from any position with Viriom; and Iain Dukes, Executive Chairman of the Company, served as Chief Executive Officer of Viriom and as a member of its board of directors. On September 9, 2025, the Company and Viriom entered into an Asset Purchase Agreement, pursuant to which the Company purchased certain intellectual property assets related to a pyrrolidine antiviral compound program, including issued patents, pending patent applications and related rights, from Viriom in exchange for $2,350,000 in cash. Effective December 2025, Viriom was sold to an unrelated third party and is no longer a related party to the Company. During the period from January 1, 2025 through December 2025 and the year ended December 31, 2024, the Company incurred R&D expense of $244,000 and $128,000, respectively, in the Company's consolidated statements of operations related to Viriom's services. As of December 31, 2025, the Company owed Viriom $15,000, which was included in accounts payable in the Company's consolidated balance sheets.

Prior to our acquisition of Trawsfynydd, on January 20, 2023, Trawsfynydd entered into a License Agreement (the "Viriom License Agreement") with Viriom, pursuant to which Trawsfynydd obtained an exclusive, royalty-free, sublicensable, world-wide license to certain Viriom patents, applications, and technical information (collectively, the "Viriom Licensed IP") to make, have made, use, sell, offer for sale and import several classes of novel compounds related to the treatment and prevention of viral diseases, specifically for use of the Viriom Licensed IP in the development of treatment and methods to prevent viral disease in Canada, China, the European Union, Hong Kong, Japan, the United States and all areas covered by PCT applications for the Viriom Licensed IP. No annual license fees, royalties, or milestone payments are required. Additionally, pursuant to the Viriom License Agreement, Trawsfynydd obtained the right to control prosecution, defense of infringement and enforcement. As a result of the Merger, the rights and obligations of Trawsfynydd under the Viriom License Agreement were transferred to the Company (through its subsidiaries).

Prior to our acquisition of Trawsfynydd, on September 23, 2022, Trawsfynydd entered into a Master Research and Development Agreement with ChemDiv, Inc. ("ChemDiv"). Pursuant to the Master Research and Development Agreement, ChemDiv provided services related to preclinical drug discovery to Trawsfynydd prior to the acquisition and continues to provide services to the Company. Dr. Nikolay Savchuk, Chief Operating Officer of the Company and a member of our Board of Directors, is a stockholder of ChemDiv and a member of its board of directors. During the years ended December 31, 2025 and 2024, the Company incurred R&D expense of $2,425,000 and $460,000, respectively, in the Company's consolidated statements of operations related to ChemDiv's services. As of December 31, 2025, the Company owed ChemDiv $63,000, which was included in accounts payable in the Company's consolidated balance sheets.

Prior to our acquisition of Trawsfynydd, on September 1, 2022, Trawsfynydd entered into a Master Research and Development Agreement with Expert Systems, Inc. ("Expert"). Pursuant to the Master Research and Development Agreement, Expert provided drug development and consulting services to Trawsfynydd prior to the acquisition and continued to provide services to the Company. An immediate family member of Dr. Savchuk had a significant ownership interest in Expert. Effective April 1, 2025, Dr. Savchuk's family member divested his ownership interests in Expert and Expert is no longer a related party. During the period from January 1, 2025 through April 1, 2025, the Company incurred immaterial expenses related to Expert's services. As of December 31, 2025, the Company did not owe Expert for services provided while Expert was a related party. During the year ended December 31, 2024, $149,000 was expensed as R&D in the Company's consolidated statements of operations related to Expert's services.

Pursuant to a Securities Purchase Agreement entered into by the Company and TPAV LLC ("TPAV") on April 1, 2024 in connection with our acquisition of Trawsfynydd, TPAV purchased 13,489 shares of Company common stock and 1,070.93 shares of Series C Preferred Stock for an aggregate purchase price of $9,499,995. Nikolay Savchuk, the Company's Chief Operating Officer and a member of our Board of Directors, serves as the sole manager on the board of managers of TPAV.

Additionally, pursuant to a Securities Purchase Agreement entered into by and between the Company and various investors on December 29, 2024 (the "December 2024 Purchase Agreement"), TPAV purchased 96,348 Class B Units, consisting of pre-funded warrants to purchase 96,348 shares of Company common stock and Series A Warrants to purchase 96,348 shares of Company common stock for an aggregate purchase price of $491,664.

