TFF Pharmaceuticals, Inc.

2023 Annual Report to Stockholders

Letter to Stockholders

Dear Stockholders,

Over the past six months, we have made considerable progress and made key decisions that we believe will generate the most value for shareholders as our company progresses forward. We have delivered three data updates on our TFF TAC and TFF VORI Phase 2 programs since last October, contributing to our effort to maximize shareholder value and supporting our dedication to transparency.

TFF closed out 2023 on a positive note with initial Phase 2 data providing meaningful clinical insights on TFF VORI and TFF TAC's safety, tolerability, and efficacy. These data demonstrated that our Thin Film Freezing technology platform has the potential to offer a safer and more effective option to both IPA and lung transplant patients. Subsequently, we announced updated positive data in March 2024 for both Phase 2 trials and while these results garnered excitement for both programs, we made the strategic decision to focus our clinical development efforts and financial resources on the TFF TAC program. TFF VORI's potential remains strong, and we will continue to explore strategic alternatives.

As of our latest update on the ongoing TFF TAC Phase 2 study, eight of eight patients in the trial were successfully transitioned from oral tacrolimus to TFF TAC. No evidence of acute rejection was seen, and new gene expression data showed no evidence of rejection in all four patients with available gene expression data from endobronchial biopsies. These updated data were presented by Professor Gregory Snell at the ISHLT 2024 Annual Meeting that took place on April 13, 2024. Based on these highly encouraging results, we plan to open an IND in the US to explore the use of TFF TAC early post-transplant in preparation for a registrational trial.

For TFF VORI, a total of nine patients have been enrolled between the Phase 2 study and the Expanded Access Program (EAP) and results remain positive. In support of TFF VORI's efficacy profile, five of six patients who completed treatment achieved a clinical and mycologic response. Updated data demonstrate that TFF VORI continues to maintain an attractive safety profile with no IPA-related mortality or all-cause mortality.

In March, we strengthened our balance sheet through a registered direct offering of $1.2M and we continue to evaluate all potential funding opportunities to move our pipeline forward.

We would like to thank our shareholders for your continued support and confidence in TFF Pharmaceuticals, and we look forward to updating you on our progress throughout the rest of the year.

Yours sincerely,

Harlan Weisman, M.D.,
Chief Executive Officer

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

FORM 10-K

☒ 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 UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 001-39102

TFF Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**82-4344737**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)

1751 River Run, Suite 400
Fort Worth, Texas 76107
(Address of principal executive offices)

(817) 438-6168
(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 $0.001	TFFP	The Nasdaq Capital Market

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 15(d) of the Exchange 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 past 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 and post 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 emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

State the aggregate market value of voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: $16.5 million.

The number of shares of the registrant's common stock outstanding as of March 22, 2024 was 2,519,220.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days after the end of the fiscal year ended December 31, 2023. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

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CAUTIONARY NOTICE

This annual report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Those forward-looking statements include our expectations, beliefs, intentions and strategies regarding the future.

These and other factors that may affect our financial results are discussed more fully in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in this report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for us to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in our forward-looking statements. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We caution readers not to place undue reliance on any forward-looking statements. We do not undertake, and specifically disclaim any obligation, to update or revise such statements to reflect new circumstances or unanticipated events as they occur, and we urge readers to review and consider disclosures we make in this and other reports that discuss factors germane to our business. See in particular our reports on Forms 10-K, 10-Q, and 8-K subsequently filed from time to time with the Securities and Exchange Commission.

Except as otherwise indicated, all share and share price in this report gives effect to a reverse stock split effected on December 19, 2023 at a ratio of one for 25.

