2023 Annual Report

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, 2023

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

Onconova Therapeutics, 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	ONTX	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, 2023, 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 $24.6 million, based on the last reported sale price of the registrant's common stock on the Nasdaq Capital Market.

There were 21,040,645 shares of Common Stock outstanding as of March 1, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's 2024 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.

ONCONOVA THERAPEUTICS, INC.
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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, our ongoing and planned preclinical development and clinical trials, 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 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, and 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 estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the success and timing of our preclinical studies and clinical trials, including 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 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;
- 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; and
- the performance of third parties, including contract research organizations (CROs) and third-party manufacturers.

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

Onconova Therapeutics, Inc., sometimes referred to as "we" or the "Company," is a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer. We have proprietary molecularly targeted agents designed to disrupt specific cellular pathways that are important for cancer cell proliferation. We believe that the product candidates in our pipeline have the potential to be efficacious in a variety of cancers with unmet medical need. We have the following two clinical-stage programs: (1) 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 (2) rigosertib administered alone or in combination for investigation in various cancers. We are currently evaluating compounds for in-licensing opportunities.

Product Candidates / Compounds

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

Source: Reaction Biology 2021

In addition to CDK 4/6, 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. The equilibrium dissociation constant (Kd) value of narazaciclib binding to ARK5 was found to be 19 nM, while a known NUAK1 specific inhibitor (HTH-015-01) was 790 nM. In addition, using a cellular based assay that measures kinase activity in intact cells, NanoBret technology, it was determined that narazaciclib inhibited ARK5 with an IC50 value of

30 nM, while 2 published inhibitors, HTH-015-01 and WZ4003, had IC50 values of >10,000 nM. ARK5 (also known as NUAK1) is a member of the AMPK catalytic subunit family and functions as a key regulator of cellular energy homeostasis (Lui 2012). 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 Kd value of narazaciclib binding to CSF1R was determined to be 0.7 nM. 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. Another established driver of resistance to CDK4/6 inhibitors in breast cancer is FGFR1-3. Preclinical Data presented at the San Antonio breast Cancer Symposium in December 2023 suggested that breast cancer cells that overexpress FGFR1-3 retained their sensitivity to narazaciclib and its metabolite, but were resistant to treatment with the currently approved CDK4/6 inhibitors.

Narazaciclib potently targets the protein BUB1. High levels of expression of BUB1is a prediction marker of core survival in breast cancer.

Narazaciclib's potent antitumor activity against mantle cell lymphoma (MCL) cell lines, independent of their sensitivity to the FDA-approved Bruton's tyrosine kinase inhibitor ibrutinib has been demonstrated in preclinical studies. Narazaciclib's activity against MCL cell lines was shown to be superior to that of the FDA-approved CDK 4/6 inhibitors palbociclib and ribociclib, and similar to that of the FDA-approved CDK 4/6 inhibitor abemaciclib. Combining narazaciclib with ibrutinib led to synergistic increases in antitumor activity against both ibrutinib-sensitive and ibrutinib-resistant MCL cell lines. Preclinical data from this study was presented at the 17th International Conference on Malignant Lymphoma, in Lugano, Switzerland, on June 14, 2023 and the European MCL Network Annual Meeting in Dublin, Ireland, on October 7, 2023.

In certain in vitro models, the kinase inhibitory profile of narazaciclib had high activity against CDK4, CDK6, ARK5, CSF1R, PDGFRß and PI3K-δ, all of which are associated with the growth, survival and metastasis of human tumor cells (Reddy, 2014). In an in vitro investigation of narazaciclib against a broad spectrum of human tumor cell lines, narazaciclib displayed potent antiproliferative activity, with 50% growth inhibitory concentrations (GI50) ranging from 0.02 μM to 1.5 μM. In these in vitro models, narazaciclib exhibited a broad range of activity against a wide spectrum of cell lines of both hematological origin (lymphoma, leukemia and myeloma) as well as solid tumors derived from multiple organ sites. Studies on drug-resistant human tumor cell lines suggested that narazaciclib is not a multidrug resistance gene (mdr1) substrate and may be active against drug-resistant tumor cell lines (IBv.1 2020; Reddy, 2014). The activity of narazaciclib does not appear to be affected by the overexpression of MDR-1 and induced apoptosis in both ibrutinib-sensitive and ibrutinib-resistant patient derived cells (Divakar, 2016). The ability of narazaciclib to inhibit the CDK4/6/RB1 pathway has also been shown in pre-clinical testing of mantle cell lymphoma (Divakar, 2016), multiple myeloma (Perumal, 2016), various breast cancer subtypes (Reddy 2014) and colorectal cancer (IBv.2 2022).

The effectiveness of first-generation non-selective CDK inhibitors (Selicilib/roscovitine and Alvocidib/ flavopiridol) in early trials was limited due to toxicities (Blachly 2013). Second-generation compounds (palbociclib and ribociclib) specifically inhibit CDK4 and 6, thereby inhibiting retinoblastoma protein phosphorylation. Abemaciclib is a multi-targeted kinase CDK4/6 inhibitor with low nano molar activity against CDK4/6. The second generation CDK4/6 inhibitors have substantially improved clinical outcomes for patients with hormonal-receptor (HR) positive metastatic breast cancer (Hortobagyi 2018, Sledge 2017, Finn 2016). Several CDK4/6 inhibitors (palbociclib, ribociclib and abemaciclib) have been approved and are now standard of care either alone (abemaciclib) or in combination with anti-estrogen therapy for patients with HR-positive, HER2-negative metastatic breast cancer. Another CDK4/6 inhibitor has recently been approved, trilaciclib, in the supportive care space, for the prevention of myelosuppression following chemotherapy.

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 Chinese FDA). In the fourth quarter of 2019, HanX filed an IND with the Chinese FDA which was approved on January 6, 2020. We and HanX also intended for these studies underlying the Chinese IND approval, to meet the US Food and Drug Administration (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) is dosed every day for 21 days followed by 7 days off therapy in each 28 -day cycle. The study is ongoing.

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. In Study 19-01 in the US, narazaciclib is dosed on a continuous daily schedule. The study will assess 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 is complete with one dose limiting toxicity (DLT) observed. The seventh dose cohort (280 mg daily) is currently ongoing.

These studies are expected to provide preliminary safety data and the recommended Phase 2 dose and schedule for narazaciclib.

Retinoblastoma (Rb) protein is a master regulator of cell division and is critical to several cellular processes including senescence, self-renewal, replication and apoptosis (Engel, 2015). It is believed that loss or inactivation of Rb leads to malignant cell formation and occurs in the pathogenesis of some cancers. In a preclinical Rb positive xenograft model for breast cancer, narazaciclib activity was shown to be similar to palbociclib (Pfizer's Ibrance ®). Moreover, based on the same preclinical model, narazaciclib may have the potential advantage of reduced neutropenia when compared to palbociclib. Whereas both compounds resulted in decreased RBC and platelet counts in this preclinical model system, palbociclib was found to have a more prominent and statistically significant ($P< 0.01$) inhibitory effect on neutrophil counts when compared to narazaciclib. These results would need to be replicated in clinical trials.

In vitro studies compared the growth inhibitory activity of narazaciclib and palbociclib in breast cancer Rb null cell lines, which demonstrated resistance to palbociclib while maintaining sensitivity towards narazaciclib (IBv.2 2022). Studies using mantle cell lymphoma cells indicated that narazaciclib was able to induce cell death via induction of apoptosis by inhibiting the AKT/PI3K/mTOR pathway while palbociclib treatment was only able to induce cell cycle arrest due to the inhibition of CDK4/6 (Divakar, 2016). Narazaciclib treatment was associated with the presence of several apoptotic markers (PARP, caspase 3, caspase 7 and caspase 9) and narazaciclib (but not palbociclib) led to the generation of apoptotic cells. Overall, apoptosis following narazaciclib exposure has been observed in the following cell lines: breast cancer (IBv.2 2022, Reddy, 2014), mantle cell lymphoma (Divakar, 2016), multiple myeloma (Perumal, 2016) and colorectal cancer (IBv.2 2022).

In addition to CDK4/6 and PI3 Kinase pathways, narazaciclib inhibits several other kinases in vitro including ARK5 (NUAK1) (IC50 of 4.95 nM) (IBv.2 2022, Reddy, 2014) while palbociclib does not. ARK5 is a member of the AMPK family and is thought to function as a key regulator of cellular energy homeo-stasis (Liu, 2012) and is important in a number of cancer cell survival pathways. Overexpression of ARK5 is associated with poor prognosis in hepatocellular cancer (Cui, 2013), ovarian cancer (Phippen, 2016), colorectal cancer (Port, 2018) and glioblastoma (Lu, 2013). ARK5 is involved in the increased invasiveness, migration, and metastatic potential of breast cancer cells (Chang, 2012), colorectal cancer (Kusakai, 2004), gastric cancer (Chen, 2017), and multiple myeloma (Suzuki et al., 2005). Narazaciclib

inhibits ARK5 which may result in down regulation of the mTOR/MYC/RB1 pathways leading to cell cycle arrest and apoptosis.

Because ARK5 activity is now recognized as a component in promoting cancer cell migration and invasion (Kusaki, 2004) the effect of narazaciclib treatment may have an impact on cell migration and metastasis. In certain in vitro models, narazaciclib was able to inhibit the percent migration of U87 cells in a concentration- dependent manner. The time and concentrations that were tested did not result in cell death but did inhibit cell division at the higher concentrations (IBv.2 2022). The ability of narazaciclib to inhibit cell migration was compared to palbociclib using a wound healing model. Triple negative cancer cell migration was inhibited for 72 hours in the presence of narazaciclib but not in the presence of palbociclib (IBv.2 2022).

The pathogenesis and progression of a number of cancers, including breast and multiple myeloma, is linked to C-Myc (Li, 2003) which was dependent on ARK5 activity (Liu, 2012) and calcium dependent metabolism (Monteverde, 2018). The inhibition of ARK5 has been shown to be lethal in MYC overexpressing tumors (Liu, 2012, Perumal, 2016) and targeting ARK5 in the inhibitory profile of narazaciclib has the potential to overcome the emergence of resistance to CDK4/6 inhibitors due to the loss of retinoblastoma function and C-Myc overexpression. Preclinical studies with tumor cell lines suggest that several malignancies including HR-positive breast cancer, colorectal carcinoma, hepatocellular carcinoma, mantle cell lymphoma and multiple myeloma, may be clinically responsive to narazaciclib exposure (Reddy, 2014, Divakar, 2016, Perumal, 2016). Furthermore, narazaciclib has been tested in four murine xenograft models (breast cancer, colorectal cancer, mantle cell lymphoma and multiple myeloma) and was found to have on-target activity and be non-toxic to the animals (Reddy, 2014; Divakar, 2016; Perumal, 2016; and IBv.2 2022).

CSF1R is in the class III kinase receptors that include c-Kit, platelet-derived growth factor receptor (PDGFR) alpha, and FLT3. CSF1R has 2 high affinity binding ligands, colony stimulating factor 1 (CSF-1), also known as macrophage colony-stimulating factor (M-CSF) and interleukin 34 (IL-34). CSF-1 is important for the differentiation and proliferation of myeloid progenitor cells into macrophages, monocytes, dendritic cells, and osteoclasts. Macrophages play an important role in the pathogenesis of not only tumor growth but multiple other diseases such as inflammatory diseases and bone metabolism. High levels of CSF-1 are critical for the recruitment of tumor associated macrophages (TAMs), predominantly the immunosuppressive phenotype (M2). They are the main inflammatory immune cells in the tumor microenvironment and are involved in tumor immunosuppression, angiogenesis, invasion, and metastasis.

Overexpression of CSF-1 or CSF1R is associated with tumor aggressiveness and poor prognosis. Inhibiting the signaling pathway of CSF1R provides a method to reduce the number of M2 macrophages/TAMs within the tumor microenvironment and thus improve anti-tumor immunological therapy. Recent studies have found that CSF-1/CSF1R axis blockade can improve the efficiency of immune checkpoint inhibitors, especially programmed death-ligand 1 inhibitors.

Cancer cells can lose Rb function through mutation and become resistant or insensitive to palbociclib. Generally, second generation 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.

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.

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).

Based on data from continuous dosing studies in rats and monkeys, the safety profile of narazaciclib is anticipated to be better than the approved CDK4/6 inhibitors with myelosuppression and gastrointestinal toxicity being most common. Management of these adverse events is expected to follow that used for the approved CDK 4/6 inhibitors. We believe that the proposed mechanism of action of narazaciclib, the unmet medical need of the advanced cancers potentially targeted by narazaciclib and the anticipated safety profile of narazaciclib as seen in pre-clinical studies, support conducting clinical studies. To date in the ongoing Phase 1 clinical trials, there has been no significant myelosuppression or gastrointestinal toxicity.

Clinical development of narazaciclib for breast cancer as well as other solid tumors and hematological malignancies in clinical trials is warranted based on the preclinical in vitro studies as well as the xenograft models. Onconova plans to advance testing on whether narazaciclib will demonstrate activity and/or safety in patients with advanced malignancies.

As previously mentioned, CDK 4/6 inhibitors have been added to aromatase inhibitors and SERDs to enhance anti-tumor activities in HR+, HER2- metastatic breast cancer. Mirza and colleagues presented the results of the randomized phase 2 study NSGO-PALEO / ENGOT-EN3 trial at ESMO 2020 and reported that palbociclib and letrozole yielded meaningful PFS benefit in women with ER+ recurrent endometrial cancer (Mirza et al. 2020).

Endometrial carcinoma (EC) is the most common gynecological malignancy (American Cancer Society 2021). Endometrioid endometrial carcinoma (EEC), the most common subtype of EC, accounts for approximately 75% of cases. In the US, approximately 65,950 new endometrial cancers and uterine sarcomas and approximately 12,550 deaths are expected in 2022, and the incidence and mortality have been increasing (American Cancer Society 2022). Low-grade (Grade 1 or 2) EECs (LGEECs) have ≥95% (Grade 1) or 50% to 94% (Grade 2) cancer tissue forming glands. Treatment includes surgery, radiotherapy, and/or systemic therapy. Systemic therapy is typically chemotherapy and/or hormonal therapy, and typical regimens include paclitaxel/carboplatin with letrozole maintenance; paclitaxel/carboplatin/bevacizumab with bevacizumab maintenance; or letrozole, anastrozole, or exemestane (NCCN 2022). Overall, five-year disease-free survival and five-year survival are high, 81.7% and 83.1%, respectively (Gottwald 2010), but for recurrent or metastatic disease morbidity and mortality are high.

In the NSGO-PALEO / ENGOT-EN3 trial presented by Mirza at ESMO 2020 participants were randomized to letrozole 2.5 mg orally D1-28 with either palbociclib 125 mg or placebo orally d1–21 in a 28-d cycle until disease progression. PFS was significantly improved with letrozole and palbociclib compared to the placebo arm (median PFS 8.3 vs. 3.0 months, HR 0.56, 95% CI 0.32 to 0.98, p=0.04). Disease control rate at 24 weeks was also improved (63.6% vs. 37.8%). This data has been reinforced by phase 2 data presented with ribociclib and letrozole as well as abemaciclib and letrozole in this patient population.

Onconova 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. Both narazaciclib and letrozole are administered orally in the ongoing Phase 1 dose escalation phase before moving to a Phase 2 expansion cohort designed to enroll approximately 30 patients once the dose escalation phase is completed. The first patient in this trial was dosed in May 2023 and the initial cohort (160mg) has completed the DLT observation period. No DLTs were observed. Currently the 200mg cohort is enrolling. There has been one DLT observed at this cohort and the cohort is being expanded to enroll three additional patients.

Additional studies

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 study (IIS) with rigosertib monotherapy in patients with advanced/metastatic squamous cell carcinoma associated with recessive dystrophic epidermolysis bullosa (RDEB-SCC) is enrolling patients. 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.

Data from the recent presentations are from a patient with a history of multiple, unresectable cutaneous SCCs (cSCC) that were unresponsive to prior treatments including cemiplimab. Results showed that intravenously administered rigosertib had an acceptable safety profile and that the patient experienced sustained clinical and histological complete remission of all lesions without signs of metastatic disease following 13 treatment cycles. The patient remained in complete remission for 16 months, at which time rigosertib administration was stopped due to disease recurrence. Another patient was recently enrolled, a patient with RDEB and multiple cSCCs and metastatic disease involving the lymph nodes whose prior treatments included surgical excision, systemic targeted therapy (cetuximab) and immunotherapy (pembrolizumab). At baseline, the patient had extensive, unresectable cSCC involving the left elbow region as well as nodal disease noted on PET-CT scan. After 4 cycles of oral rigosertib starting at 560 mg PO BID, there was reportedly complete clinical remission of all cSCC lesions. The patient has tolerated oral rigosertib and remains on therapy.

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 a very encouraging finding that warrants further study. 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. On June 27, 2023, Onconova and the investigators leading the ISS in RDEB-SCC met with the FDA to discuss the future development of rigosertib in this indication. Based on that meeting and the clinical responses in previously refractory patients we have seen and presented at major medical meetings, we are planning a company-sponsored trial for which we are pursuing orphan designation.

Oral Rigosertib and PD-1 Combination in KRAS-Mutated Cancers

On June 17, 2021, we announced a publication in Molecular Cancer (Yan, C., Saleh, N., Yang, J. *et al.* Novel induction of CD40 expression by tumor cells with RAS/RAF/PI3K pathway inhibition augments response to checkpoint blockade. *Mol Cancer* **20,** 85; 2021) which demonstrated that rigosertib synergistically combined with a check point inhibitor (CPI) improved tumor growth inhibition and survival in a murine melanoma model that did not respond to a CPI alone. It was postulated that rigosertib's anti-cancer activity was due to its ability to reverse immunosuppressive tumor microenvironments. We believe this pre-clinical data support the clinical evaluation of rigosertib in combination with a CPI in metastatic melanoma that has progressed on CPI therapy. An investigator-initiated study (IIS) at Vanderbilt University evaluating oral rigosertib in combination with pembrolizumab in patients with CPI resistant advanced/metastatic melanoma was opened for enrollment in March 2023 and continues to enroll patients.

We have supported an investigator-initiated study (IIS) that is exploring the use of oral rigosertib for cancers driven by mutated K-Ras genes, a Phase 1/2a study of rigosertib in combination with a PD-1 inhibitor (nivolumab) for patients with check point inhibitor (CPI) resistant K-Ras mutated non-small cell lung cancer (NSCLC). The combination dose was well tolerated and a formal efficacy evaluation is pending. The objectives of this study were to identify the recommended Phase 2 dose (RP2D) of the combination for future studies and characterize the safety profile of the combination treatment. To date, one patient with a DLT of hyponatremia has been observed. Interim data presented at the European Society of Medical Oncology (ESMO) meeting in September 2022 showed an early and encouraging

signal of a treatment effect in the trial's extensively pre-treated population, with one complete response, two partial responses, and one instance of stable disease achieved in fourteen evaluable patients. These responses were achieved in patients with three distinct KRAS mutations who had failed prior checkpoint inhibitor therapy, thereby confirming rigosertib's KRAS-agnostic mechanism of action and potential to synergize with anti-PD-1 agents. Enrollment in the study is now closed. No further studies are planned at this time, pending the final report.

Rare Disease Program in "RASopathies"

Preclinical studies with rigosertib are also being conducted in cardiomyopathies which are seen in children with RASopathies. Rigosertib normalized and reversed RASopathy-associated hypertrophic cardiomyopathy (HCM) as well as other syndromic features in Raf1L613V/+ mice.

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 and more recently narazacicib. We incurred research and development expenses of $11.4 million and $11.4 million during the years ended December 31, 2023 and 2022, 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)

We believe narazaciclib has the potential to overcome limitations of current generation CDK 4/6 inhibitors. 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 and HanX also intended for these studies to comply with the FDA standards. Accordingly, such studies were used by us for an IND filing with the FDA in November 2020. The FDA Study May Proceed letter was received in December 2020. Drug product for the US study was manufactured in North America and stability data was submitted as part of the IND. We maintain global rights to narazaciclib outside of China.

SymBio Pharmaceuticals Limited

In July 2011, we entered into a 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 SymBio license agreement, SymBio is obligated to use commercially reasonable efforts to develop and obtain market approval for rigosertib inside the licensed territory and we have similar obligations outside of the licensed territory. We have also entered into an agreement with SymBio providing for the Company to supply SymBio with development-stage product. Under the SymBio license agreement, we 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 our cost plus a defined profit margin. We have 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, 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.

Royalties will be payable under the SymBio agreement on a country- by-country basis in the licensed territory, until the later of the expiration of marketing exclusivity in those countries, a specified period of time after first commercial sale of rigosertib in such country, or the expiration of all valid claims of the licensed patents covering rigosertib or the

manufacture or use of rigosertib in such country. If no valid claim exists covering the composition of matter of rigosertib or the use of or treatment with rigosertib in a particular country before the expiration of the royalty term, and specified competing products achieve a specified market share percentage in such country, SymBio's obligation to pay us royalties will continue at a reduced royalty rate until the end of the royalty term. In addition, the applicable royalties payable to us may be reduced if SymBio is required to pay royalties to third-parties for licenses to intellectual property rights necessary to develop, use, manufacture or commercialize rigosertib in the licensed territory. The license agreement with SymBio will remain in effect until the expiration of the royalty term. However, the SymBio license agreement may be terminated earlier due to the uncured material breach or bankruptcy of a party, or force majeure. If SymBio terminates the license agreement in these circumstances, its licenses to rigosertib will survive, subject to SymBio's milestone and royalty obligations, which SymBio may elect to defer and offset against any damages that may be determined to be due from us. In addition, we may terminate the license agreement in the event that SymBio brings a challenge against it in relation to the licensed patents, and SymBio may terminate the license agreement without cause by providing us with written notice a specified period of time in advance of termination. The upfront payment is being recognized ratably through December 2037, the expected term of the agreement. We recognize revenues related to the supply agreement with SymBio when control of the product is transferred to Symbio. Revenues related to the supply agreement were $0 and $0 for the fiscal years ended December 31, 2023 and 2022, respectively.

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 rigosertib or the Product 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 and a subsequent equity investment in our common stock. In addition, we could receive regulatory, development and sales-based milestone payments as well as tiered, double-digit royalties based on 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 a New Drug Application (NDA) for the Pint Licensed Product.

Under the terms of the Pint Securities Purchase 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 Securities Purchase Agreement, closing of the upfront equity investment occurred on April 4, 2018 and Pint purchased 54,463 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 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) (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 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.

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 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 is for 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

Our intellectual property is derived through our internal research, the Temple Licensing Agreement with Temple University, or Temple, and licensing research agreements with the Mount Sinai School of Medicine, or Mount Sinai.

License Agreement with Temple University

In January 1999, we entered into the Temple Licensing Agreement 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.

The Temple Licensing Agreement can be terminated by mutual agreement or due to the material breach or bankruptcy of either party. We may terminate the license agreement for any reason by giving Temple prior written notice.

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 recently filed new patent applications covering methods of treatment in target indications that are projected to extend to 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. A U.S. method of treatment patent for rigosertib, which we also in-licensed from Temple, expires in 2025. A patent covering the use of rigosertib in combination with anticancer agents including azacitidine is issued and will expire in 2028. The novel formulation patent for rigosertib expires in 2037. We have recently filed new patent applications covering methods of treatment in target indications that are projected to extend to 2044 before any possible patent term extensions. Patent term extensions may be available, depending on various provisions in the law.

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, or 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 pharmaceutical products 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, 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 pharmaceutical industry is 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 oncology indications or cellular pathways on which we are focused.

It is probable that the increasing incidence and prevalence of cancer will lead to many more companies seeking to develop products and therapies for the treatment of unmet needs in oncology. 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 in the treatment of cancer patients.

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). Onconova will be studying narazaciclib and letrozole in advanced low-grade endometrioid endometrial cancer (LGEEC), as well as combinations with narazaciclib in CDK 4/6i refractory HR+/ HER2- metastatic breast cancer and other potential indications. CDK 4/6 inhibitors are currently included in NCCN Guidelines for LGEEC, although no CDK 4/6 have been approved by the FDA for treatment of LGEEC.

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 pharmaceutical ingredient and finished drug products for our products 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 pharmaceutical products prior to approval. If we or 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 an organization for the sales, marketing and distribution of pharmaceutical products. 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, 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 significant financial and management resources.

Government Regulation

As a pharmaceutical 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 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 products. The FDA also has issued a growing body of guidance documents that provide the agency's interpretation of regulatory requirements.

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. Generally, our activities in other countries 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 process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and may not be successful. In addition, approval in the United States does not automatically result in approval in the European Union or elsewhere.

United States Government Regulation

The FDA is the main regulatory body that controls pharmaceuticals in the United States, and its regulatory authority is based in the FDC Act. 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 or 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 that 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, or 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, 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, or 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, or 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, or 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 (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.

Europe and Other International Government Regulation

In addition to regulations in the United States, we will be 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, or 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, or 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 institutional review board, or 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

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, or 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.

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, or 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, or 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 permissable 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, as much as $3.0 billion, regarding certain sales practices and promoting 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, 2023, we had 17 employees (16 of which were full-time employees), in addition to several consultants or 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.

We strongly believe that our success depends, in part, on open and regular communication with employees to help foster a high performing and engaged workforce. To help ensure that employees fully understand the Company's long-term strategy and annual goals and how their work contributes to the Company's success, we utilize a variety of channels to facilitate open and direct communication, including monthly all-employee meetings and regular ongoing update communications.

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.onconova.com. The information contained in, or that can be accessed through, our website is not part of this 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 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 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.
- The recent COVID-19 pandemic, or the widespread outbreak of any other communicable disease, could adversely impact our business, including our clinical trials, drug manufacturing and nonclinical activities.
- 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, 2023 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.
- We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.
- We currently have no source of product revenue and may never become profitable.
- We need to obtain substantial additional funding to further develop our products in future clinical trials and through regulatory processes; 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.
- Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults, or non-performance could adversely affect our operations and liquidity.
- 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 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 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.
- We may not comply with the Nasdaq continued listing requirements. 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 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 on Form 10-K. As of December 31, 2023, we had cash and cash equivalents of $20.8 million and current liabilities of $9.2 million. We believe that we have sufficient resources available to support our development activities and business operations and satisfy our obligations into the third quarter of 2024. We do not have sufficient cash and cash equivalents as of the date of this Annual Report on Form 10-K to support our operations for at least the 12 months 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, 2023 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, 2023 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 on Form 10-K. 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 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.

Our consolidated financial statements for the year ended December 31, 2023 have been prepared assuming we will continue to operate as a going concern. However, due to our ongoing operating losses and our accumulated deficit, management has concluded that there is 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 on Form 10-K. Because we continue to experience net operating losses, our ability to continue as a going concern is subject to our ability to

successfully raise sufficient additional capital, through future financings or through strategic and collaborative arrangements. If we are unable to obtain additional funding, we may not be able to continue as a going concern.

We do not 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 narazaciclib, rigosertib or any other product candidates through the regulatory approval process. Accordingly, we may 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 incurred losses in every reporting period since our inception in 1998. For the years ended December 31, 2023, and 2022, we reported net losses of $18.9 million and $19.0 million, respectively, and we had an accumulated deficit of $482.6 million at December 31, 2023.

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. 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.

Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver, and created uncertainty and liquidity concerns for us, at that time, and in the broader financial services industry remain. There is no guarantee that a similar event will not occur again and that our liquidity will not be adversely affected.

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 narazaciclib and oral rigosertib. Although, we believe that there are opportunities for us to develop narazaciclib, our novel multi kinase inhibitor targeting CDK4/6 as well as other tyrosine kinases, in indications such as endometrial cancer, metastatic breast cancer, mantle cell lymphoma and multiple myeloma, and oral rigosertib in RAS mutated cancers, 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 narazaciclib and oral 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 for one indication may further impact its development for other indications. By example, our phase III study of intravenous rigosertib for HR MDS did not meet its primary endpoints. It is possible that this may impact how regulators or others view the development of rigosertib for alternative indications and via different methods of administration. If later-stage clinical trials do not produce favorable results, 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, or 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.

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.

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 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 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 narazaciclib possibly is 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 Steven Fruchtman, M.D., President and Chief Executive Officer, Mark Guerin, C.P.A., Chief Operating and Chief Financial Officer, and Victor Moyo, M.D., Chief Medical Officer, and our other executive officers. Although we have employment agreements with the persons named above, 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 recent COVID-19 pandemic, or the widespread outbreak of any other communicable disease, 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. 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, or 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 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 CMOs we utilize are 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.

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 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. In the first quarter of 2023, we returned a portion of the patents that we in-licensed from Temple University back to Temple. The long-term economic effects of doing so are uncertain.

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 Common Stock and Common Stock Warrants

We may not comply with the Nasdaq continued listing requirements. 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.