Werner Cautreels, our former Chief Executive Officer and a member of our Board of Directors, also purchased 96,348 Class B Units, consisting of pre-funded warrants to purchase 96,348 shares of Company common stock and Series A Warrants to purchase 96,348 shares of Company common stock for an aggregate purchase price of $491,664 pursuant to the December 2024 Purchase Agreement.

See "Item 10. Directors, Executive Officers and Corporate Governance; Corporate Governance, Board Composition" above for a discussion regarding the independence of the members of our Board of Directors.

ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES.*

Fees of Independent Registered Public Accounting Firms

We engaged KPMG LLP ("KPMG") as the Company's independent registered public accounting firm on July 16, 2024. Prior to that, including for part of the 2024 fiscal year and all of the 2023 fiscal year, Ernst & Young LLP ("E&Y") served as the Company's independent registered public accounting firm. E&Y was dismissed as the Company's independent registered public accounting firm on July 16, 2024. The Company disclosed the change in auditors in a Current Report on Form 8-K filed with the SEC on July 19, 2024.

The following table summarizes the fees of KPMG (Philadelphia, PA, PCAOB ID: 185) and E&Y (Philadelphia, PA, PCAOB ID: 42), our independent registered public accounting firms for fiscal 2025 and 2024, billed to us for each of the last two fiscal years.

Fee Category	Fiscal 2025	Fiscal 2024
Audit Fees(1)	$ 638,135	$ 720,000
Audit-Related Fees(2)	—	—
Tax Fees(3)	—	—
Total Fees	$ 638,135	$ 720,000

(1) Audit fees include fees for professional services rendered in connection with the audit of our annual financial statements for fiscal years 2025 and 2024 and for reviews of our quarterly financial statements and those services normally provided in connection with statutory or regulatory filings or engagements including comfort letters, consents and other services related to SEC matters.

(2) Audit-related fees consist of fees for assurance and related services that are reasonably related to the performance of the audit and the review of our consolidated financial statements and which are not reported under "Audit Fees."

(3) Tax fees for fiscal 2025 and fiscal 2024 include fees for tax advice, tax return preparation assistance and review.

Pre-Approval Policies and Procedures

Our Audit Committee's policy is that all audit services and all non-audit services to be provided to us by our independent registered public accounting firm must be approved in advance by the Audit Committee. The Audit Committee's approval procedures include the review and approval of engagement letters from our independent registered public accounting firm that document the fees for all audit services and non-audit services, primarily tax advice and tax return preparation and review.

All audit services in fiscal 2025 were pre-approved by our Audit Committee. KPMG did not provide any non-audit services in fiscal 2025.

PART IV

ITEM 15. ***EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.***

(a) Documents filed as part of the Annual Report on Form 10-K, as amended by this Amendment:

(1) Financial Statements. See Part II, Item 8, which appears on Page 71 of the Original Form 10-K.

(2) Financial Statement Schedules. All schedules have been omitted from the Original Form 10-K and this Amendment because they are not required or because the required information is given in the Financial Statements or Notes thereto set forth under Item 8 of the Original 10-K.

(b) The exhibits listed in Part IV, Item 15(b) of the Original 10-K and the exhibits listed below are filed with, or incorporated by reference into, this report.

Exhibit Number	Exhibit Description
31.3#	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.4#	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
101.INS †	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH†	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents.
104 †	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101 attachments)

Filed herewith.

† The XBRL related information in Exhibit 101 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability of that section and shall not be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing or document.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: April 30, 2026

Traws Pharma, Inc.

By: /s/ Iain Dukes, D. Phil
Iain Dukes, D. Phil
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Iain Dukes Iain Dukes, D. Phil	Chief Executive Officer and Director (Principal Executive Officer)	April 30, 2026
/s/ Charles Parker Charles Parker	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 30, 2026
/s/ Jack E. Stover Jack E. Stover	Chairman, Board of Directors	April 30, 2026
/s/ Nikolay Savchuk, Ph.D. Nikolay Savchuk, Ph.D.	Director	April 30, 2026
/s/ Trafford Clarke, Ph.D. Trafford Clarke, Ph.D.	Director	April 30, 2026
/s/ Mary Teresa Shoemaker Mary Teresa Shoemaker	Director	April 30, 2026
/s/ John Leaman, MD John Leaman, MD	Director	April 30, 2026
/s/ Werner Cautreels, Ph.D. Werner Cautreels, Ph.D.	Director	April 30, 2026