RISK FACTOR SUMMARY

Our business is subject to numerous risks and uncertainties, including those described in "Risk Factors" in this Annual Report on Form 10-K. These risks include, but are not limited to the following:

- We will need additional financing to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all.
- We are a clinical-stage biopharmaceutical company with limited operating history.
- We have a history of significant operating losses and anticipate continued operating losses for the foreseeable future.
- The report of our independent registered public accounting firm for the year ended December 31, 2023 states that due to our lack of revenue from commercial operations, significant losses and need for additional capital there is substantial doubt about our ability to continue as a going concern.
- Our business model is entirely dependent on certain patent rights licensed to us from the University of Texas at Austin, and the loss of those license rights would, in all likelihood, cause our business, as presently contemplated, to fail.
- Our business model includes, in part, the licensing of our TFF Platform to other pharmaceutical companies, however technology licensing in the pharmaceutical industry is a lengthy process and subject to several risks and factors outside of our control, and we cannot forecast our ability to successfully license our technology or the length of time it may take to establish a new licensing relationship.
- Unfavorable geopolitical and macroeconomic developments could adversely affect our business, financial condition or results of operations.
- Our business model also depends on our successful development, regulatory approval and commercialization of our product candidates, which may never occur. Our TFF TAC and TFF VORI product candidates are currently undergoing Phase 2 clinical trials. In March 2024, we announced our decision to prioritize clinical development of TFF TAC based on positive Phase 2 data and to evaluate strategic options for TFF VORI, however, there can be no assurance that the Phase 2 trial for TFF TAC will be successful, we will be successful in finding a strategic option for TFF VORI or that we will continue clinical development of TFF TAC in support of an approval from the FDA or comparable foreign regulatory authorities for any indication.
- Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results.
- Our business operations could suffer in the event of information technology systems' failures or security breaches.
- Our success is entirely dependent on our ability to obtain the marketing approval for our product candidates by the FDA and the regulatory authorities in foreign jurisdictions in which we intend to market our product candidates, of which there can be no assurance.
- Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome.
- Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited.
- Even if we obtain marketing approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates.

- Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.
- Even though we may apply for orphan drug designation for a product candidate, we may not be able to obtain orphan drug marketing exclusivity.
- Current and future legislation 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.
- Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of any of our product candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- We will be completely dependent on third parties to manufacture our product candidates for clinical and commercial purposes, and the commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.
- Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues.
- It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.
- Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.
- We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.
- Our business could be adversely affected by conditions in the U.S. and global economies.
- The market price of our shares may be subject to fluctuation and volatility. You could lose all or part of your investment.
- If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.
- Future capital raises may dilute your ownership and/or have other adverse effects on our operations.
- If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.
- We may be at an increased risk of securities class action litigation.
- Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.
- Our certificate of incorporation and amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

PART I

Item 1. Business

Background

TFF Pharmaceuticals, Inc. was formed as a Delaware corporation on January 24, 2018 for the purpose of developing and commercializing innovative drug products based on our patented Thin Film Freezing, or TFF, technology platform. Since our formation, we have focused on the development of our initial drug candidates, the establishment of strategic relationships with established pharmaceutical companies and certain government agencies and the pursuit of additional working capital. We have not commenced revenue-producing operations. Unless otherwise indicated, the terms "TFF Pharmaceuticals," "Company," "we," "us," and "our" refer to TFF Pharmaceuticals, Inc. and its wholly-owned subsidiaries.

Overview

We are a clinical stage biopharmaceutical company focused on developing and commercializing innovative drug products based on our patented Thin Film Freezing, or TFF, technology platform. Based on our internal and sponsored testing and studies, we believe that our TFF platform can significantly improve the solubility of poorly water-soluble drugs, which make up approximately 40% of marketed pharmaceuticals worldwide, thereby improving the bioavailability and pharmacokinetics of those drugs. We believe that in the case of some new drugs that cannot be developed due to poor water solubility, our TFF platform has the potential to increase the pharmacokinetic effect of the drug to a level allowing for its development and commercialization. When administered as an inhaled dry powder for treatment of lung disorders, we believe the TFF platform formulations can be used to increase efficacy and minimize systemic toxicities and drug-drug interactions.