We are required to meet certain qualitative and financial tests to maintain the listing of our securities on the Nasdaq Capital Market (Nasdaq). As of March 25, 2024, we were not in compliance with the Nasdaq continued listing requirements related to minimum bid price.

On September 25, 2023, we received a letter from Nasdaq indicating that we failed to comply with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2), which requires that companies listed on Nasdaq maintain a minimum closing bid price of at least $1.00 per share.

Under Nasdaq Listing Rule 5810(c)(3)(A), we had a 180 calendar day grace period, or until March 25, 2024, to regain compliance by meeting the continued listing standard. The continued listing standard will be met if the Company's common stock has a minimum closing bid price of at least $1.00 per share for a minimum of ten consecutive business days during the 180-calendar day grace period.

We did not regain compliance with the minimum bid price requirement by March 25, 2024. On March 27, 2024, we received a letter from Nasdaq granting the Company a second 180 calendar day period to regain compliance under Nasdaq Listing Rule 5810(c)(3)(A), or until September 23, 2024. Their determination to grant the second compliance period was based on our meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement, and our notification to Nasdaq of its intention to cure the minimum bid price deficiency during the second compliance period, by effecting a reverse stock split, if necessary.

If we do not regain compliance by September 25, 2024, Nasdaq will provide notice that the Company's common stock will be delisted. At that time, we may appeal the Nasdaq staff's determination to a Nasdaq Hearings Panel.

We intend to monitor the closing bid price of the Company's common stock and continue to consider our available options to resolve the noncompliance with the minimum bid price requirement.

There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria.

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.

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.

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, or 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 February 29, 2024, we had no shares of 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 amended and restated 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

We monitor our information systems for potential cybersecurity issues and assess risks from cybersecurity threats as an element of our overall business risks. To protect our information systems from cybersecurity threats, we use various security tools supporting protection, detection, and response/mitigation capabilities. 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. Third-party vendor cybersecurity risks and procedures are evaluated by our Quality Assurance and Regulatory Department during our prequalification process and during subsequent periodic reviews.

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 Management

Our board of directors has oversight responsibility for risk management, 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 the steps management has taken to monitor and mitigate cybersecurity threats and risks. The audit committee receives reports annually from management on our cybersecurity strategy and program. Significant changes are reported to the audit committee quarterly. Cybersecurity incidents which are determined by management to be material will be reported immediately to the audit committee.

We take a risk-based approach to cybersecurity and have implemented cybersecurity procedures designed to address cybersecurity threats and risks. The Director – Information Technology, who has a combination of 15 years of professional experience and education, as well as certifications in cybersecurity, leads the Company’s cybersecurity program and is responsible for assessing and managing cybersecurity risk. The Director- Information Technology reviews cybersecurity risks with and reports cybersecurity incidents to the Chief Executive Officer, Chief Operating Officer/Chief Financial Officer, and Senior Director – Financial Reporting.

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*

We are not a party to any legal proceedings and we are not aware of any such proceedings contemplated by government authorities.

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 ONTX on the Nasdaq Capital Market.

Stockholders

As of February 29, 2024, there were approximately 96 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.

Securities Authorized for Issuance Under Equity Compensation Plans

Information regarding securities authorized for issuance under the Company's equity compensation plans is contained in Part III, Item 11 of this Annual Report.

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.

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

We are a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer. We have proprietary molecularly targeted agents designed to disrupt specific cellular pathways that are important for cancer cell proliferation. We believe that the product candidates in our pipeline have the potential to be efficacious in a variety of cancers with unmet medical need. We have the following two clinical-stage programs: (1) 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 (2) rigosertib administered alone or in combination for the treatment of various cancers. We are currently evaluating potential compounds for in-licensing opportunities.

We were incorporated in Delaware in December 1998 and commenced operations in January 1999. Our operations to date have included our organization and staffing, business planning, raising capital, in-licensing technology from research institutions, identifying potential product candidates, developing product candidates and building strategic alliances, as well as undertaking preclinical studies and clinical trials of our product candidates.

Since commencing operations, we have dedicated a significant portion of our resources to the development of our clinical-stage product candidates, particularly narazaciclib and rigosertib. We incurred research and development expenses of $11.4 million and $11.4 million during the years ended December 31, 2023 and 2022, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development as we continue to advance narazaciclib and our other programs.

Our net losses were $18.9 million and $19.0 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $482.6 million. 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.

As of December 31, 2023 we had $20.8 million in cash and cash equivalents. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the third quarter of 2024; however, based on current projections, we do not have sufficient cash and cash equivalents as of the date of this Annual Report on Form 10-K to support our operations for at least the 12 months following the date that the financial statements are issued. Accordingly, 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.

Financial Overview

Revenue

During the years ended December 31, 2023 and 2022, our revenues were derived exclusively from activities conducted in accordance with our collaboration arrangement with SymBio.

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.

We are recognizing the $7.5 million upfront payment received in 2011 under the SymBio collaboration agreement as revenue on a straight-line basis through December 2037, reflecting our estimate of when we will complete our obligations under the agreement. For the years ended December 31, 2023 and 2022, we recognized revenues of $226,000 and $226,000, respectively, under the SymBio collaboration agreement. In addition, we recognized revenues of $0 and $0 for the years ended December 31, 2023 and 2022, respectively, related to the supply agreement.

Operating Expenses

The following table summarizes our operating expenses for the years ended December 31, 2023 and 2022:

	2023	2022
General and administrative	$ 9,094,000	$ 8,447,000
Research and development	11,430,000	11,406,000
Total operating expenses	$ 20,524,000	$ 19,853,000

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.

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 narazaciclib, oral rigosertib, other candidates in our pipeline, 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 and by compound.

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.

Other Income, Net

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

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.

Stock-Based Compensation

We account for stock-based payments to employees and non-employees 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, net of forfeitures. Compensation expense is recognized for the portion that is ultimately expected to vest over the period during which the recipient renders the required services, using the straight-line single option method.

We record stock-based compensation expense as a component of research and development expenses or general and administrative expenses, depending on the function performed by the optionee. For the years ended December 31, 2023 and 2022, we allocated stock-based compensation as follows:

	Year ended December 31,	
	2023	2022
General and administrative	$ 586,000	$ 538,000
Research and development	715,000	617,000
	$ 1,301,000	$ 1,155,000

Fair Value Estimates

We estimate the fair value of share-based awards to employees and non-employees using the Black-Scholes option pricing model. The Black-Scholes model requires the input of highly complex and subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of the expected term of the award, (c) the risk free interest rate and (d) expected dividends. Expected volatility is based on the historical volatility of the Company's common stock. We estimate the expected life of our employee stock options using the "simplified" method, whereby, the expected life equals the arithmetic average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period when the options were granted. We have never paid, and do not expect to pay dividends in the foreseeable future.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

	Year ended December 31,		
	2023	2022	Change
Revenue	$ 226,000	$ 226,000	$ —
Operating expenses:			
General and administrative	9,094,000	8,447,000	(647,000)
Research and development	11,430,000	11,406,000	(24,000)
Total operating expenses	20,524,000	19,853,000	(671,000)
Loss from operations	(20,298,000)	(19,627,000)	(671,000)
Other income, net	1,350,000	663,000	687,000
Net loss	$ (18,948,000)	$ (18,964,000)	$ 16,000

Revenues

Revenues for 2023 were consistent with 2022 and were due to the recognition of deferred revenue from our collaboration with SymBio.

General and administrative expenses

General and administrative expenses increased by $0.6 million or 7.7%, to $9.1 million for the year ended December 31, 2023 from $8.4 million for the year ended December 31, 2022. The increase was attributable primarily to $0.6 million higher expenses for investor relations, proxy solicitation, and fees related to our shareholder meetings in the 2023 period, $0.3 million higher professional and consulting fees, and $0.2 million higher stock-based compensation costs in 2023. These increases were partially offset by $0.3 million lower insurance and other costs and lower personnel related costs of $0.1 million in the 2023 period due to lower bonus accrual and headcount.

The details of our general and administrative expenses are:

	Year Ended December 31,	
	2023	2022
Professional & consulting fees	$ 2,162,000	$ 1,824,000
Stock based compensation	715,000	538,000
Personnel related	3,264,000	3,408,000
Public company costs	1,968,000	1,382,000
Insurance & other	985,000	1,295,000
	$ 9,094,000	$ 8,447,000

Research and development expenses

Research and development expenses were flat in 2023 compared to 2022 at $11.4 million. There was an increase of $0.3 million in consulting fees, which was offset by decreases of $0.1 million preclinical and clinical development, as well as $0.1 million lower manufacturing and formulation costs.

The details of our research and development expenses are:

	Year ended December 31,	
	2023	2022
Preclinical & clinical development	$ 4,060,000	$ 4,206,000
Personnel related	2,400,000	2,399,000
Manufacturing, formulation & development	2,798,000	2,851,000
Stock based compensation	586,000	617,000
Consulting fees	1,586,000	1,333,000
	$ 11,430,000	$ 11,406,000

Other income, net

Other income, net, increased by $0.7 million for the year ended December 31, 2023 compared to the year ended December 31, 2022 due primarily to $0.7 million higher interest income in the 2023 period, partially offset by $49,000 higher foreign currency exchange loss in the 2023 period.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and experienced negative cash flows from our operations. We incurred net losses of $18.9 million and $19.0 million for the years ended December 31, 2023 and 2022, respectively. Our operating activities used $17.9 million and $16.3 million of net cash during the year ended December 31, 2023 and 2022, respectively. At December 31, 2023, we had an accumulated deficit of $482.6 million, working capital of $13.4 million, and cash and cash equivalents of $20.8 million. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and business operations into the third quarter of 2024; however, based on current projections, we do not have sufficient cash and cash equivalents as of the date of this Annual Report on Form 10-K to support our operations for at least the 12 months following the date that the financial statements 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. Due to the inherent uncertainty involved in making estimates and the risks associated with the research, development, and commercialization of biotechnology products, we may have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us.

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 sources of funding, including equity financings, strategic alliances, business development and/or combinations, and other sources. 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 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, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (17,932,000)	$ (16,294,000)
Investing activities	(14,000)	—
Financing activities	—	—
Effect of foreign currency translation	10,000	(19,000)
Net decrease in cash and cash equivalents	$ (17,936,000)	$ (16,313,000)

Net cash used in operating activities

Net cash used in operating activities was $17.9 million for the year ended December 31, 2023 and consisted primarily of a net loss of $18.9 million, including $1.3 million of noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net decrease in cash of $0.3 million. Significant changes in operating assets and liabilities included a $1.3 million increase in prepaid assets and other current assets related to our agreements with clinical and manufacturing vendors, partially offset by $1.2 million higher accounts payable and accrued liabilities as a result of the timing of clinical trial and other accruals, and receipt and payment of vendor invoices. Deferred revenue decreased $0.2 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio.

Net cash used in operating activities was $16.3 million for the year ended December 31, 2022 and consisted primarily of a net loss of $19.0 million, including $1.2 million of noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net increase in cash of $1.5 million. Significant changes in operating assets and liabilities included an increase in accounts payable and accrued liabilities of $1.9 million as a result of the timing of clinical trial and other accruals, and receipt and payment of vendor invoices, and an increase of $0.2 million in prepaid expenses and other current assets. Deferred revenue decreased $0.2 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio.

Net cash used in investing activities

Net cash used in investing activities was $14,000 in the 2023 period related to information technology asset purchases. There was no net cash used in investing activities in the 2022 period.

Net cash provided by financing activities

There was no net cash used in or provided by financing activities in the 2023 or 2022 periods.

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 2024 to be higher than 2023 due to clinical trials with narazaciclib and increased headcount in our clinical and regulatory groups. We also expect an increase in costs for potential in-licensing, the timing of which will be determined by the timing of any potential in-licensing. 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. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the third quarter of 2024; however, based on current projections, we do not have sufficient cash and cash equivalents as of the date of this Annual Report on Form 10-K to support our operations for at least the 12 months

following the date that the financial statements 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 of narazaciclib 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 an organization for the sales, marketing and distribution of pharmaceutical products. 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.

Segment Reporting

We view our operations and manage our business in one segment, which is the identification and development of oncology therapeutics.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (FASB) issued new guidance on the accounting for credit losses on financial instruments. The guidance was amended in November 2019. The new guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The guidance is effective for fiscal years beginning after December 15, 2022, and interim periods within those years, for companies deemed to be smaller reporting companies, with early adoption permitted. We adopted the guidance effective January 1, 2023. The guidance did not have a material effect on 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 President and Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2023. Based upon this evaluation, our principal executive officer and principal financial officer concluded that, as of such date, disclosure controls and procedures were effective.

Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework issued in 2013. Based upon the assessments, management has concluded that as of December 31, 2023 our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to exemptions provided to issuers that are non-accelerated filers or qualify as an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the JOBS Act.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the fiscal quarter ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. *OTHER INFORMATION*

Notice of Delisting or Failure to Satisfy a Continuing Listing Rule or Standard; Transfer of Listing.

On September 25, 2023, the Company received a letter from The Nasdaq Capital Market ("Nasdaq") indicating that the Company has failed to comply with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2). Nasdaq Listing Rule 5550(a)(2) requires that companies listed on Nasdaq maintain a minimum closing bid price of at least $1.00 per share.

Under Nasdaq Listing Rule 5810(c)(3)(A), the Company had a 180 calendar day grace period, or until March 25, 2024, to regain compliance by meeting the continued listing standard. The continued listing standard will be met if the Company's common stock has a minimum closing bid price of at least $1.00 per share for a minimum of ten consecutive business days during the 180 calendar day grace period.

The Company did not regain compliance with the minimum bid price requirement by March 25, 2024. On March 27, 2024, the Company received a letter from Nasdaq granting the Company a second 180 calendar day period to regain compliance under Nasdaq Listing Rule 5810(c)(3)(A), or until September 23, 2024. Their determination to grant the second compliance period was based on the Company meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement, and its notification to Nasdaq of its intention to cure the minimum bid price deficiency during the second compliance period, by effecting a reverse stock split, if necessary.

If the Company does not regain compliance by September 25, 2024, Nasdaq will provide notice that the Company's common stock will be delisted. At that time, the Company may appeal the Nasdaq Staff's determination to a Nasdaq Hearings Panel.

The Company intends to monitor the closing bid price of the Company's common stock and continue to consider its available options to resolve the noncompliance with the minimum bid price requirement.

There can be no assurance that the Company will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria.

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 2024 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 pages 61 to 65

ITEM 16. *FORM 10-K SUMMARY*

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

EXHIBITS INDEX

Exhibit Number	Exhibit Description
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	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).*
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	Eighth Amended and Restated Stockholders' Agreement, effective as of July 27, 2012, by and among Onconova Therapeutics, Inc. and certain stockholders named therein *(Incorporated by reference to Exhibit 4.2 to Pre-Effective Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on July 11, 2013).*
4.3	Amendment No. 1 to Eighth Amended and Restated Stockholders' Agreement, effective as of July 9, 2013 *(Incorporated by reference to Exhibit 4.3 to Pre-Effective Amendment No. 1 the Company's Registration Statement on Form S-1 filed on July 11, 2013).*

Exhibit Number	Exhibit Description
4.4	Form of Warrant Certificate, issued pursuant to Warrant Agreement, dated as of July 27, 2016, by and between Onconova Therapeutics, Inc. and Wells Fargo Bank, N.A., as Warrant Agent (*Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on August 15, 2016*).
4.5	Warrant Agreement, dated as of July 27, 2016, by and between Onconova Therapeutics, Inc. and Wells Fargo Bank, N.A., as Warrant Agent (*Incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q filed on August 15, 2016*).
4.6	Form of Pre-Funded Warrants, issued as of July 27, 2016 (*Incorporated by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q filed on August 15, 2016*).
4.7	Form of Underwriter Warrant, issued as of February 12, 2018 (*Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 8, 2018*).
4.8	Form of Preferred Stock Warrant, issued as of February 12, 2018 (*Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on February 8, 2018*).
4.9	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*).
4.10	Form of Preferred Stock Warrant, issued as of May 1, 2018 (*Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on April 30, 2018*).
4.11	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*).
4.12	First Amendment to Underwriter Series A Convertible Preferred Stock Purchase Warrant, dated as of September 24, 2018 (*Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2018*).
4.13	Form of Placement Agent Common Stock Purchase Warrant, issued as of September 25, 2019 (*Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 25, 2019*).
4.14	Form of Letter Amendment to Warrants, dated as of September 23, 2019 (*Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on November 12, 2019*).
4.15	Form of Common Stock Purchase Warrant, issued as of November 25, 2019 (*Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 26, 2019*).
4.16	Form of Pre-Funded Common Stock Warrant, issued as of November 25, 2019 (*Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on November 26, 2019*).
4.17	Form of Placement Agent Common Stock Purchase Warrant, issued as of November 25, 2019 (*Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on November 26, 2019*).
4.18	Form of Common Stock Purchase Warrant, issued as of December 10, 2019 (*Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on December 10, 2019*).
4.19	Form of Placement Agent Common Stock Purchase Warrant, issued as of December 10, 2019 (*Incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed on December 10, 2019*).
4.20	Form of Common Stock Purchase Warrant, issued as of December 2019 (*Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 19, 2019*).
4.21	Form of Placement Agent Common Stock Purchase Warrant, issued as of December 19, 2019 (*Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on December 19, 2019*).
4.22	Form of Placement Agent Common Stock Purchase Warrant, issued as of January 3, 2020 (*Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 3, 2020)*.
4.23	Description of the Company's Securities Registered under Section 12 of the Securities Exchange Act of 1934, as amended (*Incorporated by reference to Exhibit 4.22 to the Company's Annual Report on Form 10-K filed on March 27, 2020).*
10.1*	License Agreement, effective as of July 5, 2011, by and between Onconova Therapeutics, Inc. and SymBio Pharmaceuticals Limited *(Incorporated by reference to Exhibit 10.2 to Pre-Effective Amendment No. 2 the Company's Registration Statement on Form S-1 filed on July 18, 2013).*
10.2*	First Amendment to License Agreement, effective as of September 2, 2011, by and between Onconova Therapeutics, Inc. and SymBio Pharmaceuticals Limited *(Incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.3*	License Agreement, effective as of January 1, 1999, by and between Onconova Therapeutics, Inc. and Temple University — Of The Commonwealth System of Higher Education *(Incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*

Exhibit Number	Exhibit Description
10.4*	Amendment to License Agreement, effective as of September 1, 2000, by and between Temple University — Of The Commonwealth System of Higher Education and Onconova Therapeutics, Inc. *(Incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.5*	Amendment #1 to Exclusive License Agreement, effective as of March 21, 2013, by and between Temple University — Of The Commonwealth System of Higher Education and Onconova Therapeutics, Inc. *(Incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.6+	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).*
10.7+	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).*
10.8+	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).*
10.9+	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).*
10.10+	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).*
10.11+	Employment Agreement, effective as of July 1, 2015, by and between Onconova Therapeutics, Inc. and Mark Guerin *(Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on February 17, 2016).*
10.12+	Amended and Restated Employment Agreement, effective as of July 1, 2015, by and between Onconova Therapeutics, Inc. and Steven M. Fruchtman, M.D. *(Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 13, 2015).*
10.13*	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*).
10.14	Securities Purchase Agreement, dated as of March 2, 2018, by and between Onconova Therapeutics, Inc. and Pint Pharma GmbH (*Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 15, 2018*).
10.15.1+	Amended and Restated Employment Agreement, effective as of June 19, 2018, by and between Onconova Therapeutics, Inc. and Steven M. Fruchtman, M.D. (*Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2018*).
10.15.2+	Amendment to Employment Agreement, dated as of March 18, 2021, by and between Onconova Therapeutics, Inc. and Steven M. Fruchtman, M.D. (Incorporated by reference to Exhibit 10.15.2 to the Company's Annual Report on Form 10-K filed on March 18, 2021).
10.15.3+	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*).
10.16+	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*).
10.17+	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*).
10.18+	Employment Agreement, effective as of November 5, 2018, by and between Onconova Therapeutics, Inc. and Richard C. Woodman, M.D. (*Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2018*).

Exhibit Number	Exhibit Description
10.19	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*).
10.20	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*).
10.21	Securities Purchase Agreement, effective as of May 10, 2019, by and between Onconova Therapeutics, Inc. and Abundant New Investments Ltd. (*Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2019*).
10.22	Form of Securities Purchase Agreement, effective as of September 23, 2019, by and between Onconova Therapeutics, Inc. and each purchase identified on the signature pages thereto (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 25, 2019*).
10.23**	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*).
10.24	Form of Securities Purchase Agreement, effective as of November 21, 2019, by and between Onconova Therapeutics, Inc. and each purchaser identified on the signature pages thereto (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 26, 2019*).
10.25	Form of Securities Purchase Agreement, effective as of December 6, 2019, by and between Onconova Therapeutics, Inc. and each purchaser identified on the signature pages thereto (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 10, 2019*).
10.26**	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*).
10.27	Form of Securities Purchase Agreement, by and between Onconova Therapeutics, Inc. and each purchaser identified on the signature pages thereto, effective as of December 17, 2019 (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 19, 2019*).
10.28	Form of Securities Purchase Agreement, by and between Onconova Therapeutics, Inc. and each purchaser identified on the signature pages thereto, effective as of December 31, 2019 (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 3, 2020)*.
10.29+	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)*.
10.30	Form of Purchase Agreement, dated as of January 7, 2021, by and among Onconova Therapeutics, Inc. and the investors party thereto (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 8, 2021)*.
10.31	Underwriting Agreement, dated February 10, 2021, by and between Onconova Therapeutics, Inc. and Guggenheim Securities, LLC (*Incorporated by reference as Exhibit 1.1 to the Company's Current Report of Form 8-K filed on February 12, 2021*).
10.32+	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)*.
10.33+	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)*.
10.34+	Employment Agreement, dated June 14, 2021, by and between Onconova Therapeutics, Inc. and Mark Stephen Gelder, M.D. *(Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 16, 2021*).
10.35+	Employment Agreement, dated March 9, 2021, by and between Onconova Therapeutics, Inc. and Abraham N. Oler *(Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 16, 2021*).
10.36	Equity Distribution Agreement, dated as of August 20, 2021, by and between Onconova Therapeutics, Inc. and Piper Sandler & Co. (*Incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on August 20, 2021*).

Exhibit Number	Exhibit Description
10.37	Underwriting Agreement, dated September 23, 2021, by and between Onconova Therapeutics, Inc. and Guggenheim Securities, LLC (*Incorporated by reference as Exhibit 1.1 to the Company's Current Report of Form 8-K filed on September 24, 2021*).
10.38+	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*).
10.39+	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*).
10.40+	Amendment to Employment Agreement, effective as of June 10, 2022, by and between Onconova Therapeutics, Inc. and Mark Guerin *(Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 13, 2022).*
10.41+	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)*.
21.1#	Subsidiaries of Onconova Therapeutics, Inc.
23.1#	Consent of Ernst & Young, 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#	Compensation Recoupment Policy of Onconova Therapeutics, Inc., dated as of December 1, 2023.
101.INS	XBRL Instance – The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File – The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

+ 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.

** Portions of the exhibit have been omitted.

Filed herewith.

Furnished herewith.

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 1, 2024

Onconova Therapeutics, Inc.

By: /s/ Steven M. Fruchtman, M.D.
Steven M. Fruchtman
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/ Steven M. Fruchtman, M.D. Steven M. Fruchtman, M.D.	Director, President and Chief Executive Officer (Principal Executive Officer)	April 1, 2024
/s/ Mark Guerin Mark Guerin	Chief Operating Officer and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 1, 2024
/s/ James J. Marino James J. Marino	Chairman, Board of Directors	April 1, 2024
/s/ Peter Atadja Ph.D. Peter Atadja, Ph.D.	Director	April 1, 2024
/s/ Trafford Clarke, Ph.D. Trafford Clarke, Ph.D.	Director	April 1, 2024
/s/ Jerome E. Groopman, M.D. Jerome E. Groopman, M.D.	Director	April 1, 2024
/s/ Viren Mehta, Ph.D. J Viren Mehta, Ph.D.	Director	April 1, 2024
/s/ Mary Teresa Shoemaker Mary Teresa Shoemaker	Director	April 1, 2024
/s/ Jack E. Stover Jack E. Stover	Director	April 1, 2024

ONCONOVA THERAPEUTICS, INC.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Onconova Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Onconova Therapeutics, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a 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 suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding 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 financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 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 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 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 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 financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the 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.

Clinical Trial Expense Accruals

Description of the Matter

As described in Note 2 to the consolidated financial statements, the Company records accruals for estimated costs of research and development activities that include contract services for clinical trials. At December 31, 2023, the Company recorded accrued expenses for clinical trial accruals, which are included in accrued expenses and other current liabilities on the consolidated balance sheet. Clinical trial activities performed by third parties are accrued based upon estimates of the proportion of work completed over the life of the individual clinical trial in accordance with agreements established with contract research organizations, clinical trial sites and other third parties.

Auditing management's clinical trial expense accruals is especially challenging because of the judgment applied by management to determine the progress or stage of completion of the activities under the Company's research and development agreements and the cost and extent of work performed during the reporting period for services not yet billed by contracted third-party vendors. The testing of the Company's accrued clinical trial expense models also involves a significant level of effort to test the high volume of data from third parties.

How We Addressed the Matter in Our Audit

To test the clinical trial expense accruals, our audit procedures included, among others, testing the completeness and accuracy of the inputs used in the estimates and evaluating the significant assumptions including, but not limited to, patient activity and costs per patient, that are used by management to estimate the recorded accruals. To assess the reasonableness of the significant assumptions, our audit procedures included, on a sample basis, agreeing the cost per patient to the Company’s contracts with third parties, corroborating the progress of clinical trials with the Company’s clinical personnel and confirming certain data directly with third parties. To evaluate the completeness of the accruals, we also examined subsequent invoices from the third parties and cash disbursements to the third parties, to the extent such invoices were received, or payments were made, prior to the date that the consolidated financial statements were issued.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2013.

Philadelphia, Pennsylvania

April 1, 2024

ONCONOVA THERAPEUTICS, INC.

Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 20,821,000	$ 38,757,000
Receivables	18,000	29,000
Prepaid expenses and other current assets	1,821,000	561,000
Total current assets	22,660,000	39,347,000
Property and equipment, net	22,000	24,000
Other non-current assets	1,000	1,000
Total assets	$ 22,683,000	$ 39,372,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,619,000	$ 3,860,000
Accrued expenses and other current liabilities	3,375,000	3,960,000
Deferred revenue	226,000	226,000
Total current liabilities	9,220,000	8,046,000
Deferred revenue, non-current	2,791,000	3,017,000
Total liabilities	12,011,000	11,063,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2023 and December 31, 2022	—	—
Common stock, $0.01 par value, 125,000,000 shares authorized, 21,003,409 and 20,925,992 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	210,000	209,000
Additional paid in capital	493,116,000	491,816,000
Accumulated deficit	(482,631,000)	(463,683,000)
Accumulated other comprehensive loss	(23,000)	(33,000)
Total stockholders' equity	10,672,000	28,309,000
Total liabilities and stockholders' equity	$ 22,683,000	$ 39,372,000

See accompanying notes to consolidated financial statements.

ONCONOVA THERAPEUTICS, INC.

Consolidated Statements of Operations

	Years ended December 31,	
	2023	2022
Revenue	$ 226,000	$ 226,000
Operating expenses:		
General and administrative	9,094,000	8,447,000
Research and development	11,430,000	11,406,000
Total operating expenses	20,524,000	19,853,000
Loss from operations	(20,298,000)	(19,627,000)
Other income, net	1,350,000	663,000
Net loss	(18,948,000)	(18,964,000)
Net loss per share, basic and diluted	$ (0.90)	$ (0.91)
Basic and diluted weighted average shares outstanding	20,988,863	20,908,235

See accompanying notes to consolidated financial statements.

ONCONOVA THERAPEUTICS, INC.

Consolidated Statements of Comprehensive Loss

	Years ended December 31,	
	2023	2022
Net loss	$ (18,948,000)	$ (18,964,000)
Other comprehensive income (loss), net of tax:		
Foreign currency translation adjustments, net	10,000	(19,000)
Other comprehensive income (loss), net of tax	10,000	(19,000)
Comprehensive loss	$ (18,938,000)	$ (18,983,000)

See accompanying notes to consolidated financial statements.

ONCONOVA THERAPEUTICS, INC.