As of the date of this report, we have two product candidates in clinical trials, TFF Tacrolimus Inhalation Powder, or TFF TAC, and TFF Voriconazole Inhalation Powder, or TFF VORI. To date, we have completed one Phase 1 study in healthy volunteers and one Phase 1b study in patients with asthma exploring the safety, tolerability and pharmacokinetics of TFF VORI. We have initiated Phase 2 clinical trials of TFF TAC and TFF VORI and, in December 2023, we released positive initial data from both trials, along with clinical data from our ongoing TFF VORI Expanded Access Program. In March 2024, we announced our decision to prioritize clinical development of TFF TAC based on positive Phase 2 data and to evaluate strategic options for TFF VORI. We expect to conclude our Phase 2 clinical trials of TFF VORI in the first half of 2024 and TFF TAC in the second half of 2024.

We are also actively engaged in the analysis and testing of dry powder formulations of several drugs and vaccines through parenteral, topical, ocular, pulmonary and nasal applications through feasibility studies and material transfer agreements with U.S. and international pharmaceutical companies and certain government agencies. We intend to initially focus on the development of inhaled dry powder drugs for the treatment of pulmonary diseases and conditions. While the TFF platform was designed to improve solubility of poorly water-soluble drugs generally, the researchers at University of Texas at Austin, or UT, found that the technology was particularly useful in generating dry powder particles with properties which allow for superior inhalation delivery to the deep lung, which is an area of high interest in respiratory medicine. We believe that our TFF platform can significantly increase the number of pulmonary drug products that can be delivered directly to the lung. We intend to design our dry powder drug products for use with dry powder inhalers, which are generally considered to be the most effective and convenient for patients-friendly of all breath-actuated inhalers. We plan to focus on developing inhaled dry powder formulations of existing drugs and that will be off-patent by launch and are suited for lung diseases and conditions, which we believe includes dozens of potential drug candidates, many have a potential market of over $1 billion.

We initially intend to directly pursue the development of dry powder formulations of off-patent drugs through the U.S. Food and Drug Administration's, or FDA's, 505(b)(2) New Drug Application (NDA) regulatory pathway and in similar regulatory paths in other foreign jurisdictions. The 505(b)(2) pathway contains full reports of investigations of safety and effectiveness and some of the information required for approval comes from studies not conducted by or for the NDA applicant. The commercialization of 505(b)(2) products has the potential advantages: significantly lower development costs and shorter development timelines to approval than traditional new molecular entities. The clinical requirements for a 505(b)(2) drug candidate can vary widely from product to product and depend primarily on whether the product candidate claims a new indication, provides for a different route of administration, or claims improved

safety compared to the existing approved product, and may include bioequivalence trials, limited safety and efficacy trials, or full Phase I through III trials. Generally, the clinical requirements for a 505(b)(2) product candidate may vary depending on the patient population, route of administration, dosing regimen, and other development considerations, and requires ongoing alignment with the FDA and other applicable health authorities. For example, based on our meetings to date with the FDA, we believe we need to conduct additional clinical trials beyond the current Phase 2 trials for TFF TAC and TFF VORI prior to filing for marketing approval for either product.

TFF TAC has been awarded orphan drug status. We also believe that in some cases our other dry powder drug products may qualify for the FDA's orphan drug status.

We intend to commercialize our TFF platform and internally developed product candidates through the following means:

- We may out-license our internally developed product candidates, such as TFF TAC and TFF VORI, or agree to jointly develop such products with a third-party pharmaceutical company;
- Upon and subject to receipt of the requisite approvals, we may directly commercialize our internally developed product candidates through a combination of our internal direct sales and third-party marketing and distribution partnerships; and
- We may pursue the licensing of our TFF platform or a joint development arrangement for a particular field of use with a third-party pharmaceutical company.