Consolidated Statements of Stockholders' Equity

	Stockholders' Equity					
	Common Stock		Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total
	Shares	Amount				
Balance at December 31, 2021	20,895,563	$ 209,000	$ 490,644,000	$ (444,719,000)	$ (14,000)	$ 46,120,000
Net loss	—	—	—	(18,964,000)	—	(18,964,000)
Other comprehensive loss	—	—	—	—	(19,000)	(19,000)
Stock-based compensation	—	—	1,172,000	—	—	1,172,000
Shares issued for vested restricted stock units	30,429	—	—	—	—	—
Balance at December 31, 2022	20,925,992	$ 209,000	$ 491,816,000	$ (463,683,000)	$ (33,000)	$ 28,309,000
Net loss	—	—	—	(18,948,000)	—	(18,948,000)
Other comprehensive loss	—	—	—	—	10,000	10,000
Stock-based compensation	—	—	1,301,000	—	—	1,301,000
Shares issued for vested restricted stock units	77,417	1,000	(1,000)	—	—	—
Balance at December 31, 2023	21,003,409	$ 210,000	$ 493,116,000	$ (482,631,000)	$ (23,000)	$ 10,672,000

See accompanying notes to consolidated financial statements.

ONCONOVA THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2023	2022
Operating activities:		
Net loss	$ (18,948,000)	$ (18,964,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	16,000	14,000
Stock compensation expense	1,301,000	1,172,000
Changes in assets and liabilities:		
Receivables	11,000	(1,000)
Prepaid expenses and other current assets	(1,260,000)	(229,000)
Other assets	—	9,000
Accounts payable	1,759,000	1,103,000
Accrued expenses and other current liabilities	(585,000)	828,000
Deferred revenue	(226,000)	(226,000)
Net cash used in operating activities	(17,932,000)	(16,294,000)
Investing activities:		
Payments for purchase of property and equipment	(14,000)	—
Net cash used in investing activities	(14,000)	—
Effect of foreign currency translation on cash	10,000	(19,000)
Net decrease in cash and cash equivalents	(17,936,000)	(16,313,000)
Cash and cash equivalents at beginning of period	38,757,000	55,070,000
Cash and cash equivalents at end of period	$ 20,821,000	$ 38,757,000

See accompanying notes to consolidated financial statements.

1. Nature of Business

The Company

Onconova Therapeutics, Inc. (the Company) 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. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer. The Company has proprietary targeted anti-cancer agents designed to disrupt specific cellular pathways that are important for cancer cell proliferation. The Company believes that the product candidates in its pipeline have the potential to be efficacious in a variety of cancers with unmet medical need. The Company has the following two clinical-stage programs: (1) narazaciclib (ON 123300), a multi-kinase inhibitor in solid tumors and hematological malignancies as a single agent or in combination with other anti-cancer therapies; and (2) oral rigosertib administered alone or in combination for investigation in various cancers. The Company is currently evaluating potential compounds for in-licensing opportunities. In 2012, Onconova Europe GmbH was established as a wholly owned subsidiary of the Company for the purpose of further developing business in Europe.

Liquidity

The Company has incurred recurring operating losses since inception. For the year ended December 31, 2023, the Company incurred a net loss of $18,948,000 and as of December 31, 2023 the Company had generated an accumulated deficit of $482,631,000. 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, 2023, the Company had cash and cash equivalents of $20,821,000. Based on current projections, the Company does not have sufficient cash and cash equivalents as of the date of this Annual Report on Form 10-K to support its operations for at least the 12 months following the date that the financial statements are issued. These conditions raise substantial doubt about the Company’s ability to continue as a going concern through the one year period after the date that the financial statements are issued. 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 Company will require substantial additional financing to fund its ongoing clinical trials and operations, and to continue to execute its strategy. To alleviate the conditions that raise substantial doubt about the Company’s ability to continue as a going concern, management plans to explore various dilutive and non-dilutive sources of funding, including equity financings, strategic alliances, business development and/or combinations, and other sources. The future success of the Company is dependent upon its ability to obtain additional funding. 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. 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. Accordingly, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date that these financial statements are issued.

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 financial statements include the consolidated accounts of the Company and its wholly-owned subsidiary, Onconova Europe GmbH. All significant intercompany transactions have been eliminated.

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 and in assessing performance. The Company views its operations and manages its business in one segment, which is the identification and development of oncology therapeutics.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, other comprehensive income and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to clinical trial accruals, warrant liability, and allocation of consideration for revenue recognition. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

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, 2023 the Company had $20,559,000 of its cash and cash equivalents in a Morgan Stanley Institutional Liquidity Fund. The fund is a AAA rated money market fund that invests in a portfolio of liquid, high-quality debt securities issued by the U.S. government. The fund resides in a custodial account held by U.S. Bank for which SVB Asset Management is the advisor.

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 year ended December 31, 2023, the Company received $1,391,000 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.

Fair Value of Financial Instruments

The carrying amounts reported in the accompanying consolidated financial statements for cash and cash equivalents, accounts payable, and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts. The fair value of the warrant liability is discussed in Note 8, Fair Value Measurements.

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, 2023.

Warrant Accounting

Common stock warrants are accounted for in accordance with applicable accounting guidance provided in ASC Topic 815, *Derivatives and Hedging—Contracts in Entity's Own Equity* (ASC Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. (See Note 4).

Foreign Currency Translation

The reporting currency of the Company and its U.S. subsidiaries is the U.S. dollar. The functional currency of the Company's non-U.S. subsidiary is the local currency. Assets and liabilities of the foreign subsidiary are translated into U.S. dollars based on exchange rates at the end of the period. Revenues and expenses are translated at average exchange rates during the reporting period. Gains and losses arising from the translation of assets and liabilities are included as a component of accumulated other comprehensive income. Gains and losses resulting from foreign currency transactions are reflected within the Company's results of operations. The Company has not utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

Revenue Recognition

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.

The Company derives revenue from its collaboration and licensing agreements.

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 services. 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.

Research and Development Expenses

Research and development 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 research and development expense, as the case may be.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources.

Leases

The Company accounts for leases in accordance with Accounting Standards Codification Topic 842, *Leases* (ASC 842). The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration.

Right of Use (ROU) Assets and Lease Liabilities are recognized at the lease commencement date based on the present value of all minimum lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments, when the implicit rate is not readily determinable. Lease terms may include options to extend or terminate the lease. These options are included in the lease term when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term.

The Company has elected the following policy elections on adoption: use of portfolio approach on leases of assets under master service agreements, exclusion of short-term leases (term of 12 months or less) on the balance sheet, and not separating lease and non-lease components.

The Company does not have any material lease agreements.

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 (see Note 9, Income Taxes), 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 FASB Accounting Standards Codification (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. 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 financial models taking into account 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, 2023 and 2022, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Basic and Diluted Net Loss Per Share of Common Stock

Basic net loss per share of common stock is computed by dividing net loss applicable to common stockholders by the weighted-average number of shares of Common Stock outstanding during the period, excluding the dilutive effects of stock options and warrants. Diluted net loss per share of common stock is computed by dividing the net loss applicable to common stockholders by the sum of the weighted-average number of shares of Common Stock outstanding during the period plus the potential dilutive effects of stock options and warrants outstanding during the period calculated in accordance with the treasury stock method but are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between basic and diluted net loss per share of Common Stock for the years ended December 31, 2023 and 2022.

Recent Accounting Pronouncements

In June 2016, the FASB issued new guidance on the accounting for credit losses on financial instruments. The guidance was amended in November 2019. The new guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The

guidance was effective for fiscal years beginning after December 15, 2022, and interim periods within those years, for companies deemed to be smaller reporting companies, with early adoption permitted. The Company adopted the guidance effective January 1, 2023. The guidance did not have a material effect on the Company's consolidated financial statements.

3. Property and Equipment

Property and equipment and related accumulated depreciation are as follows:

	December 31,	
	2023	2022
Computer and office equipment	$ 84,000	$ 70,000
Less accumulated depreciation	(62,000)	(46,000)
	$ 22,000	$ 24,000

Depreciation and amortization expense was $16,000 and $14,000 for the years ended December 31, 2023 and 2022, respectively.

4. Warrants

Common stock warrants are accounted for in accordance with applicable accounting guidance provided in ASC Topic 815, *Derivatives and Hedging-Contracts in Entity's Own Equity* (ASC Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement.

Warrants outstanding at December 31, 2022 and 2023, and warrant activity for the year ended December 31, 2023 is as follows (reflects the number of common shares as if the warrants were converted to common stock):

Description	Classification	Exercise Price	Expiration Date	Balance December 31, 2022	Warrants Issued	Warrants Exercised	Warrants Expired	Balance December 31, 2023
Non-tradable pre-funded warrants	Equity	$ 2.25	July 2023	26	—	—	(26)	—
Non-tradable pre-funded warrants	Equity	$ 2.25	none	3,522	—	—	—	3,522
Non-tradable pre-funded warrants	Equity	$ 2.25	none	4,974	—	—	—	4,974
Non-tradable warrants	Equity	$ 30.00	September 2023	7,306	—	—	(7,306)	—
Non-tradable warrants	Equity	$ 3.00	November 2024	244,500	—	—	—	244,500
Non-tradable warrants	Equity	$ 6.54375	December 2024	16,953	—	—	—	16,953
Non-tradable warrants	Equity	$ 6.75450	December 2024	46,263	—	—	—	46,263
Non-tradable warrants	Equity	$ 6.77850	December 2023	29,968	—	—	(29,968)	—
				353,512	—	—	(37,300)	316,212

5. Net Loss Per Share of Common Stock

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2023 and 2022:

	Year ended December 31,	
	2023	2022
Basic and diluted net loss per share of common stock:		
Net loss attributable to Onconova Therapeutics, Inc.	$ (18,948,000)	$ (18,964,000)
Weighted average shares of common stock outstanding	20,988,863	20,908,235
Net loss per share of common stock—basic and diluted	$ (0.90)	$ (0.91)

The following potentially dilutive securities outstanding at December 31, 2023 and 2022 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive (reflects the number of common shares as if the dilutive securities had been converted to common stock):

	December 31,	
	2023	2022
Warrants	307,716	344,990
Stock options	2,311,021	1,397,763
	2,618,737	1,742,753

6. Revenue

The Company recognized revenue under its license and collaboration agreement with SymBio as follows (See Note 14):

	Year ended December 31,	
	2023	2022
Symbio		
Upfront license fee recognition over time	$ 226,000	$ 226,000

Deferred revenue is as follows:

	Symbio Upfront Payment
Deferred balance at December 31, 2022	$ 3,243,000
Recognition to revenue	(226,000)
Deferred balance at December 31, 2023	$ 3,017,000

7. Balance Sheet Detail

Prepaid expenses and other current assets are as follows:

	December 31,	
	2023	2022
Research and development	$ 1,060,000	$ 233,000
Manufacturing	186,000	97,000
Insurance	174,000	191,000
Other	401,000	40,000
	$ 1,821,000	$ 561,000

Accrued expenses and other current liabilities are as follows:

	December 31,	
	2023	2022
Research and development	$ 2,196,000	$ 2,593,000
Employee compensation	1,002,000	1,187,000
Professional fees	177,000	180,000
	$ 3,375,000	$ 3,960,000

8. Fair Value Measurements

At both December 31, 2023 and 2022, the Company had no financial assets and liabilities measured at fair value on a recurring basis, other than cash equivalents which are valued using Level 1 inputs.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The Company utilizes a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

9. 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,	
	2023	2022
Domestic	$ (18,949,000)	$ (18,977,000)
Foreign	1,000	13,000
	$ (18,948,000)	$ (18,964,000)

As of December 31, 2023, the Company had federal net operating loss (NOL) carry forwards of $302,078,000, state NOL carry forwards of $265,482,000 and federal research and development tax credit carry forwards of $93,031,000, which may be available to reduce future taxable income. The federal NOL, that was generated before the 2023 tax year, and the tax credit carry forwards will be begin to expire at various dates starting in 2023. The state NOL carry forwards will begin to expire at various dates starting in 2025. 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 2018 and has not completed an ownership change analysis pursuant to Section 382. 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, 2023, 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, 2023	December 31, 2022
Deferred tax assets:		
Net operating loss carryovers	$ 74,029,000	$ 73,394,000
R&D tax credits	93,031,000	90,522,000
Non-qualified stock options	641,000	2,135,000
Deferred revenue	752,000	809,000
Fixed assets	1,000	—
Accrued expenses	486,000	395,000
Capitalized research and development costs	5,339,000	2,867,000
Healthcare withholding - SARs	12,000	12,000
Deferred tax assets	174,291,000	170,134,000
Less valuation allowance	(174,291,000)	(170,134,000)
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, 2023. The Company experienced a net change in valuation allowance of $4,157,000 and $3,720,000 for the years ended December 31, 2023 and 2022, respectively.

A reconciliation of income tax (expense) benefit at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

	December 31, 2023	December 31, 2022
Federal income tax expense at statutory rate	21.0 %	21.0 %
Permanent items	(0.1)	—
State income tax, net of federal benefit	5.4	1.3
State expirations	(8.6)	—
Tax credits	17.7	9.5
Change in valuation allowance	(21.9)	19.6
Deferred tax adjustment	(9.4)	(0.2)
State tax rate change	—	(50.2)
Other	(4.1)	(1.0)
Effective income tax rate	— %	— %

10. Stock-Based Compensation

The 2018 Omnibus Incentive Compensation Plan (the 2018 Plan) was unanimously approved by the Company's Board of Directors on May 24, 2018 and was approved by the Company's stockholders on June 27, 2018.

Under the 2018 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 and consultants, and advisors. The maximum aggregate number of shares of the Company's common stock that may be issued under the 2018 Plan is 26,823.

The 2018 Plan was amended and restated following unanimous approval of the Company's Board of Directors on April 24, 2019 and was approved by the Company's shareholders on June 17, 2019. The amended 2018 Plan (the Amended 2018 Plan) allowed for an additional 39,300 shares of the Company's common stock that may be issued under the Amended 2018 Plan with respect to awards made on and after June 17, 2019.

The 2021 Incentive Compensation Plan (the 2021 Plan) was approved by the Company's shareholders on July 30, 2021. Upon stockholders' approval of the 2021 Plan, no further awards will be made under the Amended 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 and consultants, and advisors. The maximum aggregate number of shares of the Company's common stock that may be issued under the 2021 Plan is 2,000,000. At December 31, 2023, there were 942,848 shares available for future issuance.

Stock-based compensation expense includes stock options granted to employees and non-employees and has been reported in the Company's statements of operations and comprehensive loss in either research and development 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 as follows for the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
General and administrative	$ 586,000	$ 538,000
Research and development	715,000	617,000
	$ 1,301,000	$ 1,155,000

A summary of stock option activity for the twelve months ended December 31, 2023 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, 2022	1,397,763	$ 7.15	9.18	$ —
Granted	1,108,526	$ 0.85	9.46	—
Exercised	—	$ —	—	$ —
Forfeitures/adjustments	(195,278)	$ 1.85	—	
Balance, December 31, 2023	2,311,011	$ 3.04	8.53	$ 20,814
Exercisable at December 31, 2023	961,968	$ 5.75	7.56	$ 2,597

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, including 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, 2023, there was $1,027,000 of unrecognized compensation expense related to the unvested stock options which is expected to be recognized over a weighted-average period of approximately 1.40 years.

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

	Year ended December 31,	
	2023	2022
Risk-free interest rate	4.0 %	2.7 %
Expected volatility	122.8 %	121.1 %
Expected term	5.74 years	5.77 years
Expected dividend yield	0 %	0 %
Weighted average grant date fair value	$ 0.85	$ 1.19

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 life 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%.

On August 2, 2021, the compensation committee of the board of directors approved restricted stock unit grants to the Company's employees (2021 RSU). An aggregate of 104,700 service-based RSUs were issued at a grant date fair value of $5.19. The 2021 RSU awards will be settled in stock, vest 33% on each of the first and second anniversary of the date of grant, and vest 34% on the third anniversary of the date of grant. The 2021 RSU awards were granted under the 2021 Plan.

On February 7, 2022, the compensation committee of the board of directors approved restricted stock unit grants to the Company's employees (2022 RSU). An aggregate of 148,343 service-based RSUs were issued at a grant date fair value of $1.82. The 2022 RSU awards will be settled in stock, vest 33% on each of the first and second anniversary of the date of grant, and vest 34% on the third anniversary of the date of grant. The 2022 RSU awards were granted under the 2021 Plan.

On June 10, 2022, the compensation committee of the board of directors approved restricted stock unit grants to certain of the Company's employees (2022 RSU2). An aggregate of 24,200 service-based RSUs were issued at a grant date fair value of $1.33. The 2022 RSU2 awards will be settled in stock, vest 33% on each of the first and second anniversary of the date of grant, and vest 34% on the third anniversary of the date of grant.

On March 13, 2023, the compensation committee of the Board of Directors approved restricted stock unit grants to the Companies employees (2023 RSU). An aggregate of 169,217 service-based RSUs were issued at a grant date fair value of $0.73. The 2023 RSU awards will be settled in stock, vest 33% on each of the first and second anniversary of the date of grant, and vest 34% on the third anniversary of the date of grant.

A summary of RSU activity for the twelve months ended December 31, 2023 is as follows:

	2021 RSU	2022 RSU	2022 RSU2	2023 RSU
Outstanding and unvested January 1, 2023	60,871	130,710	24,200	-
Granted	-	-	-	169,217
Vested	(25,784)	(43,567)	(8,066)	-
Forfeited/Cancelled	(9,300)	(12,667)	(5,134)	(33,334)
Outstanding and unvested December 31, 2023	25,787	74,476	11,000	135,883

At December 31, 2023, the unrecognized compensation cost related to unvested service-based RSUs was $236,000, which will be recognized over the remaining service period of 0.95 years.

Grants of PSUs and SARs

During 2020 and 2021, the compensation committee of the board of directors 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 2018 Plan and the 2021 Plan. As the Company's stock price has decreased since these awards, their impact on the results of operations and balance sheet of the Company are not material as of and for the years ended December 31, 2023 and 2022.

11. Employee Benefit Plan

The Company has a 401(k) Retirement Savings Plan. Employees are eligible to participate in the plan as soon as they join the Company if they are at least 21 years of age and work a minimum of 1,000 hours per year. The Company matches $0.75 for every dollar of the first 6% of payroll that employees invest, up to the legal limit. Employer contributions vest immediately. For the years ended December 31, 2023 and 2022, the Company contributed $163,000 and $131,000, respectively.

12. Commitments and Contingencies

Employment agreements

The Company has entered into employment agreements with certain of its executives. The agreements provide for, among other things, salary, bonus and severance payments.

13. Research Agreements

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. As no sales had been generated through December 31, 2023 under the licensed patents, the Company has not incurred any royalty expenses related to this agreement. In addition, the Company is required to pay Temple a percentage of any sublicensing fees received by the Company. No sublicense fees were incurred during 2023 or 2022.

14. 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. In addition, the Company 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.

Royalties will be payable under the SymBio agreement on a country-by-country basis in the licensed territory, until the later of the expiration of marketing exclusivity in those countries, a specified period of time after first commercial sale of rigosertib in such country, or the expiration of all valid claims of the licensed patents covering rigosertib or the manufacture or use of rigosertib in such country. If no valid claim exists covering the composition of matter of rigosertib or the use of or treatment with rigosertib in a particular country before the expiration of the royalty term, and specified competing products achieve a specified market share percentage in such country, SymBio's obligation to pay the Company royalties will continue at a reduced royalty rate until the end of the royalty term. In addition, the applicable royalties payable to the Company may be reduced if SymBio is required to pay royalties to third-parties for licenses to intellectual property rights necessary to develop, use, manufacture or commercialize rigosertib in the licensed territory. The license agreement with SymBio will remain in effect until the expiration of the royalty term. However, the SymBio license agreement may be terminated earlier due to the uncured material breach or bankruptcy of a party, or force majeure. If SymBio terminates the license agreement in these circumstances, its licenses to rigosertib will survive, subject to SymBio's milestone and royalty obligations, which SymBio may elect to defer and offset against any damages that may be determined to be due from the Company. In addition, the Company may terminate the license agreement in the event that SymBio brings a challenge against it in relation to the licensed patents, and SymBio may terminate the license agreement without cause by providing the Company with written notice within a specified period of time in advance of termination.

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 is being recognized as revenue ratably through December 2037, the expected period over which the Company expects the research and development services to be performed.

SymBio's purchases of rigosertib as development-stage product or for commercial requirements represent options under the agreement and revenues are therefore recognized when control of the product is transferred, which is typically when shipped. If SymBio orders the supplies from the Company, the Company expects the pricing for this supply to equal its third-party manufacturing cost plus a pre-negotiated percentage, which will not result in a significant incremental discount to market rates. In January 2018, the agreement was amended to provide SymBio a discount of 35% on future purchases, limited to a cumulative total amount of $300,000.

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.

Traws Pharma, Inc.
12 Penns Trail
Newtown, PA 18940 USA

October 10, 2024

Dear Stockholder,

We cordially invite you to attend our 2024 Annual Meeting of Stockholders to be held at 9:00 a.m.

Eastern Daylight Time on Thursday, October 31, 2024. The 2024 Annual Meeting of Stockholders will be held virtually via the Internet exclusively at www.virtualshareholdermeeting.com/TRAW2024 (the "Annual Meeting"). There will not be a physical meeting location, and stockholders will not be able to attend the annual meeting in person. Instructions on how to participate in the Annual Meeting and demonstrate proof of stock ownership are posted at www.virtualshareholdermeeting.com/TRAW2024 and your proxy card.

This means that you can attend the annual meeting online, vote your shares electronically and submit questions during the online meeting by visiting the above-mentioned website. We believe that hosting a "virtual meeting" will enable greater stockholder attendance and participation from any location around the world. The attached Notice of Annual Meeting and Proxy Statement describes the business we will conduct at the meeting and provides information about Traws Pharma, Inc. that you should consider when you vote your shares.

Your vote is very important, regardless of the number of shares you hold. Whether or not you plan to attend the meeting (via the virtual meeting), please carefully review the enclosed Proxy Statement and then cast your vote.

We hope that you will join us virtually on October 31, 2024.

Sincerely,

/s/ Werner Cautreels

Werner Cautreels
Chief Executive Officer

Traws Pharma, Inc.

12 Penns Trail

Newtown, PA 18940

Notice of 2024 Annual Meeting of Stockholders

NOTICE IS HEREBY GIVEN that the 2024 Annual Meeting (the "Annual Meeting") of Stockholders of Traws Pharma, Inc., a Delaware corporation (the "Company"), will be held on:

Date:	October 31, 2024
Time:	9:00 a.m. Eastern Daylight Time
Place:	www.virtualshareholdermeeting.com/TRAW2024
Purposes:	1. To elect seven directors, each to hold office until the 2025 Annual Meeting of Stockholders and until his or her successor is elected and qualified; 2. To consider and vote upon the Amendment and Restatement of the 2021 Incentive Compensation Plan (the "Incentive Plan Proposal"); 3. To approve, on an advisory basis, the compensation of our named executive officers; 4. To consider and vote upon the ratification of the selection of KPMG LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2024; and 5. To transact such other business as may properly come before the Annual Meeting or any adjournments or postponements thereof.
Record Date:	The Board of Directors has fixed the close of business on September 27, 2024 as the record date for determining stockholders entitled to notice of, and to vote at, the Annual Meeting or any adjournment or postponement thereof.

The Company has enclosed a copy of the proxy statement, the proxy card and the Company's annual report to stockholders for the year ended December 31, 2023 (the "Annual Report"). The proxy statement, the proxy card and the Annual Report are also available on the Company's website at www.trawspharma.com.

Your vote is important. Whether or not you plan to attend the meeting, we urge you to vote as soon as possible by submitting your proxy. You may vote your proxy three different ways: by mail, via the internet, or by telephone. You may also be entitled to vote in person (via the virtual meeting) at the meeting. Please refer to detailed instructions included in the accompanying proxy statement.

FOR THE BOARD OF DIRECTORS

/s/ Werner Cautreels

Werner Cautreels
Chief Executive Officer

Newtown, PA
October 10, 2024

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Traws Pharma, Inc.

12 Penns Trail

Newtown, PA 18940

PROXY STATEMENT
ANNUAL MEETING OF STOCKHOLDERS TO BE HELD OCTOBER 31, 2024

GENERAL INFORMATION

This Proxy Statement is furnished to stockholders of Traws Pharma, Inc., a Delaware corporation ("we," "us," or the "Company"), in connection with the solicitation by our Board of Directors of proxies for use at our 2024 Annual Meeting of Stockholders (the "Annual Meeting"). The Annual Meeting is scheduled to be held at 9:00 a.m. Eastern Daylight Time on Thursday, October 31, 2024, at a virtual location. We anticipate that this Proxy Statement and the enclosed form of proxy will be mailed to stockholders on or about October 10, 2024.

At the Annual Meeting, stockholders will be asked to consider and vote upon: (1) the election of seven directors, each to hold office until the 2025 Annual Meeting of Stockholders and until his or her successor is elected and qualified; (2) a proposal to adopt and approve the Amendment and Restatement of the 2021 Incentive Compensation Plan; (3) a proposal to approve, on an advisory basis, of the compensation of our named executive officers; (4) the ratification of the selection of KPMG LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2024; and (5) such other business as may properly come before the Annual Meeting or any adjournments or postponements thereof.

On September 20, 202, the Company amended its certificate of incorporation to effect a one-for-twenty-five reverse stock split of its common stock (the "Reverse Stock Split"). All common stock, equity, share and per share amounts included in this Proxy Statement have been retroactively adjusted to reflect the Reverse Stock Split.

Voting Rights and Votes Required

The close of business on September 27, 2024 has been fixed as the record date for the determination of stockholders entitled to receive notice of and to vote at the Annual Meeting. As of the close of business on such date, we had outstanding and entitled to vote 3,025,431 shares of our common stock, par value $0.01 per share. Holders of the Company's Series C Non-Voting Convertible Preferred Stock are not entitled to vote at the Annual Meeting. You may vote your shares of common stock in person (all references to "present" or "in person" in this proxy statement relate to the virtual presence at the Annual Meeting) or by proxy. You may submit your proxy by telephone, via the Internet or by completing the enclosed proxy card and mailing it in the envelope provided. Stockholders who hold shares in "street name" should refer to their proxy card or the information forwarded by their bank, broker or other nominee for instructions on the voting options available to them. To vote in person at the virtual meeting, you may attend the Annual Meeting and deliver your completed proxy card electronically or vote your shares electronically during the virtual meeting.

The presence at the Annual Meeting, whether in person or by valid proxy, of one-third of the shares of our common stock entitled to vote will constitute a quorum, permitting us to conduct our business at the Annual Meeting. The record holder of each share of common stock entitled to vote at the Annual Meeting will have one vote for each share so held. Abstentions and broker non-votes will count for quorum purposes.

If a broker that is a record holder of common stock does not return a signed proxy, the shares of common stock represented by such proxy will not be considered present at the Annual Meeting and will not be counted toward establishing a quorum. If a broker that is a record holder of common stock does return a signed proxy, but is not authorized to vote on one or more matters (with respect to each such matter, a "broker non-vote"), the shares of common stock represented by such proxy will be considered present at the Annual Meeting for purposes of determining the presence of a quorum. A broker that is a member of the New York Stock Exchange is prohibited, unless the stockholder provides the broker with

written instructions, from giving a proxy on non-routine matters. Consequently, your brokerage firm or other nominee will have discretionary authority to vote your shares with respect to routine matters but may not vote your shares with respect to non-routine matters.

Election of Directors

Election of directors is a non-routine matter and brokers do not have discretionary authority to vote on this matter. If you hold shares in a brokerage account and wish to vote those shares on this proposal, then you should instruct on how to vote the shares using the voting instructions provided.

Directors are elected by a plurality of the votes cast when a quorum is present. Stockholders may not cumulate their votes. Because directors are elected by a plurality of the votes, votes withheld from a director nominee and broker non-votes will have no effect on the outcome of the vote.

Amendment and Restatement of the 2021 Incentive Compensation Plan

The approval of the Amendment and Restatement of the 2021 Incentive Compensation Plan requires the affirmative vote of a majority of the votes cast at the Annual Meeting. With respect to this proposal, stockholders may (i) vote "For" the proposal, (ii) vote "Against" the proposal, or (iii) abstain from voting. Abstentions are not considered to be votes cast and will have no effect on the outcome of the vote. If you are a stockholder of record and you return your signed and dated proxy card without providing specific voting instructions on the Amendment and Restatement of the 2021 Incentive Compensation Plan proposal, or do not specify your vote on the Amendment and Restatement of the 2021 Incentive Compensation Plan proposal when voting using the telephone or internet, your shares will be voted "For" the Amendment and Restatement of the 2021 Omnibus Incentive Compensation Plan proposal in accordance with the recommendations of the Board of Directors. If you are a stockholder of record and you fail to return your proxy card, or to vote at all using the telephone or internet, it will have no effect.