The Problem We Address

Solubility is an issue that all drugs must address. No matter how active or potentially active a new drug is against a particular molecular target, if the drug is not available in solution at the site of action, it is most likely not a viable development candidate. Based on independent third-party studies, at least 75% of drugs under development have poor water solubility, which can prohibit development since most pharmaceutical companies cannot or will not conduct rigorous preclinical and clinical studies on a molecule that does not have a sufficient pharmacokinetic profile due to poor water solubility. Water solubility can also be an issue for some marketed drugs. Based on independent third-party studies, only two-thirds of the drugs on the World Health Organization, or WHO, Essential Drug List were classified as high solubility and 40% of currently marketed drugs have poor water solubility. A marketed drug with poor water solubility can show performance limitations, such as incomplete or erratic absorption, poor bioavailability, and slow onset of action. Effectiveness can vary from patient to patient, and there can be a strong effect of food on drug absorption. Finally, it may be necessary to increase the dose of a poorly soluble drug to obtain the efficacy required, which can lead to adverse side effects, toxicity issues and increased costs.

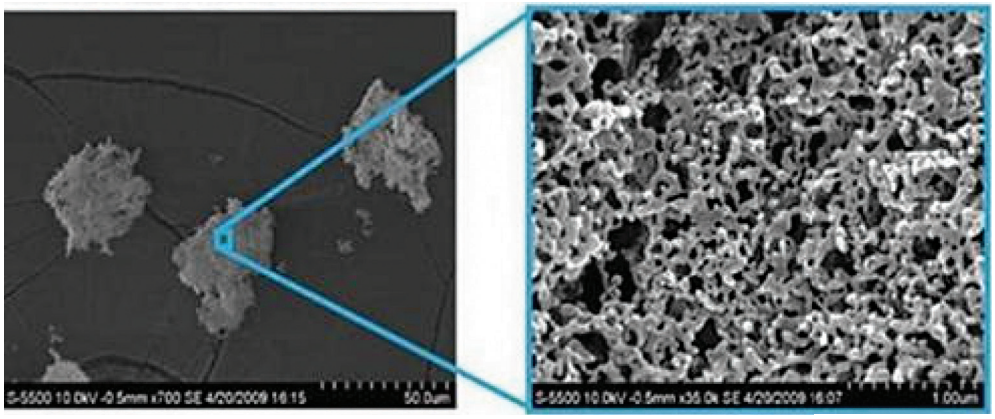
In addition to water solubility issues generally, certain drugs that target lung conditions and diseases have poor solubility that precludes them from being delivered by way of inhalation, especially via a breath-actuated inhaler and can only be given orally or intravenously. Breath-actuated inhalers include dry powder inhalers, metered dose inhalers and some nebulizers. A dry powder inhaler delivers drugs in a dry powder form directly to the lungs by way of a deep, fast breath on the mouth of the inhaler. A metered dose inhaler uses propellant to push medication to the lungs. A nebulizer creates a mist that is breathed into the lungs through a mouthpiece. The dry powder inhaler is generally considered to be the most effective and convenient form of breath-actuated inhaler for all users, other than for those whose severe condition does not allow them to take a sufficiently deep breath.

We believe the primary benefit of a breath-actuated inhaler is its ability to administer a greater portion of the drug dosage directly to the target site. Dosing directly to the lungs has been shown to allow for better effect with fewer adverse events. It has been shown that dosing directly to the lungs requires a lower dose of drug, compared to delivery by oral or parenteral routes. While breath-actuated inhalers allow for a greater portion of the administered drug to reach the treatment site, which should allow for much smaller dosages compared to oral or intravenous delivery, not all drugs targeting lung conditions and diseases can currently be formulated for use with a breath-actuated inhaler. We believe there are dozens of these off-patent drugs targeting lung conditions and diseases that can be reformulated using our TFF platform for delivery by way of breath-actuated inhalers, many of which have a potential market of over $1 billion. This is the market we intend to initially address through our development of dry powder drugs utilizing our TFF platform.