Approval of the Amendment and Restatement of the 2021 Incentive Compensation Plan is a non-routine matter and brokers do not have discretionary authority to vote on this matter. If you hold shares in a brokerage account and wish to vote those shares on this proposal, then you should instruct on how to vote the shares using the voting instructions provided. Broker non-votes will have no effect on the outcome of the proposal.

Advisory Vote on Executive Compensation

The approval, on an advisory basis, of the compensation of our named executive officers requires the affirmative vote of a majority of the votes cast at the Annual Meeting. With respect to this proposal, stockholders may (i) vote "For" the proposal, (ii) vote "Against" the proposal, or (iii) abstain from voting. Abstentions are not considered to be votes cast and will have no effect on the outcome of the vote. If you are a stockholder of record and you return your signed and dated proxy card without providing specific voting instructions on the advisory vote on executive compensation proposal, or do not specify your vote on the on the advisory vote on executive compensation proposal when voting using the telephone or internet, your shares will be voted "For" the approval, on an advisory basis, of the compensation of our named executive officers proposal in accordance with the recommendations of the Board of Directors. If you are a stockholder of record and you fail to return your proxy card, or to vote at all using the telephone or internet, it will have no effect.

The advisory vote on executive compensation is a non-routine matter and brokers do not have discretionary authority to vote on this matter. If you hold shares in a brokerage account and wish to vote those shares on this proposal, then you should instruct on how to vote the shares using the voting instructions provided. Broker non-votes will have no effect on the outcome of the proposal.

Ratification of Independent Public Accounting Firm

The affirmative vote of a majority of the votes cast is required to approve the proposal to ratify the selection of our independent registered public accounting firm. Abstentions are not considered to be votes cast and will have no effect on the outcome of the vote. If you are a stockholder of record and you return your

signed and dated proxy card without providing specific voting instructions on this proposal, or do not specify your vote on this proposal when voting using the telephone or internet, your shares will be voted "For" the ratification of the selection of our independent registered public accounting firm in accordance with the recommendations of the Board of Directors. If you are a stockholder of record and you fail to return your proxy card, or to vote at all using the telephone or internet, it will have no effect.

We believe that the proposal to ratify the selection of our independent registered public accounting firm is deemed to be a "routine" matter. Therefore, if you are a beneficial owner of shares registered in the name of your broker or other nominee and you fail to provide instructions to your broker or nominee as to how to vote your shares on this proposal, your broker or nominee will have the discretion to vote your shares on this proposal.

Voting of Proxies

Most stockholders have three ways to submit a proxy: by telephone, via the Internet or by completing the enclosed proxy card and mailing it in the envelope provided. To submit a proxy by telephone or via the Internet, follow the instructions set forth on each proxy card you receive. To submit a proxy by mail, sign and date each proxy card you receive, mark the boxes indicating how you wish to vote and return the proxy card in the postage-paid envelope provided. Do not return the proxy card if you submit your proxy via the Internet or by telephone.

Our Board of Directors recommends a vote **FOR** the election of each director nominee, **FOR** the proposal to adopt and approve the Amendment and Restatement of the 2021 Incentive Compensation Plan, **FOR** the approval, on an advisory basis, of the compensation of our named executive officers, and **FOR** the ratification of the selection of KPMG LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2024.

Revocation of Proxies

Any proxy given pursuant to this solicitation may be revoked by a stockholder at any time before it is exercised by providing written notice to our Secretary at Traws Pharma, Inc., 12 Penns Trail, Newtown, PA 18940, by delivery to us of a properly executed proxy bearing a later date, or by virtually attending the meeting and voting in person electronically at the Annual Meeting.

Solicitation of Proxies

We will bear the cost of this solicitation, including amounts paid to banks, brokers and other nominees to reimburse them for their expenses in forwarding solicitation materials regarding the Annual Meeting to beneficial owners of our common stock. The solicitation will be by mail, with the materials being forwarded to stockholders of record and certain other beneficial owners of our common stock, and by our officers and other regular employees (at no additional compensation). Our officers and employees may also solicit proxies from stockholders by personal contact, by telephone, or by other means, if necessary, in order to assure sufficient representation at the Annual Meeting.

Broadridge Financial Solutions ("Broadridge") has been retained to act as inspector of elections at the Annual Meeting. We expect to pay Broadridge approximately $10,000 for these services.

PROPOSAL ONE ELECTION OF DIRECTORS

Pursuant to our bylaws, our directors are elected at each annual meeting of stockholders, and serve until their successors are elected and qualified at the next annual meeting of stockholders, or until their prior death, resignation, retirement, disqualification or other removal.

Our Board of Directors currently consists of seven directors. Our Board of Directors has nominated the seven persons listed in the table below for election as directors with terms expiring at the 2025 Annual Meeting of Stockholders. Accordingly, our stockholders may not vote their shares for a greater number of persons than the nominees named below. Unless a contrary direction is indicated, it is intended that proxies received will be voted for the election as directors of the seven nominees, each to hold office until the 2025 Annual Meeting of Stockholders and until his or her successor is elected and qualified. Each of the nominees has consented to being named in this Proxy Statement and to serve as a director if elected. In the event any nominee for director declines or is unable to serve, the proxies may be voted for a substitute nominee selected by the Board of Directors.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS A VOTE "FOR" *ALL* NOMINEES.

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 the nominees below contains information regarding the person's business experience, director positions held currently or at any time during the last five years, and the experiences, 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.	65	Executive Chairman	2024
Werner Cautreels, Ph.D.	71	Director and Chief Executive Officer	2024
Trafford Clarke, Ph.D.	66	Director	2022
Luba Greenwood	45	Director	2024
Nikolay Savchuk, Ph.D.	55	Director and Chief Operating Officer	2024
M. Teresa Shoemaker	63	Director	2020
Jack E. Stover	71	Director	2016

Iain Dukes, D. Phil. Dr. Dukes has served as Executive Chairman since April 1, 2024. Dr. Dukes is a Venture Partner of OrbiMed, a global investment firm, since 2016. He 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 and Development at Amgen. 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 development of breakthrough medicines for 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. Dr. Dukes is currently the chairman of the board of directors of Iovance Biotherapeutics, Inc. (Nasdaq: IOVA) and Executive Chairman of Angiex Inc. and also serves on the board of directors of Ikena Oncology (Nasdaq: IKNA), NeRRe Therapeutics, ENYO Therapeutics and Rathlin Therapeutics. Dr. Dukes also co-founded and serves on the board of directors of Kartos Therapeutics, and co-founded Telios Pharma, where he serves as President. He holds an M.A. in Jurisprudence. and D.Phil. from the University of Oxford, an M.Sc. in Cardiovascular Studies from the University of Leeds, and a B.Sc. in Pharmacology from the University of Bath.

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

Werner Cautreels, Ph.D. Dr. Cautreels has served as a director and CEO of the Company since April 1, 2024. Dr. Werner 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 was President and CEO of Selecta Biosciences from July 2010 until 2018. Prior to Selecta Biosciences, Dr. Cautreels served as Global CEO 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 was also a Director of Innogenetics NV (Gent, Belgium) and of Arqule Inc. (Woburn, Massachusetts). Until April 2019, Dr. Cautreels was Director and 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 CEO 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's experience holding senior leadership positions in the pharmaceutical industry and his specifically as a prior CEO in the pharmaceutical industry, provide him with the qualifications and skills to serve as a director, provide him with the qualifications and skills to serve as a director.

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. 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.

Luba Greenwood. Ms. Greenwood is a distinguished executive, investor, and company builder with over 20 years of experience in the healthcare and tech sectors. She currently serves as the Managing Partner of the Dana Farber Cancer Institute Venture Fund, Binney Street Capital (BSC), which she has founded, investing and building companies across therapeutics, diagnostics, and digital sectors. Luba has served as the Chief Executive Officer and Chair of the Board of a number of biotechnology companies, including Kojin Therapeutics. She is currently an EIR at PureTech Health. With a strong understanding of board dynamics and corporate governance best practices, and as a former lawyer, she has also guided organizations through compliance, activist actions, and human resources challenges. She has served as Chair of the board as well as on the Compensation, Audit, and Nomination committees of a number of companies including In8Bio (INAB), BenchSci, Closed Loop Medicine, Swiss-based Stalicla, Abcam (Abcam), where she has spearheaded the sale to Danaher (DHR), and non-profit, Massachusetts Biotechnology Council (MassBio).

Ms. Greenwood has previously served in leadership roles at Google Life Sciences (Verily) and as Vice President of Global Business Development and Mergers & Acquisitions at Roche, where she also led diagnostics BD and established and led the East Coast Innovation Hub. Luba has led $10B+ in M&A, BD deals, and investments across multiple therapeutic areas, diagnostics, life sciences and tech sectors globally. She has also co-founded and advised biotech and digital health companies in the immunotherapy, AI/ML, women's health, and microbiome space, including Luca Biologics. Her invaluable contributions to the healthcare industry have earned her recognition as a thought leader and a trusted advisor to CEOs of leading academic centers worldwide, including the Dana Farber Institute and Wyss Center for Bio and Neuroengineering in Geneva. She is a Thought Leader for the New England Journal of Medicine (NEJM) Catalyst and serves on Investor Committee for the National Cancer Institute. She has also served as a lecturer at Harvard University in the School of Engineering and Applied Sciences.

Our Board of Directors believes that Ms. Greenwood's background as a former lawyer at Wilmer Cutler Pickering Hale and Dorr and expertise in regulatory, policy, and intellectual property matters provide her with the qualifications and skills to serve as a director. Upon joining the board in September 2024, Ms. Greenwood joined as a member of the Company's audit committee and compensation committee and as the chair of the Company's nominating and corporate governance committee.

Nikolay Savchuk, Ph.D. Dr. Savchuck has served as director and COO since April 1, 2024. Dr. Savchuk is the co-founder and Managing Member at Torrey Pines Investment LLC, a life-science investment company, since 2002. Dr. Savchuk is also the Managing General Partner of Teal Ventures, LP, a venture capital firm focused on early-stage investing in health technology, since October 2018. Prior to joining life science investment and research in the United States, Dr. Savchuk held various business and research management positions in the IT industry with companies in Singapore and Russia. Dr. Savchuk is currently the executive chairman of the board of directors of Viriom Inc., a company dedicated to advancing a pipeline of effective and affordable treatments for diseases of global interest, and chairman of the board of directors of ChemDiv Inc., a company dedicated to partnering in discovery and development of breakthrough therapies based on its unique chem-bio platforms. Dr. Savchuk obtained his M.S. degree in physics and his Ph.D. in applied mathematics from 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.

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 CEO of Medexus Pharmaceuticals, Inc. ("Medexus") from October 2018 to May 2020. Prior to joining Medexus, she served as President and CEO and board member of Medac Pharma, Inc. from its inception in June 2012 until its acquisition by Medexus in October 2018. Ms. Shoemaker implemented Medac's commercial strategy in support of a commercial product for the treatment of rheumatoid arthritis. 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. From 2002 to 2008, Ms. Shoemaker served as National Sales Director and then Sr. Director US Commercial Operations for Pharmion Corporation ("Pharmion"). 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.

Jack E. Stover. Mr. Stover has served as a member of our Board of Directors since May 2016. Since March 2021, Mr. Stover has been Chief Executive Officer of NorthView Acquisition Corp. From June 2022 until November 2022 when he resigned Mr. Stover was director and Chairman of the Audit Committee of PharmaCyte Biotech, a Nasdaq company. From December 2015 until June 2016, Mr. Stover served as Interim President and CEO of Interpace Diagnostics Group, Inc. ("Interpace") and, since August 2005, served on the Board of Directors of Interpace and was chairman of Interpace's audit committee from August 2005 until December 2015. Mr. Stover has been a member of the board of directors of Stero Therapeutics, Inc. since February 2024. In June 2016 until December 2020, Mr. Stover was President, CEO and Director of Interpace, which in 2019 changed its name to Interpace Biosciences, Inc. From June 2016 to December 2016, Mr. Stover was chairman of the audit committee and a member of the Board of Directors of Viatar CTC Solutions, Inc. From 2004 to 2008, he served as Chief Executive Officer, President and Director of Antares Pharma, Inc., a publicly held specialty pharmaceutical company then listed on the American Stock Exchange and subsequently Nasdaq. In addition to other relevant experience, Mr. Stover 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.

Executive Officers

The following table sets forth certain information regarding our executive officers who are not also directors.

Name	Age	Position(s) with Traws Pharma, Inc.
Werner Cautreels, Ph.D.	71	Chief Executive Officer
Mark P. Guerin	55	Chief Financial Officer
Victor Moyo, M.D.	56	Chief Medical Officer, Oncology
C. David Pauza, Ph.D.	70	Chief Science Officer, Virology
Robert R. Redfield, M.D.	73	Chief Medical Officer
Nikolay Savchuk, Ph.D.	55	Chief Operating Officer

Mark P. Guerin. Mr. Guerin has served as our Chief Financial Officer since September 1, 2016. From June 10, 2022 to April 1, 2024, he was our Chief Financial Officer and Chief Operating Officer. Previously, he served as Vice President — Financial Planning & Accounting, and Chief Accounting Officer since May 2014, and as Vice President — Financial Planning & Accounting from September 2013 to May 2014. He has also served as our principal financial officer since February 12, 2016. Between January 2012 and September 2013, Mr. Guerin was self-employed as a financial and accounting consultant. For more than six years, through December 2011, Mr. Guerin was employed by CardioKine, Inc. and served as Chief Financial Officer from mid-2009 through December 2011. Mr. Guerin received his B.A. in Accounting from DeSales University.

Victor Moyo, M.D. Dr. Moyo has served as our 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. Most recently Dr. Moyo has been serving as Chief Medical Officer (CMO) of OncoPep, Inc. and Executive Vice-President, CMO and Head of R&D at L.E.A.F. Pharmaceuticals. 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.

C. David Pauza, Ph.D. Dr. Pauza has served as the Chief Scientific 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. and Viriom, Inc., which held the rights to an influenza therapeutic drug, which was sublicensed to Trawsfynydd Therapeutics, Inc. Dr. Pauza previously served as Chief Science Officer of American Gene Technologies International, Inc. from 2016 to 2021, where he lead 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 Acting 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 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 or R3 Enterprises and Consulting, the Co-Founder and President of Prevention, Diagnosis, Treatment Inc. (PDTi) and a practicing physician with Greater Baltimore Medical Center (GBMC) Health Partners. 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.

Director Compensation

The following table summarizes compensation paid to our non-employee directors in fiscal 2023.

Name	Fees Earned or Paid in Cash ($)	Stock Option Awards ($)[1][2]	All Other Compensation ($)	Total ($)
Peter Atadja, Ph.D.[3]	52,000	59,220	—	63,602
Trafford Clarke, Ph.D.	45,000	59,220	—	63,310
Jerome E. Groopman, M.D[3]	44,000	59,220	—	116,009
James J. Marino[4]	82,500	59,220	—	154,509
Viren Mehta, Pharm.D.[3]	51,500	59,220	—	131,176
M. Teresa Shoemaker	59,000	59,220	—	131,009
Jack E. Stover	67,500	59,220	—	139,509

(1) The amounts shown represent the aggregate grant date fair value related to the grant of 66,468 non-qualified stock options to each of our non-employee directors as of August 10, 2023, calculated in accordance with FASB ASC Topic 718. These stock options vest on the first anniversary of the grant and expire ten years after the grant date and are subject to the director's continued service. Additional information concerning our financial reporting of stock appreciation rights is presented in Note 10 to our Consolidated Financial Statements set forth in our Annual Report on Form 10-K for the year ended December 31, 2023.

(2) As of December 31, 2023, the aggregate number of outstanding stock option awards held by each non-employee director was: Dr Atadja — 166,468; Dr. Clarke — 166,468; Dr. Groopman — 146,730; Mr. Marino — 146,735; Dr. Mehta — 146,730; Ms. Shoemaker — 145,936; and Mr. Stover — 146,730. As of December 31, 2023, the aggregate number of stock appreciation rights held by each non-employee director was: Dr. Groopman — 8,333; Mr. Marino — 8,333; Dr. Mehta — 8,333; Ms. Shoemaker — 8,333; and Mr. Stover — 8,333.

(3) Resigned on April 1, 2024 in connection with the acquisition of Trawsfynydd Therapeutics, Inc. ("Trawsfynydd") (the "Trawsfynydd Acquisition").

(4) Resigned on September 16, 2024.

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. Under the new policy, each non-employee director receives an annual equity award with a grant date value of $28,400 which is awarded at the first Board of Directors meeting after the Annual Meeting; provided however, that for the first Board meeting following this 2024 Annual Meeting, each non-employee director will receive an equity

award with a grant date value of $59,000. 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. The cash components to the non-employee director compensation policy remain the same and, in accordance with this policy, each non-employee director receives an annual base retainer of $40,000. In addition, our non-employee directors 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 receives 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 receives 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.

All amounts are paid in quarterly installments.

All of our directors are eligible to receive additional discretionary awards under our 2021 Incentive Compensation Plan, subject to the annual limit set forth in such 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.

Corporate Governance Board Composition

Our Board of Directors currently consists of seven members. Our Board of Directors has undertaken a review of the independence of our directors and has determined that all directors except Werner Cautreels, Ph.D., 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 11 directors, as such number of directors may from time to time be fixed by our Board of Directors. 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.

Board Leadership Structure and Role in Risk Oversight

Our Board of Directors recognizes the time, effort and energy that the chief executive officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our chairman, particularly 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, 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, 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 Luba Greenwood, Trafford Clarke and Jack E. Stover, with Jack E. Stover serving as chairperson. The current members of our compensation committee are M. Teresa Shoemaker, Luba Greenwood 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 Luba Greenwood, with Luba Greenwood serving as chairperson.

Our Board of Directors has determined that Luba Greenwood, Trafford Clarke and Jack E. Stover meet the additional test for independence for audit committee members imposed by Securities and Exchange Commission ("SEC") regulations and Section 5605(c)(2)(A) of the NASDAQ Stock Market listing rules and that M. Teresa Shoemaker, Luba Greenwood and Jack E. Stover 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 met four times during fiscal year 2023. The functions of our audit committee include, among other things:

- hiring 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;
- reviewing potential conflicts of interest under and violations of our code of conduct;
- 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 this 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 http://www.trawspharma.com.

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 met seven times during fiscal year 2023.

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, our 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, 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
- 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 http://www.trawspharma.com.

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 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 compensation program and evolving industry practices and providing market information and analysis regarding the competitiveness of our program 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 met one time during fiscal year 2023. 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 http://www.trawspharma.com.

Code of Conduct for Employees, Executive Officers and Directors

We have adopted a code of conduct applicable to all of our employees, executive officers and directors.

The code of conduct is available in the corporate governance section of our website at http://www.trawspharma.com.

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.

Meetings of the Board of Directors

The Board of Directors held eight meetings during fiscal 2023. During fiscal 2023, 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 the annual meeting of stockholders. All seven of our directors attended the 2023 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 believe 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 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).

Your 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.

Board Diversity

We believe it is important that our Board is composed of individuals reflecting the diversity represented by our employees, our clients, and our communities. Below, we provide an enhanced disclosure regarding the diversity of our Board as required by the listing standards of the NASDAQ Capital Market.

Board Diversity Matrix (as of October 2, 2024)				
Total Number of Directors	7			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	2	5	0	0
Part II: Demographic Background				
African American or Black	0	0	0	0
Alaskan Native or Native American	0	0	0	0
Asian	0	0	0	0
Hispanic or Latinx	0	0	0	0
Native Hawaiian or Pacific Islander	0	0	0	0
White	1	2	0	0
Two or More Races or Ethnicities	0	0	0	0
LGBTQ+	0			
Did Not Disclose Demographic Background	4			

Board Diversity Matrix (as of June 6, 2023)				
Total Number of Directors	8			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	1	7	0	0
Part II: Demographic Background				
African American or Black	0	1	0	0
Alaskan Native or Native American	0	0	0	0
Asian	0	1	0	0
Hispanic or Latinx	0	0	0	0
Native Hawaiian or Pacific Islander	0	0	0	0
White	1	3	0	0
Two or More Races or Ethnicities	0	0	0	0
LGBTQ+	0			
Did Not Disclose Demographic Background	2			

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.

PROPOSAL TWO

AMENDMENT AND RESTATEMENT OF THE 2021 INCENTIVE COMPENSATION PLAN

The Board of Directors is asking stockholders to approve the Traws Pharma, Inc. 2021 Incentive Compensation Plan, as amended and restated (the "Amended Plan"). On October 10, 2024, acting on the recommendation of our Compensation Committee (the "Compensation Committee"), the Board of Directors unanimously approved the Amended Plan, subject to stockholder approval and, accordingly, the Board of Directors directed that the Amended Plan be submitted to the Company's stockholders for approval at the Annual Meeting. The Amended Plan will become effective upon the approval of the Company's stockholders. Awards granted prior to the effective date of the Amended Plan will continue to be governed by the applicable award agreements and the terms of the Onconova Therapeutics, Inc. 2021 Incentive Compensation Plan, as amended and restated (the "2021 Plan"), prior to the effective date of the Amended Plan.

The Amended Plan is further amendment and restatement of the 2021 Plan, which was originally effective as of July 30, 2021 and amended and restated on July 21, 2022 upon the approval of the Company's stockholders. The 2021 Plan is a successor to the Onconova Therapeutics, Inc. 2018 Omnibus Incentive Compensation Plan, as amended and restated (the "2018 Plan"). The 2018 Plan replaced the Onconova Therapeutics, Inc. 2013 Equity Incentive Plan (the "2013 Plan", and together with the 2018 Plan, the "Prior Plans"). No further awards have been or will be made under the Prior Plans after the original effective date of the 2021 Plan. Awards granted under the Prior Plans will continue in effect in accordance with the terms of the applicable award agreement and the terms of the applicable Prior Plan in effect when the awards were granted.

Stockholder approval of the Amended Plan is being sought in order to (i) meet NASDAQ listing requirements, (ii) extend the term of the Amended Plan and (iii) allow for incentive stock options to meet the requirements of the Internal Revenue Code of 1986, as amended (the "Code").

The principal changes made to the Amended Plan are to:

- increase the number of shares of our common stock reserved for issuance by an additional 300,000 shares; and
- extend the term of the Amended Plan until the day immediately preceding the tenth anniversary of the effective date of the Amended Plan.

The Amended Plan will enable the Company to continue its compensation program that is intended to attract, motivate and retain experienced, highly-qualified directors, employees, consultants and advisors of the Company who will contribute to the Company's success, and will align the interests of the directors, employees, consultants and advisors of the Company with those of its stockholders through the ability to grant a variety of stock-based awards. If the stockholders approve the Amended Plan, awards granted under the Amended Plan will be governed by the terms of the Amended Plan.

Determination of the Number of Shares Available for Awards under the Amended Plan

As of December 31, 2023, 37,714 shares remain available for grant under the 2021 Plan. The Board of Directors and the Compensation Committee believe that attracting and retaining employees, non-employee directors, and consultants and advisors of high quality has been and will continue to be essential to the Company's growth and success. Consistent with this view, the Board of Directors and its Compensation Committee believe that the number of shares currently available for issuance under the 2021 Plan is not sufficient for future grants in light of our compensation structure and strategy.

If this Proposal 2 is approved by our stockholders at the Annual Meeting, subject to adjustments as described in the Amended Plan and summarized below, the number of additional shares of our common stock that may be issued under the Amended Plan with respect to awards made on and after the Amended Plan is approved by our stockholders will be 300,000 shares. In addition, subject to adjustments as described in the Amended Plan, shares of our common stock that remained available for awards under the 2021 Plan

as of the effective date of the Amended Plan and any shares of our common stock subject to outstanding awards under the 2021 Plan and the Prior Plans, as of the effective date of the Amended Plan, that terminate, expire, or are cancelled, forfeited, exchanged, or surrendered without having been exercised, vested, or paid in shares after the effective date of the Amended Plan will be available for issuance under the Amended Plan.

In determining the number of additional shares to be authorized for issuance under the Amended Plan, the Board of Directors considered a number of factors, including the number of shares available under the 2021 Plan, our past share usage (burn rate), the number of shares needed for future awards, a dilution analysis, competitive data from relevant peer companies, the current and future accounting expenses associated with our equity award practices, and input from our stockholders.

Dilution Analysis

As of September 27, 2024, the Company's capital structure consisted of 3,025,431 shares of common stock outstanding. As described above, 37,714 shares remain available for grant of awards under the 2021 Plan as of December 31, 2023. The proposed share authorization is a request for 300,000 additional shares to be available for awards under the Amended Plan. The table below shows our potential dilution (referred to as "overhang") levels based on our fully diluted shares of common stock and our request for an additional 300,000 shares to be available for awards under the Amended Plan. The 300,000 new shares represent 8.7% of fully diluted shares of our common stock, including all shares that will be authorized under the Amended Plan, as described in the table below. The Board of Directors believes that this number of shares of common stock under the Amended Plan represents a reasonable amount of potential equity dilution, which will allow the Company to continue awarding equity awards, and that equity awards are an important component of the Company's equity compensation program.

Potential Overhang with 300,000 Additional Shares

Stock Options Outstanding as of December 31, 2023[(1)]	92,440
Weighted Average Exercise Price of Stock Options Outstanding as of December 31, 2023	$76.00
Weighted Average Remaining Term of Stock Options Outstanding as of December 31, 2023	8.53 years
Outstanding Time-Based Restricted Stock Units as of December 31, 2023[(2)]	9,886
Total Equity Awards Outstanding as of December 31, 2023[(3)]	102,326
Shares Available for Grant under the 2021 Plan as of December 31, 2023	37,714
Additional Shares Requested under the Amended Plan	300,000
Total Potential Overhang under the Amended Plan and the Prior Plans	440,040
Shares of Common Stock Outstanding as of September 27, 2024	3,025,431
Fully Diluted Shares of Common Stock[(4)]	3,465,471
Potential Dilution of 300,000 shares as a Percentage of Fully Diluted Shares of Common Stock	8.7%

(1) Represents the number of outstanding stock options granted under the 2021 Plan and the Prior Plans. No additional awards have been or will be made under the 2013 Plan after June 27, 2018 or under the 2018 Plan after July 30, 2021.

(2) Represents the number of outstanding time-based restricted stock units granted under the 2021 Plan.

(3) Represents the number of shares subject to outstanding awards under the 2021 Plan and the Prior Plans that could again become available under the Amended Plan, subject to adjustments as described in the Amended Plan.

(4) The Fully Diluted Shares of Common Stock in the foregoing table consists of the Shares of Common Stock Outstanding as of September 27, 2024, plus the Total Potential Overhang under the Amended Plan.

Based on our historic and projected future usage patterns, the Board of Directors estimates that the shares reserved under the Amended Plan will be sufficient to provide awards under the Amended Plan for

approximately two to three years, although the number of awards granted for any year could vary as our Compensation Committee deems appropriate. This is only an estimate, and circumstances could cause the share reserve to be used more quickly or more slowly. These circumstances include, but are not limited to, the future price of our common stock, the mix of cash, options and full value awards provided as long-term incentive compensation, award amounts provided by our competitors, hiring activity, and promotions during the next few years.

Burn Rate

The table below sets forth the following information regarding the awards granted under the 2021 Plan: (i) the burn rate for each of the last three calendar years and (ii) the average burn rate over the last three calendar years. The burn rate for a year has been calculated as follows:

i. all stock options granted in the applicable year and all time-based restricted stock units granted in the applicable year, divided by

ii. the weighted average number of shares of common stock outstanding for the applicable year.

Burn Rate

Element	2023	2022	2021
Stock Options Granted	44,431	41,767	16,543
Time-Based Restricted Stock Units Granted	6,769	6,902	4,188
Total Granted	51,110	48,668	20,731
Weighted Average Shares of Common Stock Outstanding as of December 31	839,555	836,329	673,288
Burn Rate	6.09%	5.82%	3.08%

The burn rate means that the Company used an annual average of 5.00% of the weighted average shares outstanding for awards granted over the prior three years under the 2021 Plan.

The Board of Directors believes that the current number of shares available for grants under the 2021 Plan is not sufficient in light of our compensation structure and strategy. Equity incentives form an integral part of the compensation paid to many of our employees, particularly those in positions of key importance. Equity incentives also are a major part of our non-employee director annual retainer compensation. The Board of Directors has concluded that our ability to attract, retain and motivate top quality employees, non-employee directors, and consultants and advisors is critical to our success and growth, and would be enhanced by our continued ability to grant awards under the Amended Plan. In addition, the Board of Directors believes that our interests and the interests of our stockholders will be advanced if the Company can continue to offer employees, non-employee directors and consultants and advisors the opportunity to acquire or increase their proprietary interests in the Company. The Board of Directors believes that adopting the Amended Plan will ensure that the Company continues to have a sufficient number of shares with which to achieve our compensation strategy and to allow for growth.

Summary of the Amended Plan

The material terms of the Amended Plan are summarized below. A copy of the full text of the Amended Plan is attached to this Proxy Statement as Appendix A. This summary of the Amended Plan is not intended to be a complete description of the Amended Plan and is qualified in its entirety by the actual text of the Amended Plan to which reference is made.

Purpose and Types of Awards

The purpose of the Amended Plan is to attract and retain employees, non-employee directors and consultants, and advisors. The Amended Plan provides for the issuance of incentive stock options, non-qualified stock options, stock awards, stock units, stock appreciation rights and other stock-based

awards. The Amended Plan is intended to provide an incentive to participants to contribute to our economic success by aligning the economic interests of participants with those of our stockholders.

Administration

The Amended Plan will be administered by our Compensation Committee, and our Compensation Committee will determine all of the terms and conditions applicable to awards under the Amended Plan. Our Compensation Committee will also determine who will receive awards under the Amended Plan and the number of shares of common stock that will be subject to awards. Our Compensation Committee may delegate authority under the Amended Plan to one or more subcommittees as it deems appropriate. Our Compensation Committee will consist of "non-employee directors" as defined under Rule 16b-3 promulgated under the Securities Exchange Act of 1934 (the "Exchange Act") and "independent directors," as determined in accordance with the independence standards established by the stock exchange on which our common stock is at the time primarily traded. Subject to compliance with applicable law and the applicable stock exchange rules, our Board of Directors, in its discretion, may perform any action of our Compensation Committee under the Amended Plan. Subject to compliance with applicable law and applicable stock exchange requirements, the Compensation Committee (or our Board of Directors or a subcommittee, as applicable) may delegate all or part of its authority to our Chief Executive Officer, as it deems appropriate, with respect to awards to employees or consultants or advisors who are not executive officers or directors under Section 16 of the Exchange Act. Our Compensation Committee, our Board of Directors, any subcommittee or the Chief Executive Officer, as applicable, that has authority with respect to a specific award will be referred to as "the committee" in this description of the Amended Plan.

Shares Subject to the Amended Plan

Subject to adjustment described below, the maximum aggregate number of shares of common stock that may be issued or transferred under the Amended Plan with respect to awards made on and after the effective date of the Amended Plan is 300,000 shares. In addition, subject to adjustments as described below, any shares of common stock that remained available for awards under the 2021 Plan as of the effective date of the Amended Plan and any shares of common stock subject to outstanding awards granted under the 2021 Plan and the Prior Plans that terminate, expire, or are cancelled, forfeited, exchanged, or surrendered without having been exercised, vested, or paid in shares after the effective date of the Amended Plan will be available for issuance under the Amended Plan.

If any options or stock appreciation rights, including outstanding options granted under the 2021 Plan or the Prior Plans, terminate, expire, or are cancelled, forfeited, exchanged, or surrendered without having been exercised, or if any stock awards, stock units or other stock-based award, including stock units granted under the 2021 Plan, are forfeited, terminated, or otherwise not paid in full, the shares of our common stock subject to such awards will again be available for purposes of the Amended Plan. Shares of our common stock that are surrendered in payment of the exercise price of an option (including an option granted under the 2021 Plan or granted under Prior Plans that is exercised on or after the effective date of the 2021 Plan) or a stock appreciation right will not be available for issuance under the Amended Plan. Shares of our common stock that are withheld in satisfaction of the withholding taxes, or surrendered for the payment of taxes, incurred in connection with the issuance, vesting or exercise of any award, or the issuance of our common stock (including an option or stock unit award granted under the 2021 Plan or an option granted under the Prior Plans) will not be available for issuance under the Amended Plan. When stock appreciation rights are granted, the full number of shares subject to the stock appreciation rights will be considered issued under the Amended Plan regardless of the number of shares issued upon exercise of the stock appreciation rights. If we repurchase shares of our common stock on the open market with the proceeds from the exercise price we receive from options (including options granted under the 2021 Plan and the Prior Plans), the repurchased shares will not be available for issuance under the Amended Plan. If any awards are paid in cash, and not in shares of our common stock, any shares of our common stock subject to such awards will also be available for future awards. In addition, shares of our common stock issued under awards made pursuant to assumption, substitution, or exchange of previously granted awards of a company that we acquire will not reduce the number of shares of our common stock available under the Amended Plan. Available shares under a stockholder approved plan of an acquired company may be used for awards under

the Amended Plan and will not reduce the share reserve, subject to compliance with the applicable stock exchange requirements and the Code.

The maximum aggregate grant date value of shares of common stock subject to awards made to any non-employee member of our Board of Directors during any calendar year for services rendered as a non-employee director, including any cash fees earned for services rendered as a non-employee director during the calendar year, will not exceed $300,000 in total value. In determining the foregoing dollar limit in this paragraph, the value of awards will be calculated based on the grant date fair value of the awards for financial reporting purposes.

Adjustments

In connection with stock splits (reverse stock splits), stock dividends, recapitalizations, and certain other events affecting our common stock, the committee will make adjustments as it deems appropriate in the maximum number of shares of common stock reserved for issuance as awards or for which individuals may receive awards in any year; the number and kind of shares covered by outstanding awards; the kind of shares that may be issued or transferred under the Amended Plan; the price per share or market value of any outstanding awards; the exercise price of options; the base amount of stock appreciation rights; and the performance goals or other terms; and conditions as the committee deems appropriate.

Eligibility

All of our employees are eligible to receive awards under the Amended Plan. In addition, our non-employee directors and consultants or advisors who perform services for us may receive awards under the Amended Plan. Incentive stock options may be granted only to our employees.

As of September 27, 2024, approximately 7 employees and 4 non-employee directors that would be eligible to participate in the Amended Plan. The committee, in its discretion, selects the persons to whom awards may be granted, determines the type of awards, determines the times at which awards will be made, determines the number of shares subject to each such award (or the dollar value of certain performance awards), and determines the other terms and conditions relating to the awards. For this reason, it is not possible to determine the benefits or amounts that will be received by any particular person in the future. Because our executives and non-employee directors are eligible to receive awards under the Amended Plan, they may be deemed to have a personal interest in the approval of this Proposal 2.

Vesting

The committee determines the vesting and exercisability terms of awards granted under the Amended Plan. Awards granted under the Amended Plan shall include regular vesting schedules that provide that no portion of an award will vest earlier than one year from the date of grant. However, up to 5% of the shares reserved under the Amended Plan as of the effective date of the Amended Plan (subject to adjustment as set forth in the Amended Plan) may be granted without regard to this minimum vesting requirement. Except in connection with a change in control (in which case, awards will be treated as described below), the committee may accelerate vesting of any award in its discretion. Dividends and dividend equivalents granted in connection with any awards made under the Amended Plan will vest and be paid only if and to the extent the underlying awards vest and are paid.

At the committee's discretion, performance objectives for awards may be based on the attainment of specified levels of one or more performance goals established by the committee. If the committee so determines, the vesting of any such award subject to performance objectives may be described in terms of company-wide objectives or objectives that are related to the performance of the individual participant or the subsidiary, division, department or function within the company or subsidiary in which the participant is employed. Performance objectives may be measured on an absolute or relative basis. Relative performance may be measured by a group of peer companies or by a financial market index. Performance objectives may include: specified levels of or increases in, a division's or a subsidiary's return on capital, equity or assets; earnings measures/ratios (on a gross, net, pre-tax or post-tax basis), including basic earnings per share, diluted earnings per share, total earnings, operating earnings, earnings growth, earnings before interest and taxes and earnings before interest, taxes, depreciation and amortization; net economic profit (which is operating

earnings minus a charge to capital); net income; operating income; sales; sales growth; gross margin; direct margin; costs; share price (including but not limited to growth measures and total stockholder return); operating profit; per period or cumulative cash flow (including but not limited to operating cash flow and free cash flow) or cash flow return on investment (which equals net cash flow divided by total capital); inventory turns; financial return ratios; market share; balance sheet measurements such as receivable turnover; improvement in or attainment of expense levels; improvement in or attainment of working capital levels; debt reduction; strategic innovation; customer or employee satisfaction; the consummation of one or more acquisitions of a certain size as measured by one or more of the financial criteria listed above; individual objectives; regulatory body approval for commercialization of a product; implementation or completion of critical projects (including, but not limited to, milestones such as clinical trial enrollment targets, commencement of phases of clinical trials and completion of phases of clinical trials); and any combination of the foregoing.

Options

Under the Amended Plan, the committee will determine the exercise price of the options granted and may grant options to purchase shares of common stock in such amounts as it determines. The committee may grant options that are intended to qualify as incentive stock options under Section 422 of the Code, or non-qualified stock options, which are not intended to so qualify. Incentive stock options may only be granted to our employees. Anyone eligible to participate in the Amended Plan may receive a grant of non-qualified stock options. The exercise price of an option granted under the Amended Plan cannot be less than the fair market value of a share of our common stock on the date the option is granted. If an incentive stock option is granted to a 10% stockholder, the exercise price cannot be less than 110% of the fair market value of a share of our common stock on the date the option is granted. The aggregate number of shares of common stock that may be issued or transferred under the Amended Plan pursuant to incentive stock options under Section 422 of the Code granted on and after the effective date of the Amended Plan may not exceed 300,000 shares of common stock. The fair market value of our common stock is generally equal to the closing price for the common stock on the date the option is granted (or if there was no closing price on that date, on the last preceding date on which a closing price was reported).

The exercise price for any option is generally payable in cash. In certain circumstances as permitted by the committee, the exercise price may be paid by the surrender of shares of our common stock with an aggregate fair market value on the date the option is exercised equal to the exercise price; by payment through a broker in accordance with procedures established by the Federal Reserve Board; by withholding shares of common stock subject to the exercisable option which have a fair market value on the date of exercise equal to the aggregate exercise price; or by such other method as the committee approves.

The term of an option cannot exceed ten years from the date of grant, except that if an incentive stock option is granted to a 10% stockholder, the term cannot exceed five years from the date of grant. In the event that on the last day of the term of a non-qualified stock option, the exercise is prohibited by applicable law, including a prohibition on purchases or sales of our common stock under our insider trading policy, the term of the non-qualified option will be extended for a period of 30 days following the end of the legal prohibition, unless the committee determines otherwise.

Except as provided in the award agreement, an option may only be exercised while a participant is employed by or providing service to us. The committee will determine in the award agreement under what circumstances and during what time periods a participant may exercise an option after termination of employment.

Stock Appreciation Rights

Under the Amended Plan, the committee may grant stock appreciation rights, which may be granted separately or in tandem with any option. Stock appreciation rights granted with a non-qualified stock option may be granted either at the time the non-qualified stock option is granted or any time thereafter while the option remains outstanding. Stock appreciation rights granted with an incentive stock option may be granted only at the time the grant of the incentive stock option is made. The committee will establish the base amount of the stock appreciation right at the time the stock appreciation right is granted, which will be equal to or greater than the fair market value of a share of our common stock as of the date of grant.

If a stock appreciation right is granted in tandem with an option, the number of stock appreciation rights that are exercisable during a specified period will not exceed the number of shares of our common stock that the participant may purchase upon exercising the related option during such period. Upon exercising the related option, the related stock appreciation rights will terminate, and upon the exercise of a stock appreciation right, the related option will terminate, to the extent of an equal number of shares of our common stock. Generally, stock appreciation rights may only be exercised while the participant is employed by, or providing services to, us. When a participant exercises a stock appreciation right, the participant will receive the excess of the fair market value of the underlying common stock over the base amount of the stock appreciation right. The appreciation of a stock appreciation right will be paid in shares of our common stock, cash or both.

The term of a stock appreciation right cannot exceed ten years from the date of grant. In the event that on the last day of the term of a stock appreciation right, the exercise is prohibited by applicable law, including a prohibition on purchases or sales of our common stock under our insider trading policy, the term of the stock appreciation right will be extended for a period of 30 days following the end of the legal prohibition, unless the committee determines otherwise.

Stock Awards

Under the Amended Plan, the committee may grant stock awards. A stock award is an award of our common stock that may be subject to restrictions as the committee determines. The restrictions, if any, may lapse over a specified period of employment or based on the satisfaction of pre-established criteria, in installments or otherwise, as the committee may determine. Except to the extent restricted under the award agreement relating to the stock award, a participant will have all of the rights of a stockholder as to those shares, including the right to vote and the right to receive dividends or distributions on the shares; provided, however, that dividends with respect to stock awards shall vest and be paid if and to the extent that the underlying stock award vests and is paid. All unvested stock awards are forfeited if the participant's employment or service is terminated for any reason, unless the committee determines otherwise.

Stock Units

Under the Amended Plan, the committee may grant restricted stock units to anyone eligible to participate in the Amended Plan. Restricted stock units are phantom units that represent shares of our common stock. Restricted stock units become payable on terms and conditions determined by the committee and will be payable in cash or shares of our stock as determined by the committee. All unvested restricted stock units are forfeited if the participant's employment or service is terminated for any reason, unless the committee determines otherwise.

Other Stock-Based Awards

Under the Amended Plan, the committee may grant other types of awards that are based on, measured by, or payable to, anyone eligible to participate in the Amended Plan in shares of our common stock. The committee will determine the terms and conditions of such awards. Other stock-based awards may be payable in cash, shares of our common stock, or a combination of the two.

Dividend Equivalents

Under the Amended Plan, the committee may grant dividend equivalents in connection with awards of stock units or other stock-based awards made under the Amended Plan. Dividend equivalents entitle the participant to receive amounts equal to ordinary dividends that are paid on the shares underlying an award while the award is outstanding. Dividend equivalents may be paid in cash, in shares of our common stock, or in a combination of the two. The committee will determine the terms and conditions of the dividend equivalent awards, including whether the awards are payable upon the achievement of specific performance goals; provided, however, that dividend equivalents shall vest and be paid only if and to the extent that the underlying stock units or other stock-based awards vest and are paid. For the avoidance of doubt, no dividends or dividend equivalents will be granted with respect to options or stock appreciation rights.

Change in Control

If we experience a change in control where we are not the surviving corporation (or survive only as a subsidiary of another corporation), all outstanding awards that are not exercised or paid at the time of the change in control will be assumed by, or replaced with awards that have comparable terms by, the surviving corporation (or a parent or subsidiary of the surviving corporation). In the event that the surviving corporation (or a parent or subsidiary of the surviving corporation) does not assume or replace awards with grants that have comparable terms, outstanding options and stock appreciation rights will accelerate and become fully exercisable and the restrictions and conditions on outstanding stock awards, stock units, other stock-based awards and dividend equivalents immediately lapse, provided that if the vesting of any such awards is based, in whole or in part, on performance, such awards shall vest based on the greater of (i) actual performance as of the change in control or (ii) target performance, pro-rated based on the period elapsed between the beginning of the applicable performance period and the date of the change in control. At the committee's discretion, if a participant incurs an involuntary termination of employment or service on or after a change in control, the participant's outstanding awards may become vested, in whole or in part, as of the date of termination; provided that if the vesting of any such award is based, in whole or in part, on performance, such awards shall vest only based on the greater of (i) actual performance as of the change in control or (ii) target performance, pro-rated based on the period elapsed between the beginning of the applicable performance period and the date of the termination.

If there is a change in control and all outstanding awards are not assumed by, or replaced with awards that have comparable terms by, the surviving corporation, the committee may take any of the following action without the consent of any participant:

- pay participants, in an amount and form determined by the committee, in settlement of outstanding stock units, other stock-based awards or dividend equivalents;
- require that participants surrender their outstanding options, stock appreciation rights or any other exercisable award, in exchange for a payment by us, in cash or shares of our common stock, equal to the difference between the exercise price and the fair market value of the underlying shares of common stock; provided, however, if the per share fair market value of the common stock does not exceed the per share option exercise price or stock appreciation right base amount, as applicable, we will not be required to make any payment to the participant upon surrender of the option or stock appreciation right; or
- after giving participants an opportunity to exercise all of their outstanding options and stock appreciation rights, terminate any unexercised options and stock appreciation rights on the date determined by the committee.

In general terms, a change in control under the Amended Plan includes:

- the acquisition, directly or indirectly, by a person of more than 50% of the combined voting power of our voting securities entitled to vote generally in the election of directors; provided, however, that the following acquisitions of voting securities shall not constitute a change in control: (a) any acquisition by or from us or any of our subsidiaries, or by any employee benefit plan (or related trust) sponsored or maintained by us or any of our subsidiaries, (b) any acquisition by any underwriter in any firm commitment underwriting of securities to be issued by us, or (c) any acquisition by any corporation (or other entity) if, immediately following such acquisition, 50% or more of the then outstanding shares of common stock (or other equity unit) of such corporation (or other entity)
- and the combined voting power of the then outstanding voting securities of such corporation (or other entity), are beneficially owned, directly or indirectly, by all or substantially all of the individuals or entities who, immediately prior to such acquisition, were the beneficial owners of our then outstanding shares of common stock and the voting securities in substantially the same proportions, respectively, as their ownership immediately prior to the acquisition of our stock and voting securities;
- the consummation of the sale or other disposition of all or substantially all of our assets, other than to a wholly-owned subsidiary or to a holding company of which we are a direct or indirect wholly owned subsidiary prior to such transaction;

- the consummation of a reorganization, merger or consolidation of our company, other than a reorganization, merger or consolidation which would result in our voting securities outstanding immediately prior to the transaction continuing to represent (whether by remaining outstanding or
- by being converted to voting securities of the surviving entity) 65% or more of the voting securities or the voting power of the voting securities of such surviving entity outstanding immediately after such transaction;
- the consummation of a plan for our complete liquidation; or
- the following individuals cease for any reason to constitute a majority of our Board of Directors: individuals who, as of the effective date of the Amended Plan, constitute our Board of Directors and any new director (other than a director whose initial assumption of office is in connection with an actual or threatened election contest, including, but not limited to, a consent solicitation relating to
- the election of our directors) whose appointment or election by the Board of Directors or nomination for election by our stockholders was approved and recommended by a vote of at least two-thirds of the directors then still in office who either were directors on the effective date of the Amended Plan or whose appointment, election or nomination for election was previously so approved or recommended.

Notwithstanding the above, in the case of a distribution under the Amended Plan of an amount which is subject to Section 409A of the Code, only an event which constitutes a "change in control event" as defined under Section 409A of the Code shall constitute a "change in control" for purposes of the payment provisions under the Amended Plan.

Deferrals

The committee may permit or require participants to defer receipt of the payment of cash or the delivery of shares of common stock that would otherwise be due to the participant in connection with an award under the Amended Plan. The committee will establish the rules and procedures applicable to any such deferrals, consistent with the requirements of Section 409A of the Code.

Withholding

All awards under the Amended Plan are subject to applicable U.S. federal (including FICA), state and local, foreign, or other tax withholding requirements. We may require participants or other persons receiving awards or exercising awards to pay an amount sufficient to satisfy such tax withholding requirements with respect to such awards, or we may deduct from other wages and compensation paid by us the amount of any withholding taxes due with respect to such award.

The committee may permit or require that our tax withholding obligation with respect to awards paid in our common stock will paid by having shares withheld up to an amount that does not exceed the participant's applicable withholding tax rate for U.S. federal (including FICA), state and local, foreign, or other tax liabilities. In addition, the committee may, in its discretion, and subject to such rules as the committee may adopt, allow participants to elect to have such share withholding applied to all or a portion of the tax withholding obligation arising in connection with any particular award.

Transferability

Except as permitted by the committee with respect to non-qualified stock options, only a participant may exercise rights under an award during the participant's lifetime. Upon death, the personal representative or other person entitled to succeed to the rights of the participant may exercise such rights. A participant cannot transfer those rights except by will or by the laws of descent and distribution or, with respect to awards other than incentive stock options, pursuant to a domestic relations order. The committee may provide in an award agreement that a participant may transfer non-qualified stock options to family members, or one or more trusts or other entities for the benefit of or owned by family members, consistent with applicable securities laws.

Amendment; Termination

Our Board of Directors may amend or terminate the Amended Plan at any time, except that our stockholders must approve an amendment if such approval is required in order to comply with the Code, applicable laws, or applicable stock exchange requirements. Unless terminated sooner by our Board of Directors or extended with stockholder approval, the Amended Plan will terminate on the day immediately preceding the tenth anniversary of the effective date of the Amended Plan.

Stockholder approval is required to amend the terms of outstanding options or stock appreciation rights to reduce the exercise price or base price of options or stock appreciation rights, respectively, cancel outstanding options or stock appreciation rights in exchange for options or stock appreciation rights with an exercise price or base price, as applicable, that is (1) less than the exercise price or base price of the original options or stock appreciation rights or (2) above the current stock price in exchange for cash or other securities. However, such stockholder approval is not required in connection with certain corporate transactions or other actions with respect to our securities, such as a stock split, extraordinary cash dividend, recapitalization, change in control, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase or exchange of shares of our common stock.

Establishment of Sub-Plans

Our Board of Directors may, from time to time, establish one or more sub-plans under the Amended Plan to satisfy applicable blue sky, securities, or tax laws of various jurisdictions. Our Board of Directors may establish such sub-plans by adopting supplements to the Amended Plan setting forth limitations on the committee's discretion and such additional terms and conditions not otherwise inconsistent with the Amended Plan as our Board of Directors will deem necessary or desirable. All such supplements will be deemed part of the Amended Plan, but each supplement will only apply to participants within the affected jurisdiction.

Clawback

Subject to applicable law, the committee may provide in any award agreement that if a participant breaches any restrictive covenant agreement between the participant and us, or otherwise engages in activities that constitute cause either while employed by, or providing services to, us or within the applicable period of time thereafter, all awards held by the participant will terminate, and we may rescind any exercise of an option or stock appreciation right and the vesting of any other award and delivery of shares upon such exercise or vesting, as applicable on such terms as the committee will determine, including the right to require that in the event of any rescission:

- the participant must return the shares received upon the exercise of any option or stock appreciation right or the vesting and payment of any other awards; or
- if the participant no longer owns the shares, the participant must pay to us the amount of any gain realized or payment received as a result of any sale or other disposition of the shares (if the participant transferred the shares by gift or without consideration, then the fair market value of the shares on the date of the breach of the restrictive covenant agreement or activity constituting cause), net of the price originally paid by the participant for the shares.

The committee may also provide for clawbacks pursuant to a clawback policy, which our Board of Directors may in the future adopt and amend from time to time. Payment by the participant will be made in such manner and on such terms and conditions as may be required by the committee. We will be entitled to set off against the amount of any such payment any amounts that we otherwise owe to the participant.

Federal Income Tax Consequences

The following discussion summarizes certain federal income tax considerations of awards under the Amended Plan. However, it does not purport to be complete and does not describe the state, local or foreign tax considerations or the consequences for any particular individual.

Options. A participant does not realize ordinary income on the grant of an option. Upon exercise of a non-qualified stock option, the participant will realize ordinary income equal to the excess of the fair market

value of the shares of common stock over the option exercise price. The cost basis of the shares acquired for capital gain treatment is their fair market value at the time of exercise. Upon exercise of an incentive stock option, the excess of the fair market value of the shares of common stock acquired over the option exercise price will be an item of tax preference to the participant, which may be subject to an alternative minimum tax for the year of exercise. If no disposition of the shares is made within two years from the date of granting of the incentive stock option or within one year after the transfer of the shares to the participant, the participant does not realize taxable income as a result of exercising the incentive stock option; the tax basis of the shares received for capital gain treatment is the option exercise price; any gain or loss realized on the sale of the shares is long-term capital gain or loss. If the participant disposes of the shares within the two-year or one-year periods referred to above, the participant will realize ordinary income at that time in an amount equal to the excess of the fair market value of the shares at the time of exercise (or the net proceeds of disposition, if less) over the option exercise price. For capital gain treatment on such a disposition, the tax basis of the shares will be their fair market value at the time of exercise.

Stock Appreciation Rights. No ordinary income will be realized by a participant in connection with the grant of a SAR. When the SAR is exercised, the participant will realize ordinary income in an amount equal to the sum of the amount of any cash received and the fair market value of the shares of common stock or other property received upon the exercise.

Restricted Stock, Performance and Restricted Stock Unit Awards. The participant will not realize ordinary income on the grant of a restricted stock award (or a performance award if the shares of common stock are issued on grant), but will realize ordinary income when the shares subject to the award become vested in an amount equal to the excess of (i) the fair market value of the shares on the vesting date over (ii) the purchase price, if any, paid for the shares. The participant may, however, elect under Section 83(b) of the Code to include as ordinary income in the year the shares are granted an amount equal to the excess of (i) the fair market value of the shares on the date of issuance, over (ii) the purchase price, if any, paid for the shares. If the Section 83(b) election is made, the participant will not realize any additional taxable income when the shares become vested.

The participant will not realize ordinary income on the grant of a restricted stock unit award (or a performance award under which shares of common stock are not issued on grant), but will realize ordinary income when the shares subject to the award are issued to the participant after they become vested. The amount of ordinary income will be equal to the excess of (i) the fair market value of the shares on the date they are issued over (ii) the purchase price, if any, paid for the award.

Upon disposition of shares of common stock acquired under a restricted stock award, performance award or restricted stock unit award, the participant will realize a capital gain or loss equal to the difference between the selling price and the sum of the amount paid for the shares plus any amount realized as ordinary income upon grant (or vesting) of the shares.

Company Tax Deduction

Prior to 2018, Section 162(m) of the Code imposed a $1 million limit on the amount a public company may deduct for compensation paid to a company's chief executive officer or any of the company's three other most highly compensated executive officers (other than the chief financial officer) who are employed as of the end of the year. This limitation did not apply to compensation that meets the tax code requirements for "qualified performance-based" compensation (*i.e.*, compensation paid only if the individual's performance meets pre-established objective goals based on performance criteria approved by stockholders, including options).

The performance-based compensation exemption and the exemption of the chief financial officer from Section 162(m)'s deduction limit have been repealed, among other changes, effective for taxable years beginning after December 31, 2017, such that awards paid to our covered executive officers (including our chief executive officer) in excess of $1 million will not be deductible in future years, unless it qualifies for transition relief applicable to certain arrangements that were in effect as of November 2, 2017 and are not materially modified thereafter.

While deductibility of executive compensation for federal income tax purposes is among the factors the committee considers when structuring our executive compensation arrangements, it is not the sole or primary

factor considered. We retain the flexibility to authorize compensation that may not be deductible if we believe it is in the best interests of the Company.

New Plan Benefits under the Amended Plan

Future benefits under the Amended Plan generally will be granted at the discretion of the Compensation Committee and are therefore not currently determinable. As of September 27, 2024, the closing price of the common stock as reported on NASDAQ was $5.74 per share.

Vote Required for Approval

The affirmative vote of a majority of the votes cast by stockholders present, in person or by proxy, and entitled to vote at the Annual Meeting, will be required to approve the Company's 2021 Incentive Compensation Plan, as amended and restated.

Recommendation

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS A VOTE "*FOR*" THE PROPOSAL TO APPROVE THE AMENDMENT AND RESTATEMENT OF THE 2021 INCENTIVE COMPENSATION PLAN.

PROPOSAL THREE

ADVISORY VOTE ON EXECUTIVE COMPENSATION

Pursuant to the proxy rules under the Exchange Act and as required by Section 951 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), we are presenting to our stockholders with a non-binding, advisory vote to approve the compensation of our named executive officers as described in this proxy statement (sometimes referred to as "say-on-pay").

Accordingly, the following resolution is being presented by our Board of Directors at the Annual Meeting:

"RESOLVED, that the compensation paid to the Company's named executive officers, as disclosed pursuant to Item 402 of Regulation S-K, including the compensation tables and narrative discussion, is hereby APPROVED."

Our executive compensation program is designed to attract, motivate and retain our executive officers, who are critical to our success. As described in the "Executive Compensation" section in this proxy statement, our executive compensation program contains elements of cash and equity-based compensation. Our Board of Directors and our compensation committee believe that our compensation programs directly and substantially link rewards to measurable corporate performance and are designed to align the interests of our named executive officers with those of our stockholders and to reward our named executive officers for the achievement of our near-term and longer-term financial and strategic goals. The process for determining compensation packages requires that our Board of Directors and our compensation committee use judgment and experience to determine the optimal components and amounts of compensation for each named executive officer.

We strongly encourage our stockholders to review this proxy statement, and in particular the information contained in the "Executive Compensation" section, including the compensation tables and narrative discussion, for a more detailed discussion of our compensation philosophy, objectives and programs.

The say-on-pay vote gives you as a stockholder the opportunity to express your views regarding the compensation of our named executive officers by voting to approve or not approve such compensation as described in this proxy statement. This vote is advisory and will not be binding upon our Board of Directors or our compensation committee. However, our Board of Directors and our compensation committee value the opinion of our stockholders and took into account the outcome of the vote when considering executive compensation arrangements during the year. For instance, our Board of Directors took into consideration the results of the vote on this proposal at the 2023 Annual Meeting of Stockholders and engaged our stockholders following the outcome of the annual vote. We will continue to take into account the outcome of the advisory vote and engage with our stockholders when considering future executive compensation arrangements. The vote on this resolution is not intended to address any specific element of compensation, but rather relates to the overall compensation of our named executive officers, as described in this proxy statement in accordance with the compensation disclosure rules of the SEC.

Our Board of Directors has determined that, based on the vote results of the "say-on-frequency" proposal at the 2020 Annual Meeting of Stockholders, we will hold an advisory vote on executive compensation every year, until our Board of Directors otherwise determines a different frequency for such votes. The next say-on-pay vote will occur at our 2025 Annual Meeting of Stockholders.

Vote Required; Recommendation of the Board of Directors

The affirmative vote of a majority of the votes cast by stockholders present, in person or by proxy, and entitled to vote at the Annual Meeting, will be required to approve the advisory resolution on executive compensation.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT YOU VOTE FOR THE APPROVAL, ON A NON-BINDING ADVISORY BASIS, OF THE FOLLOWING RESOLUTION:

"RESOLVED, THAT THE COMPENSATION PAID TO THE COMPANY'S NAMED EXECUTIVE OFFICERS, AS DISCLOSED PURSUANT TO ITEM 402 OF REGULATION S-K, INCLUDING THE COMPENSATION TABLES AND NARRATIVE DISCUSSION, IS HEREBY APPROVED."

PROPOSAL FOUR

RATIFICATION OF THE SELECTION OF KPMG LLP AS OUR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FOR THE FISCAL YEAR ENDING DECEMBER 31, 2024

Our Board of Directors, acting upon the recommendation of the audit committee, has selected KPMG LLP to audit our consolidated financial statements for the fiscal year ending December 31, 2024.

On May 17, 2024, Ernst & Young LLP notified the Company that it declines to stand for reappointment as the Company's registered public accounting firm for the audit of the fiscal year ended December 31, 2024. On July 16, 2024, the Audit Committee engaged KPMG LLP as the Company's new independent registered public accounting firm for the year ended December 31, 2024.

Although stockholder approval of the selection of KPMG LLP is not required by law, our Board of Directors and the audit committee believe it is advisable to give stockholders an opportunity to ratify this selection. If this proposal is not approved at the Annual Meeting, the audit committee may reconsider its selection of KPMG LLP. Additionally, we are considering various actions to reduce our operating expenses. Even if this proposal is approved, the audit committee may reconsider its selection of KPMG LLP as part of our expense reduction efforts.

We expect representatives of KPMG LLP to attend the annual meeting, to be available to respond to appropriate questions from stockholders, and to have the opportunity to make a statement if so desired.

Fees of Independent Registered Public Accounting Firm

The following table summarizes the fees of Ernst & Young LLP, our independent registered public accounting firm for the fiscal years ended December 31, 2023 and December 31,2022.

Fee Category	Fiscal 2023	Fiscal 2022
Audit Fees[1]	$326,000	$272,500
Audit-Related Fees[2]	—	—
Tax Fees[3]	—	—
Total Fees	$326,000	$272,500

(1) Audit fees consist of fees for the audits of fiscal 2023 and 2022 and quarterly reviews of our consolidated financial statements and other professional services provided in connection with statutory and regulatory filings or engagements.

(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 2023 and fiscal 2022 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 and all non-audit services in fiscal 2023 were pre-approved by our audit committee. Our audit committee has determined that the provision of the non-audit services for which these fees were rendered is compatible with maintaining the independent auditor's independence.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS A VOTE "FOR" THE PROPOSAL TO RATIFY THE SELECTION OF KPMG LLP AS OUR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FOR THE FISCAL YEAR ENDING DECEMBER 31, 2024.

REPORT OF AUDIT COMMITTEE

The Audit Committee has reviewed the Company's audited consolidated financial statements for the fiscal year ended December 31, 2023 and discussed them with the Company's management and the Company's independent registered public accounting firm.

The Audit Committee has also received from, and discussed with, the Company's independent registered public accounting firm various communications that the Company's independent registered public accounting firm is required to provide to the Audit Committee, including the matters required to be discussed by Auditing Standard No. 1301, Communications with Audit Committees, as adopted by the Public Company Accounting Oversight Board.

The Audit Committee has received the written disclosures and the letter from the Company's independent registered public accounting firm required by applicable requirements of the Public Company Accounting Oversight Board regarding the independent accountant's communications with the Audit Committee concerning independence, and has discussed with the Company's independent registered public accounting firm their independence.

Based on the review and discussions referred to above, the Audit Committee recommended to the Company's Board of Directors that the audited consolidated financial statements be included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

By the Audit Committee of the Board of Directors of Traws Pharma, Inc.

Jack E. Stover, *Chairperson*
Luba Greenwood*
Trafford Clarke

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* Ms. Greenwood joined the Audit Committee as of September 16, 2024 and was not a member of the committee when it reviewed and discussed the recommendation referred to above, and, as such, did not participate in, and has not made an independent inquiry, as to the accuracy of the Company's audited consolidated financial statements in its Annual Report on Form 10-K for the year ended December 31, 2023. Ms. Greenwood approved this Report of the Audit Committee solely based upon the advice and approvals of the other Audit Committee members.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the beneficial ownership of common stock as of September 27, 2024 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 on page 34 of this Proxy Statement under the heading, "2023 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 3,025,431 shares of common stock outstanding on September 27, 2024. 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 September 27, 2024 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, 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:		
Viriom, Inc.[(1)]	605,531	19.9%
TPAV, LLC[(2)]	605,531	19.9%
OrbiMed Advisors LLC[(3)]	605,531	19.9%
Directors, Director Nominees and Named Executive Officers:		
Iain Dukes, D.Phil.[(4)]	235,332	7.4%
Werner Cautreels, Ph.D.[(5)]	8,000	*
Trafford Clarke, Ph.D[(6)]	2,666	*
Luba Greenwood[(7)]	—	*
Nikolay Savchuk, Ph.D.[(8)]	235,332	7.4%
M. Teresa Shoemaker[(9)]	5,973	*
Jack E. Stover[(10)]	5,878	*
Steven M. Fruchtman, M.D.[(11)]	3,365	*
Mark P. Guerin[(12)]	10,696	*
Victor Moyo, M.D.[(13)]	1,875	*
All current executive officers, directors and director nominees as a group (12 persons)	550,371	16.1%

* Represents a beneficial ownership of less than one percent of our outstanding common stock.

(1) Based on our records and a Schedule 13D filed by Viriom, Inc. ("Viriom") on April 8, 2024 with the SEC. Represents shares of common stock also held by Nikolay Savchuk and Iain Dukes, which may be deemed to be indirectly beneficially owned by Viriom. Dr. Savchuk and Dr. Dukes have shared voting and dispositive power over 65,804 shares of common stock. Dr. Savchuk has investment control of and is a director of Viriom, and indirectly holds a majority of shares of its common stock through AAAn LLC, a limited liability company of which Dr. Savchuk is the managing member. Dr. Dukes is the Chief Executive Officer of Viriom. Each of Drs. Savchuk and Dukes disclaims any excess of his pecuniary interest in the securities held by Viriom, Inc. The address of Viriom is 1450 Research Blvd, Rockville, MD 20850.. On September 16, 2024, the Company amended its certificate of incorporation to effect a one-for-twenty-five reverse stock split of its common stock (the "Reverse Stock Split"). All common stock, equity, share and per share amounts included in this Proxy Statement have been retroactively adjusted to reflect the Reverse Stock Split.

(2) Based on our records and on a Form 3/A filed by TPAV, LLC ("TPAV, LLC") on April 11, 2024 with the SEC. Nikolay Savchuk is the sole manager on the Board of Managers of TPAV, LLC. Nikolay Savchuk disclaims beneficial ownership of the securities held by TPAV, LLC except to the extent of his pecuniary interest therein.

(3) Based on our records and a Schedule 13D filed by OrbiMed Advisors LLC ("OrbiMed Advisors") on September 16, 2024 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.

(4) Includes 2,700 RSUs and 152,166 shares of common stock issuable upon the exercise of warrants and options that are currently exercisable or exercisable within sixty days of the record date. Does not include 2,633 shares of common stock owned by Viriom.

(5) Includes 8,000 RSUs.

(6) Includes 2,666 shares of common stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of the record date.

(7) Ms. Greenwood was appointed as a director on September 16, 2024.

(8) Includes 2,700 RSUs and 152,166 shares of common stock issuable upon the exercise of warrants and options that are currently exercisable or exercisable within sixty days of the record date. Does not include 1,417 shares of common stock owned by TPAV, LLC or 2,633 shares of common stock owned by Viriom.

(9) Includes 5,837 shares of common stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of the record date.

(10) Includes 5,869 shares of common stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of the record date.

(11) Includes 373 shares of common stock issuable upon the exercise of warrants that are currently exercisable or exercisable within sixty days of the record date.

(12) Includes 1,379 RSUs and 7,746 shares of common stock issuable upon the exercise of warrants and options that are currently exercisable or exercisable within sixty days of the record date.

(13) Includes 1,875 shares of common stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of the record date.

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 2023 in a timely manner, except that Victor Moyo inadvertently failed to timely file a Form 3 to report his appointment as Chief Medical Officer in October 2023 and a Form 4 relating to a grant of options to purchase shares of Common Stock.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

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.

There were no related person transactions (as defined in SEC regulations) during 2023.

After the Trawsfynydd Acquisition on April 1, 2024, the Company has the following related party transactions all of which have been approved by the Board and the audit committee as deemed necessary:

Trawsfynydd entered into that certain Master Research and Development Agreement with Viriom, dated January 5, 2022, pursuant to which Viriom provides service related to the research and development in the area of virology. Trawsfynydd also entered into that certain License Agreement with Viriom, dated January 20, 2023, pursuant to which Trawsfynydd licensed certain intellectual property from Viriom. Dr. Dukes and Dr. Savchuk are stockholders of Viriom and members of its board of directors. Dr. Savchuk has investment control of Viriom and indirectly holds a majority of its shares of common stock through an LLC, a limited liability company of which Dr. Savchuk is the managing member. Dr. Dukes is the Chief Executive Officer of Viriom. Additionally, Dr. C. David Pauza Ph.D., our Chief Science Officer, Virology, was the Chief Science Officer of Viriom until April 1, 2024, after which time he resigned from any position with Viriom, and Dr. Robert R. Redfield, M.D., our Chief Medical Officer, is a strategic advisor and member of its board of directors.

Trawsfynydd entered into that certain Master Research And Development Agreement with ChemDiv, Inc. ("ChemDiv"), dated September 23, 2022, pursuant to which ChemDiv provides services related to preclinical drug discovery to Trawsfynydd. Dr. Savchuk is a stockholder of ChemDiv and a member of its board of directors.

Trawsfynydd also entered into the Securities Purchase Agreement (the "Securities Purchase Agreement") with OrbiMed Private Investments VIII, LP, of which Dr. Dukes is a Venture Partner and is an affiliate of OrbiMed Advisors, and TPAV, LLC, which is managed by Dr. Savchuk and is an affiliate of Torrey Pines. Pursuant to the Securities Purchase Agreement, the Company agreed to issue and sell an aggregate of (i) 496,935 shares of Common Stock and (ii) 1,578.2120 shares of Series C Preferred Stock for an aggregate purchase price of approximately $14 million.

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 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.

2023 Summary Compensation Table

The following table sets forth information for the fiscal years ended December 31, 2023 and 2022 concerning compensation of our principal executive officer and the two most highly compensated executive officers during 2023. We refer to these three executive officers as our "named executive officers."

Name and Principal Position	Year	Salary ($)	Bonus ($)[2]	Stock Awards ($)[3]	Options Awards ($)[4]	All Other Compensation ($)[5]	Total ($)
Steven M. Fruchtman, M.D.[1]	2023	660,288	232,503	50,613	131,662	26,339	1,101,404
President and Chief Executive Officer	2022	630,000	251,769	116,407	302,516	26,090	1,326,782
Mark P. Guerin	2023	500,120	143,853	18,980	50,247	32,318	745,518
Chief Operating Officer and Chief Financial Officer	2022	452,000	144,383	59,619	155,813	32,884	844,699
Victor Moyo, M.D.	2023	103,846	117,135	0	78,616	105,647	405,254
Chief Medical Officer							

(1) Resigned on June 17, 2024.

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

(3) The amounts shown for 2023 represent the aggregate grant date fair value related to the grant of restricted stock units ("RSUs") to our named executive officers in fiscal 2023. The amounts shown for 2022 represent the aggregate grant date fair value related to the grant of performance stock units ("PSUs") and RSUs to our named executive officers in fiscal 2022. 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 PSUs is presented in Note 10 to our Consolidated Financial Statements set forth in our Annual Report on Form 10-K for the year ended December 31, 2023. See the "Outstanding Equity Awards at 2023 Fiscal Year-End" table below for additional details regarding the RSUs that were granted to our named executive officers in fiscal 2023.

(4) The amounts shown for 2023 represent the aggregate grant date fair value related to the grant of non-qualified stock options to our named executive officers in fiscal 2023. The amounts shown for 2022 represent the aggregate grant date fair value related to the grant of stock appreciation rights and non-qualified stock options to our named executive officers in fiscal 2022. 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 appreciation rights and stock options is presented in Note 10 to our Consolidated Financial Statements set forth in our Annual Report on Form 10-K for the year ended December 31, 2023. See the "Outstanding Equity Awards at 2023 Fiscal Year-End" table below for additional details regarding the non-qualified stock options that were granted to our named executive officers in fiscal 2023.

(5) Includes amounts paid for insurance premiums on behalf of the named executive officer and matching funds paid pursuant to our 401(k) Plan. For Victor Moyo, also includes $103,950 of consulting payments prior to his employment.

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. Following are descriptions of the material terms of each named executive officer's employment agreement.

Steven M. Fruchtman, M.D.

We entered into an employment agreement with Dr. Fruchtman on June 19, 2018, which was amended effective March 18, 2021 (the "Fruchtman Employment Agreement"). The Fruchtman Employment Agreement continues indefinitely, unless terminated in accordance with the terms set forth therein.

The Fruchtman Employment Agreement provides for an initial base salary of $510,000, subject to adjustment upon annual review. Subject to the compensation committee's sole discretion, Dr. Fruchtman is eligible for an annual bonus, of up to 50% of such base salary (i.e., target bonus) and an annual option grant, in each case, based on the performance of Dr. Fruchtman 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 compensation committee's discretion.

Dr. Fruchtman is 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 is entitled to up to four weeks of vacation each year. The Fruchtman 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 will reimburse Dr. Fruchtman for reasonable business expenses, including certain travel and cell phone expenses.

If Dr. Fruchtman's employment is terminated for any reason , we will pay to Dr. Fruchtman 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.

If Dr. Fruchtman's employment is terminated by us without "cause" or by Dr. Fruchtman for "good reason," other than during the 12-month period following a change in control of the Company, Dr. Fruchtman will be entitled to receive the sum of (x) his current base salary and (ii) target bonus, payable in installments over 12 months. If the termination is during the 12-month period following a change in control of the Company, Dr. Fruchtman will 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 will also reimburse Dr. Fruchtman for the employer's portion of his medical insurance costs under COBRA for 12 months if Dr. Fruchtman's termination occurs other than during the 12-month period following a change in control of the Company or for 18 months if Dr. Fruchtman's termination occurs during the 12 month-period following a change in control of the Company. In addition, all of Dr. Fruchtman's stock options that are unvested as of the date of such termination will fully vest as of the date of termination and any accrued, approved and unpaid annual bonus for the year prior to the termination date will be paid. As a condition to receive the forgoing severance benefits, Dr. Fruchtman must 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 Fruchtman Employment Agreement.

Dr. Fruchtman resigned from his positions as Director, President and Chief Executive Officer on June 17, 2024.

Mark P. Guerin

We entered into an employment agreement with Mr. Guerin on July 1, 2015, which was amended on June 10, 2022 (the "Guerin Employment Agreement"). The Guerin Employment Agreement continues indefinitely, unless terminated in accordance with the terms set forth therein.

The Guerin Employment Agreement provides for an initial base salary of $475,000. Subject to the compensation committee's sole discretion, Mr. Guerin is eligible for an annual bonus, of up to 25% of such base salary (i.e., target bonus), based on the performance of Mr. Guerin 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 compensation committee's discretion.

Mr. Guerin is 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 is entitled to up to four weeks of vacation each year. The Guerin 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 will also reimburse Mr. Guerin for reasonable business expenses.

If Mr. Guerin's employment is terminated for any reason, we will pay to Mr. Guerin 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.

If Mr. Guerin's employment is terminated by us without "cause" or by Mr. Guerin for "good reason," other than during the 12-month period following a change in control of the Company, Mr. Guerin will be entitled to receive nine-twelfths of the sum of (x) his current base salary and (y) target bonus, payable in installments over nine months. If the termination is during the 12-month period following a change in control of the Company, Mr. Guerin will be entitled to receive the sum of (i) his current base salary and (ii) target bonus, payable in a lump sum. The Company will also reimburse Mr. Guerin for the employer's portion of his medical insurance costs under COBRA for nine months if Mr. Guerin's termination occurs other than during the 12-month period following a change in control of the Company or for 12 months if Mr. Guerin's termination occurs during the 12-month-period following a change in control of the Company. In addition, all of Mr. Guerin's stock options that are unvested as of the date of such termination will fully vest as of the date of termination and any accrued, approved and unpaid annual bonus for the year prior to the termination date will be paid. As a condition to receive the forgoing severance benefits, Mr. Guerin must 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 Guerin Employment Agreement.

Victor Moyo, M.D.

We entered into an employment agreement with Dr. Moyo on October 2, 2023 (the "Moyo Employment Agreement"). The Moyo Employment Agreement continues indefinitely, unless terminated in accordance with the terms of the Moyo Employment Agreement.

The Moyo Employment Agreement provides for an initial base salary of $450,000. Subject to the compensation committee's sole discretion, Dr. Moyo is eligible for an annual bonus, of up to 40% of such base salary (i.e., target bonus). The annual bonus may be paid in the form of cash, stock options, shares of our common stock, or a combination thereof, at our compensation committee's discretion. Additionally, Dr. Moyo received a sign-on bonus of $75,000 to be paid as a forgivable loan and treated as compensation on the date of payment. The sign-on bonus must be repaid if Dr. Moyo voluntarily resigns or is terminated for cause from his position as Chief Medical Officer before October 2, 2024. The Moyo Employment Agreement also provides for a nonqualified stock option to purchase 125,000 shares, which will vest over four years from the grant date.

Dr. Moyo is 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 is entitled to vacation benefits. Dr. Moyo's employment agreement contains non-solicitation, non-competition, confidentiality and inventions assignment provisions that, among other things, prevented him from competing with us during the term of his employment and for a specified time thereafter.

The Moyo Employment Agreement provides that if Dr. Moyo's employment is terminated for any reason, we shall pay to Dr. Moyo 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.

If, following October 2, 2024, Dr. Moyo's employment is terminated by us without "cause" or by Dr. Moyo for "good reason," other than during the 12-month period following a change in control of the Company, Dr. Moyo will be entitled to receive nine-twelfths of the sum of (x) his current base salary and

(y) target bonus, payable in installments over nine months. If the termination is during the 12-month period following a change in control of the Company, Dr. Moyo will be entitled to receive the sum of (i) his current base salary and (ii) target bonus, payable in a lump sum. The Company will also reimburse Dr. Moyo for the employer's portion of his medical insurance costs under COBRA for nine months if Dr. Moyo's termination occurs other than during the 12-month period following a change in control of the Company or for 12 months if Dr. Moyo's termination occurs during the 12-month-period following a change in control of the Company. In addition, all of Dr. Moyo's stock options that are unvested as of the date of such termination will fully vest as of the date of termination and any accrued, approved and unpaid annual bonus for the year prior to the termination date will be paid. As a condition to receive the forgoing severance benefits, Dr. Moyo must 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 Moyo Employment Agreement.

On April 12, 2024, Dr. Moyo entered into a new employment agreement in connection with his new title of Chief Medical Officer- Oncology, which included substantially similar terms to the Moyo Employment Agreement, except that the Dr. Moyo is immediately eligible for the severance benefits specified under the Moyo Employment Agreement, regardless of when Dr. Moyo's employment is terminated by us without "cause" or by Dr. Moyo for "good reason," and he is not required to repay the sign-on bonus in the event of a termination of employment by the Company for "cause" or by Dr. Moyo without "good reason" prior to October 2, 2024.

PAY VERSUS PERFORMANCE

Introduction

The following is a disclosure pursuant to the SEC's new pay versus performance ("PVP") rules. The PVP rules create a new definition of pay, referred to as Compensation Actually Paid ("CAP"), which is compared to certain performance measures as defined by the SEC.

Summary Compensation Table Versus Compensation Actually Paid

The Summary Compensation Table ("SCT") discloses a mix of compensation earned during the year, e.g., base salary and annual cash incentive, and the full grant date fair value of equity awards granted during the year. The new CAP definition of pay adjusts compensation reported for a particular year to reflect an annualized value of compensation by removing the values mandated by the SCT for equity awards granted during the year and instead including the value of equity awards vesting during the year and the potential change in value of unvested equity awards granted in prior years. It is important to note that the executive did not actually earn or receive the amount defined as CAP in the applicable year.

Pay Versus Performance Table

The following table summarizes the SCT compensation and CAP for our principal executive officer ("PEO") and the average for our non-PEO NEOs for 2021, 2022 and 2023. In accordance with the PVP rules, the table also includes certain prescribed performance related measures.

	Summary Compensation Table Total for PEO ($)	Average Summary Compensation Table Total Compensation for Non-PEO NEOs ($)	Compensation Actually Paid to PEO ($)	Average Compensation Actually Paid to Non-PEO NEOs ($)	Value of Initial Fixed $100 Investment Based on Total Shareholder Return ($)	GAAP Net Loss ($)
Fiscal Year						
2023[1]	1,101,404	1,150,762	1,291,201	1,248,452	10.67	(18,948,000)
2022[2]	1,326,782	761,169	1,143,688	750,769	9.36	(18,964,000)
2021[3]	2,674,213	1,196,406	1,227,645	994,136	36.17	(16,163,000)

(1) The PEO for 2023 is Steven M. Fruchtman, M.D. Non-PEO NEOs for 2023 are Mark P. Guerin and Victor Moyo.

(2) The PEO for 2022 is Steven M. Fruchtman, M.D. Non-PEO NEOs for 2022 are Mark P. Guerin and Mark S. Gelder.

(3) The PEO for 2021 is Steven M. Fruchtman, M.D. Non-PEO NEOs for 2021 are Mark P. Guerin and Abraham N. Oler.

The following table provides additional information on how CAP for each reporting year was determined, starting with SCT compensation, and applying each of the required adjustments, as applicable, in accordance with the PVP rules.

	Summary Compensation Table Total Compensation ($)	Value of Equity Awards Deducted from SCT ($)	Fair Value of Equity Awards Compensation Granted in Current Year ($)[1]	Year-Over-Year Change in Fair Value of Unvested Equity Awards ($)[2]	Year-Over-Year Change in Fair Value of Equity Awards Vested During the Year ($)[3]	Compensation Actually Paid ($)
PEO						
2023	1,101,404	182,275	185,333	14,611	172,127	1,473,476
2022	1,326,782	418,923	375,187	(122,993)	(16,365)	1,143,688
2021	2,674,213	1,770,764	344,222	(18,303)	(1,723)	1,227,645

	Summary Compensation Table Total Compensation ($)	Value of Equity Awards Deducted from SCT ($)	Fair Value of Equity Awards Compensation Granted in Current Year ($)[1]	Year-Over-Year Change in Fair Value of Unvested Equity Awards ($)[2]	Year-Over-Year Change in Fair Value of Equity Awards Vested During the Year ($)[3]	Compensation Actually Paid ($)
Average Non- PEO NEOs						
2023	1,150,762	147,843	151,952	8,337	85,244	1,493,985
2022	761,169	82,218	127,741	(51,566)	(4,357)	750,769
2021	1,196,406	321,199	126,043	(6,282)	(832)	994,136

(1) These amounts represent the fair value as of the indicated fiscal year-end of the outstanding and unvested equity awards granted during such fiscal year, calculated in accordance with the methodology used for financial reporting purposes. The fair value differs from the value in the SCT because for purposes of CAP the fair value for equity awards granted in the current year is determined as of the last day of the applicable year. Fair values in the SCT are determined as of the grant date.

(2) These amounts represent the change in fair value during the indicated fiscal year of each equity award that was granted in a prior fiscal year and that remained outstanding and unvested as of the last day of the indicated fiscal year, calculated in accordance with the methodology used for financial reporting purposes and, for awards subject to performance-based vesting conditions, based on an estimate of the probable outcome of such performance-based vesting conditions as of the last day of the fiscal year.

(3) These amounts represent the change in fair value, measured from the prior fiscal year-end to the vesting date, of each equity award that was granted in a prior fiscal year and which vested during the indicated fiscal year, calculated in accordance with the methodology used for financial reporting purposes.

Analysis of Information Presented in the Pay versus Performance Table

The Company's executive compensation program reflects a variable pay-for-performance philosophy. While the Company utilizes several performance measures to align executive compensation with Company performance, all of those Company measures are not presented in the PVP table. Moreover, the Company generally seeks to incentivize long-term performance, and therefore does not specifically align the Company's performance measures with CAP (as computed in accordance with SEC rules) for a particular year. In accordance with SEC rules, the Company is providing the following narrative disclosure regarding the relationships between information presented in the PVP table.

Relationship between CAP and TSR

During fiscal 2021, 2022 and 2023, compensation actually paid to our PEO decreased from $1,227,645 in fiscal 2021 to $1,143,688 in fiscal 2022, and increased from fiscal 2022 to $1,473,476 in fiscal 2023. Average compensation actually paid to our Non-PEO NEOs decreased from $994,136 in fiscal 2021 to $750,769 in fiscal 2022, and increased from fiscal 2022 to $1,493,985 in fiscal 2023. Over the same period, the value of an investment of $100 in our common stock on the last trading day of 2021 decreased from $36.17 in 2021 to $9.36 during fiscal 2022, and increased to $10.67 during fiscal 2023, for a total decrease over fiscal 2021, 2022 and 2023 of $25.50.

Relationship between CAP and Net Loss (GAAP)

During fiscal 2021, 2022 and 2023, compensation actually paid to our PEO decreased from $1,227,645 in fiscal 2021 to $1,143,688 in fiscal 2022, and increased from fiscal 2022 to $1,473,476 in fiscal 2023. Average compensation actually paid to our Non-PEO NEOs decreased from $994,136 in fiscal 2021 to $750,769 in fiscal 2022, and increased from fiscal 2022 to $1,493,985 in fiscal 2023. Our net loss decreased by $8,994,000 during fiscal 2021 (from a net loss in fiscal 2020 of $25,157,000 to a net loss in fiscal 2021 of $16,163,000), increased by $2,801,000 during fiscal 2022 (from a net loss in fiscal 2021 of $16,163,000 to a net loss in fiscal 2022 of $18,964,000), and decreased by $16,000 during fiscal 2023 (from a net loss in fiscal 2022 of $18,964,000 to a net loss in fiscal 2023 of $18,948,000).Stock Option and Other Compensation Plans

We maintain the Traws Pharma, Inc. 2021 Incentive Compensation Plan (the "Amended Plan") for the purpose of attracting key employees, directors and consultants, inducing them to remain with us and encouraging them to increase their efforts to make our business more successful. The Amended Plan provides for awards of stock options, stock appreciation rights, restricted stock, RSUs and other equity-based awards.

The following table contains certain information regarding equity awards held by the named executive officers as of December 31, 2023

Outstanding Equity Awards at 2023 Fiscal Year-End

	Option Awards				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 ($)**
Fruchtman[1]	53	—	9,832.50	1/12/2025				
	15	—	5,580.00	4/20/2025				
	17	—	3,330.00	9/25/2025				
	13	—	1,462.50	1/26/2026				
	41	—	1,462.50	1/26/2026				
	111	—	729.00	9/1/2026				
	33	—	596.25	12/15/2026				
	117	—	607.50	1/17/2027				
	193	—	337.50	1/3/2028				
	1,777	—	103.50	7/26/2028				
	13,333	—	4.65	12/20/2029				
	84,920[3]	—		7/9/2030				
	44,242[3]	2,824		2/17/2031				
	87,888[2]	25,112	5.19	8/2/2031				
	117,260[2]	76,620	1.82	2/7/2032				
	—[2]	207,000	0.73	3/13/2033	12,567[4]	9,370		
					42,640[4]	31,792		
					69,333[4]	51,695	47,065[5]	35,299
Guerin	5	—	14,750.00	3/31/2024				
	5	—	14,750.00	3/31/2024				
	11	—	8,955.00	12/18/2024				
	6	—	5,220.00	4/16/2025				
	7	—	3,330.00	9/25/2025				
	5	—	1,462.50	1/26/2026				
	15	—	1,462.50	1/26/2026				
	44	—	729.00	9/1/2026				
	22	—	729.00	9/1/2026				
	24	—	596.25	12/15/2026				
	86	—	607.50	1/17/2027				
	137	—	337.50	1/3/2028				

Name	Option Awards				Stock Awards			
	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 ($)
	1,710	—	103.50	7/26/2028				
	4,333	—	4.65	12/20/2029				
	36,200[3]	—		7/9/2030				
	12,268[3]	7,798		2/17/2031				
	33,246[2]	9,504	5.19	8/2/2031				
	37,950[2]	24,150	1.82	2/7/2032				
	25,122[2]	25,128	1.33	6/10/2032				
	—[2]	79,000	0.73	3/13/2033				
					4,750[4]	3,542		
					13,800[4]	10,289		
					11,000[4]	8,201		
					26,000[4]	19,385		
							20,065[5]	15,049
Moyo	—	125,000[6]	0.71	10/2/2033				

(1) Resigned on June 17, 2024.

(2) Shares vest over three years, one-third on the first anniversary of the date of grant and thereafter in 24 equal monthly installments over the following two years.

(3) These are cash-settled stock appreciation rights that vest over three years, one-third on the first anniversary of the date of grant and thereafter in 24 equal monthly installments over the following two years.

(4) These are RSUs that vest over three years from the date of grant: 33% on the first anniversary; 33% on the second anniversary; and 34% on the third anniversary.

(5) These are PSUs that will be earned and vested upon the Company's attainment of certain performance goals, subject to the executive's continued employment with the Company through each vesting date, as follows: (i) 20% of PSUs will vest upon the attainment of a new clinical program for the Company for an in-licensed compound, (ii) 20% of PSUs will vest upon obtaining the recommended phase 2 dose for a Company compound, (iii) 20% of PSUs will vest upon the first patient being enrolled in the ON 123300 (narazaciclib) expansion cohort, (iv) 20% of PSUs will vest upon the first patient enrolled in a registrational study and (v) 20% of the PSUs will vest upon attainment of registrational study topline data. The goals must be attained prior to the following expiration date ("Expiration Date"): for the goals under (i), (ii) and (iii), December 31, 2022, for the goal under (iv), December 31, 2025, and for the goal under (v), June 30, 2028. In the event a performance goal is achieved prior to February 17, 2022, the vesting date for the portion of the PSUs that will vest based on the achievement of the applicable performance goal would be February 17, 2022. The PSUs will be settled in cash and are in all cases subject to the terms and conditions of the Company form of Performance Stock Unit Award Agreement. Pursuant to the terms of the PSU awards, the maximum cash amount payable to each officer with respect to each vested PSU subject to the officer's PSU award cannot exceed maximum price per share of $38.10, subject to adjustment in accordance with the terms of the Performance Stock Unit Award Agreement. If a performance goal is not achieved on or before its corresponding Expiration Date, then all of the PSUs subject to such performance goal will be automatically forfeited as of such

date. None of the goals under (i), (ii) and (iii) were attained as of December 31, 2022. The goals under (iv) and (v) have not been attained as of December 31, 2023.

(6) Shares vest over four years, 25% on the first anniversary of the date of grant and thereafter in 36 equal monthly installments over the following three years.

Potential Payments Upon Termination of Employment or Change in Control

As discussed under the caption "— 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, 2023 or (ii) if a Change in Control, as defined in the applicable employment agreement or plan, occurred on December 31, 2023 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 2018 Omnibus Incentive Compensation Plan, as previously amended (the "2018 Plan"), applicable award agreements reflecting options and RSUs granted under the Onconova Therapeutics, Inc. 2021 Incentive Compensation Plan (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).

Equity Compensation Plan Information

The following table summarizes the total number of outstanding awards and shares available for other future issuances of options under all of our equity compensation plans as of December 31, 2023. All of the outstanding awards listed below were granted under our 2013 Equity Compensation Plan, 2018 Plan and the 2021 Plan.

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	2,311,011	3.04	942,848
Equity compensation plans not approved by stockholders . .	—	—	—

OTHER MATTERS

Other Business

As of the date of this Proxy Statement, our Board of Directors knows of no business to be presented at the Annual Meeting other than as set forth herein. If other matters properly come before the Meeting, the persons named as proxies will vote on such matters in their discretion.

Stockholder Proposals for 2025 Annual Meeting of Stockholders

In order for a stockholder proposal, including a director nomination, to be considered for inclusion in our proxy statement for the 2025 Annual Meeting of Stockholders, the written proposal must be received at our principal executive offices on or before June 12, 2025. The proposal should be addressed to Secretary, Traws Pharma, Inc., 12 Penns Trail, Newtown PA 18940. The proposal must comply with SEC regulations regarding the inclusion of stockholder proposals in company-sponsored proxy materials.

In accordance with Section 2.2 of our bylaws, a stockholder who wishes to present a proposal for consideration at the 2025 Annual Meeting of Stockholders must deliver a notice of the matter the stockholder wishes to present to our principal executive offices in Newtown, PA, at the address identified in the preceding paragraph, not less than 90 nor more than 120 days prior to the first anniversary of the date of the Annual Meeting. Accordingly, any notice given by or on behalf of a stockholder pursuant to these provisions of our bylaws (and not pursuant to Rule 14a-8 of the SEC) must be received no earlier than July 3, 2025 and no later than August 2, 2025 (except that in the event that the date of the 2025 Annual Meeting of Stockholders is advanced by more than 30 days, or delayed by more than 60 days, from the first anniversary of the meeting of stockholders, a stockholder's notice must be so received no earlier than the 120th day prior to the 2024 Annual Meeting of Stockholders and not later than the close of business on the later of (A) the 90th day prior to the 2025 Annual Meeting of Stockholders or (B) the tenth day following the day on which public disclosure of the date of the 2025 Annual Meeting of Stockholders was made).

The notice should include a brief description of the business desired to be brought before the 2025 Annual Meeting of Stockholders, the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend these bylaws, the language of the proposed amendment), the reasons for conducting such business at the meeting and any material interest in such business of such stockholder and the beneficial owner, if any, on whose behalf the proposal is made, and any other information concerning such matter that must be disclosed in proxy solicitations pursuant to Regulation 14A under the Exchange Act, as if the matter had been proposed, or intended to be proposed, by the Board of Directors. As to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made, the notice should include the information required by Section 2.2(A)(3)(c) of our bylaws.

Annual Report

Our 2023 Annual Report on Form 10-K is concurrently being mailed to stockholders. The Annual Report contains our consolidated financial statements and the report thereon of Ernst & Young LLP, independent registered public accounting firm. Stockholders may obtain an additional copy of our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2023, without charge, by writing to Traws Pharma, Inc., 12 Penns Trail, Newtown, PA 18940.

Householding of Annual Meeting Materials

Certain banks, brokers, broker-dealers and other similar organizations acting as nominee record holders may be participating in the practice of "householding" proxy statements and annual reports. This means that only one copy of this Proxy Statement and our Annual Report on Form 10-K may have been sent to multiple stockholders in your household. If you would prefer to receive separate copies of a proxy statement or Annual Report on Form 10-K for other stockholders in your household, either now or in the future, please contact your bank, broker, broker-dealer or other similar organization serving as your nominee. Upon written or oral request to our Secretary at Traws Pharma, Inc., 12 Penns Trail, Newtown PA 18940, or via telephone to our Corporate Secretary at 267-759-3680, we will promptly provide separate copies of our

Annual Report on Form 10-K and/or this Proxy Statement. Stockholders sharing an address who are receiving multiple copies of this Proxy Statement and/or Annual Report on Form 10-K and who wish to receive a single copy of these materials in the future will need to contact their bank, broker, broker-dealer or other similar organization serving as their nominee to request that only a single copy of each document be mailed to all stockholders at the shared address in the future.

BY ORDER OF THE BOARD OF DIRECTORS

/s/ Werner Cautreels, Ph.D.

Werner Cautreels, Ph.D.
Chief Executive Officer

Dated: October 10, 2024

IT IS IMPORTANT THAT PROXIES BE RETURNED PROMPTLY. THEREFORE, STOCKHOLDERS ARE URGED TO COMPLETE, SIGN, DATE AND RETURN THE ACCOMPANYING FORM OF PROXY IN THE ENCLOSED ENVELOPE.

Appendix A

ONCONOVA THERAPEUTICS, INC.

2021 INCENTIVE COMPENSATION PLAN

(As amended and restated, effective on the Restatement Effective Date)

TRAWS PHARMA, INC.

2021 INCENTIVE COMPENSATION PLAN

(As amended and restated, effective on the Restatement Effective Date)

The purpose of the Traws Pharma, Inc. 2021 Incentive Compensation Plan (the "Plan") is to provide employees of Traws Pharma, Inc. (fka Onconova Therapeutics, Inc.) (the "Company") and its subsidiaries, certain consultants and advisors who perform services for the Company or its subsidiaries, and non-employee members of the Board of Directors of the Company with the opportunity to receive grants of incentive stock options, nonqualified stock options, stock appreciation rights, stock awards, stock units and other stock-based awards.

The Plan was originally effective as of the Original Effective Date, was amended and restated upon approval of the stockholders on July 21, 2022 and is hereby amended and restated effective as of the Restatement Effective Date. The Plan is a successor to the Onconova Therapeutics, Inc. 2018 Omnibus Incentive Compensation Plan, as amended and restated (the "2018 Plan"), which was a successor to the Onconova Therapeutics, Inc. 2013 Equity Incentive Plan (together with the 2018 Plan, the "Prior Plans"). No additional grants have been or will be made under the 2018 Plan on and after the Original Effective Date. Outstanding grants under the Prior Plans shall continue in effect according to their terms, and the shares with respect to outstanding grants under the applicable Prior Plan shall be issued or transferred under the applicable Prior Plan.

The Company believes that the Plan will encourage the participants to contribute materially to the growth of the Company, thereby benefitting the Company's stockholders, and will align the economic interests of the participants with those of the stockholders.

Section 1. Definitions

The following terms shall have the meanings set forth below for purposes of the Plan:

(a) "2018 Plan" shall have the meaning given to it in the preamble.

(b) "Award" shall mean an Option, SAR, Stock Award, Stock Unit or Other Stock-Based Award granted under the Plan.

(c) "Award Agreement" shall mean the written agreement that sets forth the terms and conditions of an Award, including all amendments thereto.

(d) "Board" shall mean the Board of Directors of the Company.

(e) "Cause" shall have the meaning given to that term in any written employment agreement, offer letter, consulting agreement or severance agreement between the Employer and the Participant, or if no such agreement exists or if such term is not defined therein, and unless otherwise defined in the Award Agreement, "Cause" shall mean a finding by the Committee of conduct involving one or more of the following: (i) the substantial and continuing failure of the Participant, after notice thereof, to render services to the Company or its subsidiaries in accordance with the terms or requirements of his or her employment, engagement as a Non-Employee Director or a Key Advisor; (ii) disloyalty, gross negligence, willful misconduct, dishonesty or breach of fiduciary duty to the Company or a Subsidiary; (iii) the commission of an act of embezzlement or fraud; (iv) deliberate disregard of the rules or policies of the Company or a Subsidiary which results in direct or indirect loss, damage or injury to the Company or a Subsidiary; (v) the unauthorized disclosure of any trade secret or confidential information of the Company or a Subsidiary; or (vi) the Participant's breach of any written non-competition, non-solicitation, invention assignment or confidentiality agreement between the Participant and the Company or any of its subsidiaries.

(f) "CEO" shall mean the Chief Executive Officer of the Company.

(g) A "Change in Control" shall be deemed to have occurred if:

(i) the acquisition, directly or indirectly, by a "person" (within the meaning of Section 13(d)(3) of the Exchange Act) (a "Person") of beneficial ownership (within the meaning of Rule 13d-3

promulgated under the Exchange Act) of more than 50% of the combined voting power of the voting securities of the Company entitled to vote generally in the election of directors (the "Voting Securities"); provided, however, that the following acquisitions of Voting Securities shall not constitute a Change in Control: (A) any acquisition by or from the Company or any of its subsidiaries, or by any employee benefit plan (or related trust) sponsored or maintained by the Company or any of its subsidiaries, (B) any acquisition by any underwriter in any firm commitment underwriting of securities to be issued by the Company, or (C) any acquisition by any corporation (or other entity) if, immediately following such acquisition, 50% or more of the then outstanding shares of common stock (or other equity unit) of such corporation (or other entity) and the combined voting power of the then outstanding voting securities of such corporation (or other entity), are beneficially owned, directly or indirectly, by all or substantially all of the individuals or entities who, immediately prior to such acquisition, were the beneficial owners of the then outstanding shares of Common Stock and the Voting Securities in substantially the same proportions, respectively, as their ownership immediately prior to the acquisition of the shares of Common Stock and Voting Securities; or

(ii) the consummation of the sale or other disposition of all or substantially all of the assets of the Company, other than to a wholly-owned subsidiary of the Company or to a holding company of which the Company is a direct or indirect wholly owned subsidiary prior to such transaction; or

(iii) the consummation of a reorganization, merger or consolidation of the Company, other than a reorganization, merger or consolidation, which would result in the Voting Securities outstanding immediately prior to the transaction continuing to represent (whether by remaining outstanding or by being converted to voting securities of the surviving entity) 65% or more of the Voting Securities or the voting power of the voting securities of such surviving entity outstanding immediately after such transaction; or

(iv) the consummation of a plan of complete liquidation of the Company; or

(v) the following individuals cease for any reason to constitute a majority of the Board: individuals who, as of the Restatement Effective Date, constitute the Board and any new director (other than a director whose initial assumption of office is in connection with an actual or threatened election contest, including, but not limited to, a consent solicitation relating to the election of directors of the Company) whose appointment or election by the Board or nomination for election by the Company's stockholders was approved and recommended by a vote of at least two-thirds of the directors then still in office who either were directors on the Restatement Effective Date or whose appointment, election or nomination for election was previously so approved or recommended.

Notwithstanding the foregoing, if an Award constitutes deferred compensation subject to section 409A of the Code and the Award provides for payment upon a Change in Control, then, for purposes of such payment provisions, no Change in Control shall be deemed to have occurred upon an event described in items (i) – (v) above unless the event would also constitute a change in ownership or effective control of, or a change in the ownership of a substantial portion of the assets of, the Company under section 409A of the Code.

(h) "Code" shall mean the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

(i) "Committee" shall mean the Compensation Committee of the Board or another committee appointed by the Board to administer the Plan. The Committee shall also consist of directors who are "non-employee directors" as defined under Rule 16b-3 promulgated under the Exchange Act and "independent directors," as determined in accordance with the independence standards established by the stock exchange on which the Common Stock is at the time primarily traded.

(j) "Common Stock" shall mean common stock of the Company.

(k) "Company" shall mean Traws Pharma, Inc. (as defined in the preamble) and shall include its successors.

(l) "Disability" or "Disabled" shall mean, unless otherwise set forth in the Award Agreement, a Participant's becoming disabled within the meaning of the Employer's long-term disability plan applicable to the Participant, or, if there is no such plan, a physical or mental condition that prevents the Participant from performing the essential functions of the Participant's position (with or without reasonable accommodation) for a period of six consecutive months.

(m) "Dividend Equivalent" shall mean an amount determined by multiplying the number of shares of Common Stock subject to a Stock Unit or Other Stock-Based Award by the per-share cash dividend paid by the Company on its outstanding Common Stock, or the per-share Fair Market Value of any dividend paid on its outstanding Common Stock in consideration other than cash. If interest is credited on accumulated divided equivalents, the term "Dividend Equivalent" shall include the accrued interest.

(n) "Employee" shall mean an employee of the Employer (including an officer or director who is also an employee), but excluding any person who is classified by the Employer as a "contractor" or "consultant," no matter how characterized by the Internal Revenue Service, other governmental agency or a court. Any change of characterization of an individual by the Internal Revenue Service or any court or government agency shall have no effect upon the classification of an individual as an Employee for purposes of this Plan, unless the Committee determines otherwise.

(o) "Employed by, or providing service to, the Employer" shall mean employment or service as an Employee, Key Advisor or member of the Board (so that, for purposes of exercising Options and SARs and satisfying conditions with respect to Stock Awards, Stock Units and Other Stock-Based Awards, a Participant shall not be considered to have terminated employment or service until the Participant ceases to be an Employee, Key Advisor and member of the Board), unless the Committee determines otherwise. If a Participant's relationship is with a subsidiary of the Company and that entity ceases to be a subsidiary of the Company, the Participant will be deemed to cease employment or service when the entity ceases to be a subsidiary of the Company, unless the Participant transfers employment or service to an Employer.

(p) "Employer" shall mean the Company and its subsidiaries.

(q) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.

(r) "Exercise Price" shall mean the per share price at which shares of Common Stock may be purchased under an Option, as designated by the Committee.

(s) "Fair Market Value" shall mean:

(i) If the Common Stock is publicly traded, the Fair Market Value per share shall be determined as follows: (A) if the principal trading market for the Common Stock is a national securities exchange, the closing sales price during regular trading hours on the relevant date or, if there were no trades on that date, the latest preceding date upon which a sale was reported, or (B) if the Common Stock is not principally traded on any such exchange, the last reported sale price of a share of Common Stock during regular trading hours on the relevant date, as reported by the OTC Bulletin Board.

(ii) If the Common Stock is not publicly traded or, if publicly traded, is not subject to reported transactions as set forth above, the Fair Market Value per share shall be determined by the Committee through any reasonable valuation method authorized under the Code.

(t) "Incentive Stock Option" shall mean an Option that is intended to meet the requirements of an incentive stock option under section 422 of the Code.

(u) "Key Advisor" shall mean a consultant or advisor of the Employer.

(v) "Non-Employee Director" shall mean a member of the Board who is not an Employee.

(w) "Nonqualified Stock Option" shall mean an Option that is not intended to be taxed as an incentive stock option under section 422 of the Code.

(x) "Option" shall mean an option to purchase shares of Common Stock, as described in Section 6.

(y) "Original Effective Date" shall mean July 30, 2021.

(z) "Other Stock-Based Award" shall mean any Award based on, measured by or payable in Common Stock (other than an Option, Stock Unit, Stock Award, or SAR), as described in Section 10.

(aa) "Participant" shall mean an Employee, Key Advisor or Non-Employee Director designated by the Committee to participate in the Plan.

(bb) "Performance Objectives" shall mean the performance objectives established in the sole discretion of the Committee for Participants who are eligible to receive Awards under the Plan. Performance Objectives may be described in terms of Company-wide objectives or objectives that are related to the performance of the individual Participant or the subsidiary, division, department or function within the Company or one of its subsidiaries in which the Participant is employed. Performance Objectives may be measured on an absolute or relative basis. Relative performance may be measured by a group of peer companies or by a financial market index. Any Performance Objectives may include: specified levels of or increases in the Company's, a division's or a subsidiary's return on capital, equity or assets; earnings measures/ratios (on a gross, net, pre-tax or post-tax basis), including basic earnings per share, diluted earnings per share, total earnings, operating earnings, earnings growth, earnings before interest and taxes and earnings before interest, taxes, depreciation and amortization; net economic profit (which is operating earnings minus a charge to capital); net income; operating income; sales; sales growth; gross margin; direct margin; costs; stock price (including but not limited to growth measures and total stockholder return); operating profit; per period or cumulative cash flow (including but not limited to operating cash flow and free cash flow) or cash flow return on investment (which equals net cash flow divided by total capital); inventory turns; financial return ratios; market share; balance sheet measurements such as receivable turnover; improvement in or attainment of expense levels; improvement in or attainment of working capital levels; debt reduction; strategic innovation; customer or employee satisfaction; the consummation of one or more acquisitions of a certain size as measured by one or more of the financial criteria listed above; individual objectives; regulatory body approval for commercialization of a product; implementation or completion of critical projects (including, but not limited to, milestones such as clinical trial enrollment targets, commencement of phases of clinical trials and completion of phases of clinical trials); and any combination of the foregoing.

(cc) "Plan" shall mean this Traws Pharma, Inc. 2021 Incentive Compensation Plan, as amended and restated as of the Restatement Effective Date and as may be in effect from time to time.

(dd) "Prior Plans" shall have the meaning given to the term in the preamble.

(ee) "Restatement Effective Date" shall mean October 31, 2024 or such later date that stockholder approval of the Plan as herein amended and restated is received.

(ff) "Restriction Period" shall have the meaning given that term in Section 7(a).

(gg) "SAR" shall mean a stock appreciation right, as described in Section 9.

(hh) "Stock Award" shall mean an award of Common Stock, as described in Section 7.

(ii) "Stock Unit" shall mean an award of a phantom unit representing a share of Common Stock, as described in Section 8.

(jj) "Substitute Awards" shall have the meaning given that term in Section 4(c).

Section 2. Administration

(a) Committee. The Plan shall be administered and interpreted by the Committee. The Committee may delegate authority to one or more subcommittees, as it deems appropriate. Subject to

compliance with applicable law and the applicable stock exchange rules, the Board, in its discretion, may perform any action of the Committee hereunder. To the extent that the Board, the Committee, a subcommittee or the CEO, as described below, administers the Plan, references in the Plan to the "Committee" shall be deemed to refer to the Board, the Committee or such subcommittee or the CEO.

(b) Delegation to CEO. Subject to compliance with applicable law and applicable stock exchange requirements, the Committee may delegate all or part of its authority and power to the CEO, as it deems appropriate, with respect to Awards to Employees or Key Advisors who are not executive officers or directors under section 16 of the Exchange Act.

(c) Committee Authority. The Committee shall have the sole authority to (i) determine the individuals to whom Awards shall be made under the Plan, (ii) determine the type, size, terms and conditions of the Awards to be made to each such individual, (iii) determine the time when the Awards will be made and the duration of any applicable exercise or restriction period, including the criteria for exercisability and the acceleration of exercisability, (v) amend the terms of any previously issued Award, subject to the provisions of Section 17 below, and (vi) deal with any other matters arising under the Plan.

(d) Committee Determinations. The Committee shall have full power and express discretionary authority to administer and interpret the Plan, to make factual determinations and to adopt or amend such rules, regulations, agreements and instruments for implementing the Plan and for the conduct of its business as it deems necessary or advisable, in its sole discretion. The Committee's interpretations of the Plan and all determinations made by the Committee pursuant to the powers vested in it hereunder shall be conclusive and binding on all persons having any interest in the Plan or in any awards granted hereunder. All powers of the Committee shall be executed in its sole discretion, in the best interest of the Company, not as a fiduciary, and in keeping with the objectives of the Plan and need not be uniform as to similarly situated individuals.

(e) Indemnification. No member of the Committee or the Board, and no employee of the Company shall be liable for any act or failure to act with respect to the Plan, except in circumstances involving his or her bad faith or willful misconduct, or for any act or failure to act hereunder by any other member of the Committee or employee or by any agent to whom duties in connection with the administration of this Plan have been delegated. The Company shall indemnify members of the Committee and the Board and any agent of the Committee or the Board who is an employee of the Company or a subsidiary against any and all liabilities or expenses to which they may be subjected by reason of any act or failure to act with respect to their duties on behalf of the Plan, except in circumstances involving such person's bad faith or willful misconduct.

Section 3. Awards

(a) General. Awards under the Plan may consist of Options as described in Section 6, Stock Awards as described in Section 7, Stock Units as described in Section 8, SARs as described in Section 9 and Other Stock-Based Awards as described in Section 10. All Awards shall be subject to the terms and conditions set forth herein and to such other terms and conditions consistent with this Plan as the Committee deems appropriate and as are specified in writing by the Committee to the individual in the Award Agreement. All Awards shall be made conditional upon the Participant's acknowledgement, in writing or by acceptance of the Award, that all decisions and determinations of the Committee shall be final and binding on the Participant, his or her beneficiaries and any other person having or claiming an interest under such Award. Awards under a particular Section of the Plan need not be uniform as among the Participants. Notwithstanding anything to the contrary herein, any dividends or Dividend Equivalents granted in connection with Awards under the Plan shall vest and be paid only if and to the extent the underlying Awards vest and are paid.

(b) Minimum Vesting. Awards granted under the Plan shall include regular vesting schedules that provide that no portion of an Award will vest earlier than one year from the date of grant. However, subject to adjustments made in accordance with Section 4(e) below, up to five percent (5%) of the shares of Common Stock subject to the aggregate share reserve set forth in Section 4(a) as of the Restatement Effective Date may be granted without regard to this minimum vesting requirement.

Section 4. Shares Subject to the Plan

(a) Shares Authorized. Subject to adjustment as described below in Sections 4(b) and 4(e), the maximum aggregate number of shares of Common Stock that may be issued or transferred under the Plan with respect to Awards made under the Plan on and after the Restatement Effective Date shall be 300,000 shares of Common Stock. In addition, any shares of Common Stock that remained available for Awards under the Plan as of the Restatement Effective Date and any shares of Common Stock subject to outstanding Awards granted under the Plan and awards granted under the Prior Plans as of the Restatement Effective Date that are payable in shares and that terminate, expire, or are cancelled, forfeited, exchanged or surrendered without having been exercised, vested or paid in shares, on or after the Restatement Effective Date, subject to adjustment as provided in Section 3(e) below, may be issued with respect to Awards under this Plan. The aggregate number of shares of Common Stock that may be issued or transferred under the Plan pursuant to Incentive Stock Options granted on and after the Restatement Effective Date shall not exceed 300,000 shares of Common Stock.

(b) Source of Shares; Share Counting. Shares issued or transferred under the Plan may be authorized but unissued shares of Common Stock or reacquired shares of Common Stock, including shares purchased by the Company on the open market for purposes of the Plan. If and to the extent Options or SARs granted under the Plan or options granted under the Prior Plans terminate, expire or are canceled, forfeited, exchanged or surrendered without having been exercised, or if any Stock Awards, Stock Units, or Other Stock-Based Awards are forfeited, terminated or otherwise not paid in full, the shares subject to such Awards shall again be available for purposes of the Plan. Shares surrendered in payment of the Exercise Price of an Option (including an option granted under the Prior Plans that is exercised on or after the Original Effective Date) shall not be available for re-issuance under the Plan. Shares of Common Stock withheld or surrendered for payment of taxes with respect to Awards (including options granted under the Prior Plans) shall not be available for re-issuance under the Plan. If SARs are granted, the full number of shares subject to the SARs shall be considered issued under the Plan, without regard to the number of shares issued upon exercise of the SARs. To the extent any Awards are paid in cash, and not in shares of Common Stock, any shares previously subject to such Awards shall again be available for issuance or transfer under the Plan. For the avoidance of doubt, if shares are repurchased by the Company on the open market with the proceeds of the Exercise Price of Options (including options granted under the Prior Plans), such shares may not again be made available for issuance under the Plan

(c) Substitute Awards. Shares issued or transferred under Awards made pursuant to an assumption, substitution or exchange for previously granted awards of a company acquired by the Company in a transaction ("Substitute Awards") shall not reduce the number of shares of Common Stock available under the Plan and available shares under a stockholder approved plan of an acquired company (as appropriately adjusted to reflect the transaction) may be used for Awards under the Plan and shall not reduce the Plan's share reserve (subject to applicable stock exchange listing and Code requirements).

(d) Individual Non-Employee Director Limit. Subject to adjustment as described below in Section 4(e), the maximum aggregate grant date value of shares of Common Stock subject to Awards granted to any Non-Employee Director during any calendar year for services rendered as a Non-Employee Director, taken together with any cash fees earned by such Non-Employee Director for services rendered as a Non-Employee Director during the calendar year, shall not exceed $300,000 in total value. For purposes of the limits set forth in this Section 4(d), the value of such Awards shall be calculated based on the grant date fair value of such Awards for financial reporting purposes.

(e) Adjustments. If there is any change in the number or kind of shares of Common Stock outstanding by reason of (i) a stock dividend, spinoff, recapitalization, stock split, reverse stock split or combination or exchange of shares, (ii) a merger, reorganization or consolidation, (iii) a reclassification or change in par value, or (iv) any other unusual or infrequently occurring event affecting the outstanding Common Stock as a class without the Company's receipt of consideration, or if the value of outstanding shares of Common Stock is substantially reduced as a result of a spinoff or the Company's payment of an extraordinary dividend or distribution, the maximum number and kind of shares of Common Stock available for issuance under the Plan, the maximum number and kind of shares of

Common Stock for which any individual may receive Awards in any year, the kind and number of shares covered by outstanding Awards, the kind and number of shares issued and to be issued under the Plan, and the price per share or the applicable market value of such Awards shall be equitably adjusted by the Committee to reflect any increase or decrease in the number of, or change in the kind or value of, the issued shares of Common Stock to preclude, to the extent practicable, the enlargement or dilution of rights and benefits under the Plan and such outstanding Awards; provided, however, that any fractional shares resulting from such adjustment shall be eliminated. In addition, in the event of a Change in Control, the provisions of Section 12 of the Plan shall apply. Any adjustments to outstanding Awards shall be consistent with section 409A or 424 of the Code, to the extent applicable. Subject to Section 17(b) below, the adjustments of Awards under this Section 4(e) shall include adjustment of shares, Exercise Price of Options, base amount of SARs, Performance Objectives or other terms and conditions, as the Committee deems appropriate. The Committee shall have the sole discretion and authority to determine what appropriate adjustments shall be made and any adjustments determined by the Committee shall be final, binding and conclusive.

Section 5. Eligibility for Participation

(a) Eligible Persons. All Employees and Non-Employee Directors shall be eligible to participate in the Plan. Key Advisors shall be eligible to participate in the Plan if the Key Advisors render bona fide services to the Employer, the services are not in connection with the offer and sale of securities in a capital-raising transaction and the Key Advisors do not directly or indirectly promote or maintain a market for the Company's securities.

(b) Selection of Participants. The Committee shall select the Employees, Non-Employee Directors and Key Advisors to receive Awards and shall determine the number of shares of Common Stock subject to a particular Award in such manner as the Committee determines.

Section 6. Options

The Committee may grant Options to an Employee, Non-Employee Director or Key Advisor upon such terms as the Committee deems appropriate. The following provisions are applicable to Options:

(a) Number of Shares. The Committee shall determine the number of shares of Common Stock that will be subject to each Award of Options to Employees, Non-Employee Directors and Key Advisors.

(b) Type of Option and Exercise Price.

(i) The Committee may grant Incentive Stock Options or Nonqualified Stock Options or any combination of the two, all in accordance with the terms and conditions set forth herein. Incentive Stock Options may be granted only to employees of the Company or its parent or subsidiary corporations, as defined in section 424 of the Code. Nonqualified Stock Options may be granted to Employees, Non-Employee Directors and Key Advisors.

(ii) The Exercise Price of Common Stock subject to an Option shall be determined by the Committee and shall be equal to or greater than the Fair Market Value of a share of Common Stock on the date the Option is granted. However, an Incentive Stock Option may not be granted to an Employee who, at the time of grant, owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, or any parent or subsidiary corporation of the Company, as defined in section 424 of the Code, unless the Exercise Price per share is not less than 110% of the Fair Market Value of a share of Common Stock on the date of grant.

(c) Option Term. The Committee shall determine the term of each Option. The term of any Option shall not exceed ten years from the date of grant. However, an Incentive Stock Option that is granted to an Employee who, at the time of grant, owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, or any parent or subsidiary corporation of the Company, as defined in section 424 of the Code, may not have a term that exceeds five years from the date of grant. Notwithstanding the foregoing, in the event that on the last business day of the

term of an Option (other than an Incentive Stock Option), the exercise of the Option is prohibited by applicable law, including a prohibition on purchases or sales of Common Stock under the Company's insider trading policy, the term of the Option shall be extended for a period of 30 days following the end of the legal prohibition, unless the Committee determines otherwise.

(d) Exercisability of Options. Subject to Section 3(b), Options shall become exercisable in accordance with such terms and conditions, consistent with the Plan, as may be determined by the Committee and specified in the Award Agreement. Subject to the limitations set forth in Section 12, the Committee may accelerate the exercisability of any or all outstanding Options at any time for any reason.

(e) Awards to Non-Exempt Employees. Notwithstanding the foregoing, Options granted to persons who are non-exempt employees under the Fair Labor Standards Act of 1938, as amended, may not be exercisable for at least six months after the date of grant (except that such Options may become exercisable, as determined by the Committee, upon the Participant's death, Disability or retirement, or upon a Change in Control or other circumstances permitted by applicable regulations).

(f) Termination of Employment or Service. Except as provided in the Award Agreement, an Option may only be exercised while the Participant is employed by, or providing services to, the Employer. The Committee shall determine in the Award Agreement under what circumstances and during what time periods a Participant may exercise an Option after termination of employment or service.

(g) Exercise of Options. A Participant may exercise an Option that has become exercisable, in whole or in part, by delivering a notice of exercise to the Company. The Participant shall pay the Exercise Price for an Option as specified by the Committee (i) in cash or by check, (ii) unless the Committee determines otherwise, by delivering shares of Common Stock owned by the Participant and having a Fair Market Value on the date of exercise at least equal to the Exercise Price or by attestation (on a form prescribed by the Committee) to ownership of shares of Common Stock having a Fair Market Value on the date of exercise at least equal to the Exercise Price, (iii) by payment through a broker in accordance with procedures permitted by Regulation T of the Federal Reserve Board, (iv) if permitted by the Committee, by withholding shares of Common Stock subject to the exercisable Option, which have a Fair Market Value on the date of exercise equal to the Exercise Price, or (v) by such other method as the Committee may approve. Shares of Common Stock used to exercise an Option shall have been held by the Participant for the requisite period of time necessary to avoid adverse accounting consequences to the Company with respect to the Option. Payment for the shares to be issued or transferred pursuant to the Option, and any required withholding taxes, must be received by the Company by the time specified by the Committee depending on the type of payment being made, but in all cases prior to the issuance or transfer of such shares.

(h) Limits on Incentive Stock Options. Each Incentive Stock Option shall provide that, if the aggregate Fair Market Value of the Common Stock on the date of the grant with respect to which Incentive Stock Options are exercisable for the first time by a Participant during any calendar year, under the Plan or any other stock option plan of the Company or a parent or subsidiary, exceeds $100,000, then the Option, as to the excess, shall be treated as a Nonqualified Stock Option.

Section 7. Stock Awards

The Committee may issue or transfer shares of Common Stock to an Employee, Non-Employee Director or Key Advisor under a Stock Award, upon such terms as the Committee deems appropriate. The following provisions are applicable to Stock Awards:

(a) General Requirements. Shares of Common Stock issued pursuant to Stock Awards may be issued for consideration or for no consideration, and subject to restrictions or no restrictions, as determined by the Committee. Subject to Section 3(b), the Committee may, but shall not be required to, establish conditions under which restrictions on Stock Awards shall lapse over a period of time or according to such other criteria as the Committee deems appropriate, including, without limitation, restrictions based upon the achievement of specific Performance Objectives. The period of time

during which the Stock Awards will remain subject to restrictions will be designated in the Award Agreement as the "Restriction Period."

(b) Number of Shares. The Committee shall determine the number of shares of Common Stock to be issued or transferred pursuant to a Stock Award and the restrictions applicable to such shares.

(c) Requirement of Employment or Service. If the Participant ceases to be employed by, or provide service to, the Employer during a period designated in the Award Agreement as the Restriction Period, or if other specified conditions are not met, the Stock Award shall terminate as to all shares covered by the Award as to which the restrictions have not lapsed, and those shares of Common Stock must be immediately returned to the Company. Subject to the limitations set forth in Section 12, the Committee may, however, provide for complete or partial exceptions to this requirement as it deems appropriate.

(d) Restrictions on Transfer and Legend on Stock Certificate. During the Restriction Period, a Participant may not sell, assign, transfer, pledge or otherwise dispose of the shares of a Stock Award except under Section 15 below. Unless otherwise determined by the Committee, the Company will retain possession of certificates for shares of Stock Awards until all restrictions on such shares have lapsed. Each certificate for a Stock Award, unless held by the Company, shall contain a legend giving appropriate notice of the restrictions in the Award. The Participant shall be entitled to have the legend removed from the stock certificate covering the shares subject to restrictions when all restrictions on such shares have lapsed. The Committee may determine that the Company will not issue certificates for Stock Awards until all restrictions on such shares have lapsed.

(e) Right to Vote and to Receive Dividends. Unless the Committee determines otherwise, during the Restriction Period, the Participant shall have the right to vote shares of Stock Awards and to receive any dividends or other distributions paid on such shares, subject to any restrictions deemed appropriate by the Committee, including, without limitation, the achievement of specific Performance Objectives; provided, however, that dividends shall vest and be paid only if and to the extent that the underlying Stock Award vests and is paid.

(f) Lapse of Restrictions. All restrictions imposed on Stock Awards shall lapse upon the expiration of the applicable Restriction Period and the satisfaction of all conditions, if any, imposed by the Committee. The Committee may determine, as to any or all Stock Awards, that the restrictions shall lapse without regard to any Restriction Period.

Section 8. Stock Units

The Committee may grant Stock Units, each of which shall represent one hypothetical share of Common Stock, to an Employee, Non-Employee Director or Key Advisor upon such terms and conditions as the Committee deems appropriate. The following provisions are applicable to Stock Units:

(a) Crediting of Units. Each Stock Unit shall represent the right of the Participant to receive a share of Common Stock or an amount of cash based on the value of a share of Common Stock, if and when specified conditions are met. All Stock Units shall be credited to bookkeeping accounts established on the Company's records for purposes of the Plan.

(b) Terms of Stock Units. Subject to Section 3(b), the Committee may grant Stock Units that vest and are payable if specified Performance Objectives or other conditions are met, or under other circumstances. Stock Units may be paid at the end of a specified performance period or other period, or payment may be deferred to a date authorized by the Committee. Subject to the limitations set forth in Section 12, the Committee may accelerate vesting or payment, as to any or all Stock Units at any time for any reason, provided such acceleration complies with section 409A of the Code. The Committee shall determine the number of Stock Units to be granted and the requirements applicable to such Stock Units.

(c) Requirement of Employment or Service. If the Participant ceases to be employed by, or provide service to, the Employer prior to the vesting of Stock Units, or if other conditions established

by the Committee are not met, the Participant's Stock Units shall be forfeited. The Committee may, however, provide for complete or partial exceptions to this requirement as it deems appropriate.

(d) Payment With Respect to Stock Units. Payments with respect to Stock Units shall be made in cash, Common Stock or any combination of the foregoing, as the Committee shall determine.

Section 9. Stock Appreciation Rights

The Committee may grant SARs to an Employee, Non-Employee Director or Key Advisor separately or in tandem with any Option. The following provisions are applicable to SARs:

(a) General Requirements. The Committee may grant SARs to an Employee, Non-Employee Director or Key Advisor separately or in tandem with any Option (for all or a portion of the applicable Option). Tandem SARs may be granted either at the time the Option is granted or at any time thereafter while the Option remains outstanding; provided, however, that, in the case of an Incentive Stock Option, SARs may be granted only at the time of the grant of the Incentive Stock Option. The Committee shall establish the base amount of the SAR at the time the SAR is granted. The base amount of each SAR shall be equal to or greater than the Fair Market Value of a share of Common Stock as of the date of grant of the SAR. The term of any SAR shall not exceed ten years from the date of grant. Notwithstanding the foregoing, in the event that on the last business day of the term of a SAR, the exercise of the SAR is prohibited by applicable law, including a prohibition on purchases or sales of Common Stock under the Company's insider trading policy, the term shall be extended for a period of 30 days following the end of the legal prohibition, unless the Committee determines otherwise.

(b) Tandem SARs. In the case of tandem SARs, the number of SARs granted to a Participant that shall be exercisable during a specified period shall not exceed the number of shares of Common Stock that the Participant may purchase upon the exercise of the related Option during such period. Upon the exercise of an Option, the SARs relating to the Common Stock covered by such Option shall terminate. Upon the exercise of SARs, the related Option shall terminate to the extent of an equal number of shares of Common Stock.

(c) Exercisability. Subject to Section 3(b), an SAR shall be exercisable during the period specified by the Committee in the Award Agreement and shall be subject to such vesting and other restrictions as may be specified in the Award Agreement. Subject to the limitations set forth in Section 12, the Committee may accelerate the exercisability of any or all outstanding SARs at any time for any reason. SARs may only be exercised while the Participant is employed by, or providing service to, the Employer or during the applicable period after termination of employment or service as specified by the Committee. A tandem SAR shall be exercisable only during the period when the Option to which it is related is also exercisable.

(d) Grants to Non-Exempt Employees. Notwithstanding the foregoing, SARs granted to persons who are non-exempt employees under the Fair Labor Standards Act of 1938, as amended, may not be exercisable for at least six months after the date of grant (except that such SARs may become exercisable, as determined by the Committee, upon the Participant's death, Disability or retirement, or upon a Change in Control or other circumstances permitted by applicable regulations).

(e) Value of SARs. When a Participant exercises SARs, the Participant shall receive in settlement of such SARs an amount equal to the value of the stock appreciation for the number of SARs exercised. The stock appreciation for an SAR is the amount by which the Fair Market Value of the underlying Common Stock on the date of exercise of the SAR exceeds the base amount of the SAR as described in subsection (a).

(f) Form of Payment. The appreciation in an SAR shall be paid in shares of Common Stock, cash or any combination of the foregoing, as the Committee shall determine. For purposes of calculating the number of shares of Common Stock to be received, shares of Common Stock shall be valued at their Fair Market Value on the date of exercise of the SAR.

Section 10. Other Stock-Based Awards

The Committee may grant Other Stock-Based Awards, which are awards (other than those described in Sections 6, 7, 8 and 9 of the Plan) that are based on or measured by Common Stock, to any Employee, Non-Employee Director or Key Advisor, on such terms and conditions as the Committee shall determine. Subject to Section 3(b), Other Stock-Based Awards may be awarded subject to the achievement of Performance Objectives or other criteria or other conditions and may be payable in cash, Common Stock or any combination of the foregoing, as the Committee shall determine.

Section 11. Dividend Equivalents

The Committee may grant Dividend Equivalents in connection with Stock Units or Other Stock-Based Awards. Subject to Section 3(b), Dividend Equivalents may be payable in cash or shares of Common Stock, and upon such terms and conditions as the Committee shall determine; provided that Dividend Equivalents shall vest and be paid only if and to the extent the underlying Stock Units or Other Stock-Based Awards vest and are paid. For the avoidance of doubt, no dividends or Dividend Equivalents will be granted in connection with Options or SARs.

Section 12. Consequences of a Change in Control

(a) Assumption of Outstanding Awards. Upon a Change in Control where the Company is not the surviving corporation (or survives only as a subsidiary of another corporation), all outstanding Awards that are not exercised or paid at the time of the Change in Control shall be assumed by, or replaced with grants that have comparable terms by, the surviving corporation (or a parent or subsidiary of the surviving corporation). In the event that the surviving corporation (or a parent or subsidiary of the surviving corporation) does not assume or replace Awards with grants that have comparable terms, outstanding Options and SARs shall automatically accelerate and become fully exercisable and the restrictions and conditions on outstanding Stock Awards, Stock Units, Other Stock-Based Awards and Dividend Equivalents shall immediately lapse, provided that if the vesting of any such Awards is based, in whole or in part, on performance, such Awards shall vest based on the greater of (i) actual performance as of the Change in Control or (ii) target performance, pro-rated based on the period elapsed between the beginning of the applicable performance period and the date of the Change in Control. After a Change in Control, references to the "Company" as they relate to employment matters shall include the successor employer in the transaction, subject to applicable law.

(b) Vesting Upon Certain Terminations of Employment. At the Committee's discretion, if Awards are assumed by, or replaced with grants that have comparable terms by, the surviving corporation (or a parent or subsidiary of the surviving corporation) and if a Participant incurs an involuntary termination of employment or service on or after a Change in Control, the Participant's outstanding Awards may become vested, in whole or in part, as of the date of such termination; provided that if the vesting of any such Awards is based, in whole or in part, on performance, such Awards shall vest only based on the greater of (i) actual performance as of the date of Change in Control or (ii) target performance, pro-rated based on the period elapsed between the beginning of the applicable performance period and the date of the termination.

(c) Other Alternatives. In the event of a Change in Control, if any outstanding Awards are not assumed by, or replaced with grants that have comparable terms by, the surviving corporation (or a parent or subsidiary of the surviving corporation), the Committee may take any of the following actions with respect to any or all outstanding Awards, without the consent of any Participant: (i) the Committee may determine that Participants shall receive a payment in settlement of outstanding Stock Units, Other Stock-Based Awards or Dividend Equivalents, in such amount and form as may be determined by the Committee; (ii) the Committee may require that Participants surrender their outstanding Options and SARs in exchange for a payment by the Company, in cash or Common Stock as determined by the Committee, in an amount equal to the amount, if any, by which the then Fair Market Value of the shares of Common Stock subject to the Participant's unexercised Options and SARs exceeds the Option Exercise Price or SAR base amount, and (iii) after giving Participants an opportunity to exercise all of their outstanding Options and SARs, the Committee may terminate any or all unexercised Options and SARs at such time as the Committee deems appropriate. Such surrender, termination or payment

shall take place as of the date of the Change in Control or such other date as the Committee may specify. Without limiting the foregoing, if the per share Fair Market Value of the Common Stock does not exceed the per share Option Exercise Price or SAR base amount, as applicable, the Company shall not be required to make any payment to the Participant upon surrender of the Option or SAR.

Section 13. Deferrals

The Committee may permit or require a Participant to defer receipt of the payment of cash or the delivery of shares that would otherwise be due to such Participant in connection with any Award. If any such deferral election is permitted or required, the Committee shall establish rules and procedures for such deferrals and may provide for interest or other earnings to be paid on such deferrals. The rules and procedures for any such deferrals shall be consistent with applicable requirements of section 409A of the Code.

Section 14. Withholding of Taxes

(a) Required Withholding. All Awards under the Plan shall be subject to applicable United States federal (including FICA), state and local, foreign country or other tax withholding requirements. The Employer may require that the Participant or other person receiving Awards or exercising Awards pay to the Employer an amount sufficient to satisfy such tax withholding requirements with respect to such Awards, or the Employer may deduct from other wages and compensation paid by the Employer the amount of any withholding taxes due with respect to such Awards.

(b) Share Withholding. The Committee may permit or require the Employer's tax withholding obligation with respect to Awards paid in Common Stock to be satisfied by having shares withheld up to an amount that does not exceed the Participant's applicable withholding tax rate for United States federal (including FICA), state and local, foreign country or other tax liabilities. The Committee may, in its discretion, and subject to such rules as the Committee may adopt, allow Participants to elect to have such share withholding applied to all or a portion of the tax withholding obligation arising in connection with any particular Award. Unless the Committee determines otherwise, share withholding for taxes shall not exceed the Participant's minimum applicable tax withholding amount.

Section 15. Transferability of Awards

(a) Nontransferability of Awards. Except as described in subsection (b) below, only the Participant may exercise rights under an Award during the Participant's lifetime. A Participant may not transfer those rights except (i) by will or by the laws of descent and distribution or (ii) with respect to Awards other than Incentive Stock Options, pursuant to a domestic relations order. When a Participant dies, the personal representative or other person entitled to succeed to the rights of the Participant may exercise such rights. Any such successor must furnish proof satisfactory to the Company of his or her right to receive the Award under the Participant's will or under the applicable laws of descent and distribution.

(b) Transfer of Nonqualified Stock Options. Notwithstanding the foregoing, the Committee may provide, in an Award Agreement, that a Participant may transfer Nonqualified Stock Options to family members, or one or more trusts or other entities for the benefit of or owned by family members, consistent with the applicable securities laws, according to such terms as the Committee may determine; provided that the Participant receives no consideration for the transfer of an Option and the transferred Option shall continue to be subject to the same terms and conditions as were applicable to the Option immediately before the transfer.

Section 16. Requirements for Issuance or Transfer of Shares

No Common Stock shall be issued or transferred in connection with any Award hereunder unless and until all legal requirements applicable to the issuance or transfer of such Common Stock have been complied with to the satisfaction of the Committee. The Committee shall have the right to condition any Award on the Participant's undertaking in writing to comply with such restrictions on his or her subsequent disposition of the shares of Common Stock as the Committee shall deem necessary or advisable, and certificates representing such shares may be legended to reflect any such restrictions. Certificates representing shares of

Common Stock issued or transferred under the Plan may be subject to such stop-transfer orders and other restrictions as the Committee deems appropriate to comply with applicable laws, regulations and interpretations, including any requirement that a legend be placed thereon.

Section 17. Amendment and Termination of the Plan

(a) Amendment. The Board may amend or terminate the Plan at any time; provided, however, that the Board shall not amend the Plan without stockholder approval if such approval is required in order to comply with the Code or other applicable law, or to comply with applicable stock exchange requirements.

(b) No Repricing of Options or SARs. Except in connection with a corporate transaction involving the Company (including, without limitation, any stock dividend, distribution (whether in the form of cash, Common Stock, other securities or property), stock split, extraordinary cash dividend, recapitalization, change in control, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase or exchange of shares of Common Stock or other securities, or similar transactions), the Company may not, without obtaining stockholder approval, (i) amend the terms of outstanding Options or SARs to reduce the Exercise Price of such outstanding Options or base price of such SARs, (ii) cancel outstanding Options or SARs in exchange for Options or SARs with an Exercise Price or base price, as applicable, that is less than the Exercise Price or base price of the original Options or SARs or (iii) cancel outstanding Options or SARs with an Exercise Price or base price, as applicable, above the current stock price in exchange for cash or other securities.

(c) Termination of Plan. The Plan shall terminate on the day immediately preceding the tenth anniversary of its Restatement Effective Date, unless the Plan is terminated earlier by the Board or is extended by the Board with the approval of the stockholders.

(d) Termination and Amendment of Outstanding Awards. A termination or amendment of the Plan that occurs after an Award is made shall not materially impair the rights of a Participant unless the Participant consents or unless the Committee acts under Section 18(f) below. The termination of the Plan shall not impair the power and authority of the Committee with respect to an outstanding Award. Whether or not the Plan has terminated, an outstanding Award may be terminated or amended under Section 18(f) below or may be amended by agreement of the Company and the Participant consistent with the Plan, provided that the Participant's consent is not required if any termination or amendment to the Participant's outstanding Award does not materially impair the rights or materially increase the obligations of the Participant.

Section 18. Miscellaneous

(a) Awards in Connection with Corporate Transactions and Otherwise. Nothing contained in the Plan shall be construed to (i) limit the right of the Committee to make Awards under the Plan in connection with the acquisition, by purchase, lease, merger, consolidation or otherwise, of the business or assets of any corporation, firm or association, including Awards to employees thereof who become Employees, or (ii) limit the right of the Company to grant stock options or make other awards outside of the Plan. The Committee may make a Substitute Award to an employee of another corporation who becomes an Employee by reason of a corporate merger, consolidation, acquisition of stock or property, reorganization or liquidation involving the Company, in substitution for a stock option or stock award granted by such corporation. Notwithstanding anything in the Plan to the contrary, the Committee may establish such terms and conditions of the new Substitute Awards as it deems appropriate, including setting the Exercise Price of Options or the base price of SARs at a price necessary to retain for the Participant the same economic value as the prior options or rights.

(b) Governing Document. The Plan shall be the controlling document. No other statements, representations, explanatory materials or examples, oral or written, may amend the Plan in any manner. The Plan shall be binding upon and enforceable against the Company and its successors and assigns.

(c) Funding of the Plan. The Plan shall be unfunded. The Company shall not be required to establish any special or separate fund or to make any other segregation of assets to assure the payment of any Awards under the Plan.

(d) Rights of Participants. Nothing in the Plan shall entitle any Employee, Non-Employee Director, Key Advisor or other person to any claim or right to receive an Award under the Plan. Neither the Plan nor any action taken hereunder shall be construed as giving any individual any rights to be retained by or in the employ of the Employer or any other employment rights.

(e) No Fractional Shares. No fractional shares of Common Stock shall be issued or delivered pursuant to the Plan or any Award. Except as otherwise provided under the Plan, the Committee shall determine whether cash, other awards or other property shall be issued or paid in lieu of such fractional shares or whether such fractional shares or any rights thereto shall be forfeited or otherwise eliminated.

(f) Compliance with Law.

(i) The Plan, the exercise of Options and SARs and the obligations of the Company to issue or transfer shares of Common Stock under Awards shall be subject to all applicable laws and regulations, and to approvals by any governmental or regulatory agency as may be required. With respect to persons subject to section 16 of the Exchange Act, it is the intent of the Company that the Plan and all transactions under the Plan comply with all applicable provisions of Rule 16b-3 or its successors under the Exchange Act. In addition, it is the intent of the Company that Incentive Stock Options comply with the applicable provisions of section 422 of the Code, and that, to the extent applicable, Awards comply with the requirements of section 409A of the Code. To the extent that any legal requirement of section 16 of the Exchange Act or section 422, or 409A of the Code as set forth in the Plan ceases to be required under section 16 of the Exchange Act or section 422 or 409A of the Code, that Plan provision shall cease to apply. The Committee may revoke any Award if it is contrary to law or modify an Award to bring it into compliance with any valid and mandatory government regulation. The Committee may also adopt rules regarding the withholding of taxes on payments to Participants. The Committee may, in its sole discretion, agree to limit its authority under this Section.

(ii) The Plan is intended to comply with the requirements of section 409A of the Code, to the extent applicable. Each Award shall be construed and administered such that the Award either (A) qualifies for an exemption from the requirements of section 409A of the Code or (B) satisfies the requirements of section 409A of the Code. If an Award is subject to section 409A of the Code, (I) distributions shall only be made in a manner and upon an event permitted under section 409A of the Code, (II) payments to be made upon a termination of employment or service shall only be made upon a "separation from service" under section 409A of the Code, (III) unless the Award specifies otherwise, each installment payment shall be treated as a separate payment for purposes of section 409A of the Code, and (IV) in no event shall a Participant, directly or indirectly, designate the calendar year in which a distribution is made except in accordance with section 409A of the Code.

(iii) Any Award that is subject to section 409A of the Code and that is to be distributed to a Key Employee (as defined below) upon separation from service shall be administered so that any distribution with respect to such Award shall be postponed for six months following the date of the Participant's separation from service, if required by section 409A of the Code. If a distribution is delayed pursuant to section 409A of the Code, the distribution shall be paid within 15 days after the end of the six-month period. If the Participant dies during such six-month period, any postponed amounts shall be paid within 90 days of the Participant's death. The determination of Key Employees, including the number and identity of persons considered Key Employees and the identification date, shall be made by the Committee or its delegate each year in accordance with section 416(i) of the Code and the "specified employee" requirements of section 409A of the Code.

(iv) Notwithstanding anything in the Plan or any Award agreement to the contrary, each Participant shall be solely responsible for the tax consequences of Awards under the Plan, and in no event shall the Company or any subsidiary or affiliate of the Company have any responsibility or liability if an Award does not meet any applicable requirements of section 409A of the Code. Although the Company intends to administer the Plan to prevent taxation under section 409A of the Code, the Company does not represent or warrant that the Plan or any Award complies with any provision of federal, state, local or other tax law.

(g) Establishment of Subplans. The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable blue sky, securities or tax laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to the Plan setting forth (i) such limitations on the Committee's discretion under the Plan as the Board deems necessary or desirable and (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Employer shall not be required to provide copies of any supplement to Participants in any jurisdiction that is not affected.

(h) Clawback Rights. Subject to the requirements of applicable law, the Committee may provide in any Award Agreement that, if a Participant breaches any restrictive covenant agreement between the Participant and the Employer (which may be set forth in any Award Agreement) or otherwise engages in activities that constitute Cause either while employed by, or providing service to, the Employer or within the applicable period of time thereafter, all Awards held by the Participant shall terminate, and the Company may rescind any exercise of an Option or SAR and the vesting of any other Award and delivery of shares upon such exercise or vesting (including pursuant to dividends and Dividend Equivalents), as applicable on such terms as the Committee shall determine, including the right to require that in the event of any such rescission, (i) the Participant shall return to the Company the shares received upon the exercise of any Option or SAR and/or the vesting and payment of any other Award (including pursuant to dividends and Dividend Equivalents) or, (ii) if the Participant no longer owns the shares, the Participant shall pay to the Company the amount of any gain realized or payment received as a result of any sale or other disposition of the shares (or, in the event the Participant transfers the shares by gift or otherwise without consideration, the Fair Market Value of the shares on the date of the breach of the restrictive covenant agreement or activity constituting Cause), net of the price originally paid by the Participant for the shares. Payment by the Participant shall be made in such manner and on such terms and conditions as may be required by the Committee. The Employer shall be entitled to set off against the amount of any such payment any amounts otherwise owed to the Participant by the Employer. In addition, all Awards under the Plan shall be subject to any applicable clawback or recoupment policies, share trading policies and other policies that may be implemented by the Board from time to time.

(i) Governing Law. The validity, construction, interpretation and effect of the Plan and Award Agreements issued under the Plan shall be governed and construed by and determined in accordance with the laws of the State of Delaware, without giving effect to the conflict of laws provisions thereof.