Our Thin Film Freezing Platform

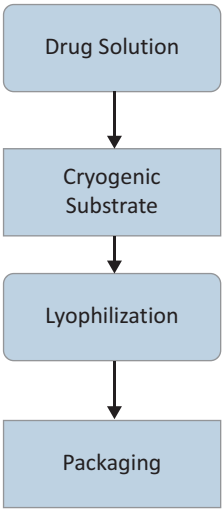
Our development of dry powder drugs is enabled by technology licensed to us by the University of Texas at Austin, or UT. Researchers at UT have developed a technology employing a process called Thin Film Freezing, or TFF. While the TFF platform was designed to improve solubility of poorly water-soluble final drug products generally, the researchers at UT found that the technology was particularly useful in generating dry powder particles with properties suitable for inhalation delivery to the deep lung, via dry powder inhaler delivery systems, an area of extreme interest in respiratory medicine. The TFF process results in a "Brittle Matrix Particle," which exhibits a low bulk density, high surface area, and optionally an amorphous morphology, allowing the particles to supersaturate when contacting the target site, such as lung tissue. The aerodynamic properties of the particles are such that the amount of drug deposited to the deep lung may, in some cases, reach ten times that achieved via the oral route.

The TFF process, outlined in the figures below, involves processing a drug or drugs in a solvent system, and it will often include agents designed to promote dispersion and avoid clumping and excipients to promote adhesion to the target site. The drug solution is then applied to a cryogenic substrate, such as a liquid nitrogen cooled stainless steel drum. When the drug solution contacts the cryogenic surface it vitrifies, or flash freezes, resulting in a "drug ice." The solvent system is removed by lyophilization, resulting in Brittle Matrix Particles, shown in the photographs below, that are highly porous, large surface area, low-density particles. The process uses industry standard solvents, recognized excipients, a custom-made TFF drum and conventional process equipment.



TFF processed Brittle Matrix Particles

High magnification of Brittle Matrix Particles



We believe our TFF platform is a breakthrough platform technology for making dry powders from drugs that previously were not candidates for the dry powder inhaler or any breath-actuated inhaler. We believe our TFF technology opens the way for direct-to-lung delivery of dozens of pharmaceuticals, including the reformulation of existing drugs into a more safe and convenient inhaled dry powder product. We believe the technology can be used with molecules of all types and works with existing and off-the-shelf dry powder inhalers without the need for any additional equipment or devices.

We believe our TFF platform presents the following high value opportunities:

- **Reformulation of drugs for lung conditions.** Today, many drugs intended for lung conditions are only given orally or intravenously due to properties that make them ill-suited for direct delivery by inhalers. Given by these routes, typically only a small fraction of the drug reaches the lungs, and these drugs may cause unwanted and even deadly side effects. We believe that our TFF platform will for the first time allow many of these medications to be formulated into the convenient, direct-to-lung dry powder inhaler format, thereby enhancing efficacy and reducing or eliminating side effects by directly delivering the drug to the target site.

- **Biologics.** Biopharmaceuticals (or biologics) are by far the fastest growing sector in the pharmaceutical industry today. According to GlobalData, the market for biologics was valued at approximately $430 billion in 2022 and is expected to reach $720 billion by 2027. Biologics are most commonly delivered intravenously,

and they can be an especially challenging class of drugs for formulation into a dry powder. We believe our TFF platform is uniquely suited to meet many of the challenges of biologic formulations, and our UT collaborators have demonstrated, via animal model testing and in vitro testing, the effectiveness of the TFF technology to produce dry powder biologics with, in some cases, up to 100% activity retained. We intend to explore dry powder forms of numerous biological drugs, including drugs intended to treat indications other than lung conditions and diseases. We are also pursuing TFF formulations of aluminum salt containing vaccines, which by virtue of providing a dry powder formulation would remove the requirement for liquid suspension and cold chain.

- **Combination Drugs.** Combination drugs are products with two or more active pharmaceutical ingredients. In addition to providing for increased patient compliance with multiple medications, some drugs act synergistically and provide for superior benefit when given as a combination. However, combining pharmaceutical agents can be challenging, especially for inhalation delivery. Our TFF platform has shown the ability to produce fixed dose combinations of many agents in a manner that delivers the drugs simultaneously to the site of action in a precise amount.

The TFF platform was invented and developed by researchers at University of Texas at Austin, or UT, led by Robert O. Williams, III, Ph.D. UT has granted to us an exclusive worldwide, royalty-bearing license to the patent rights for the TFF platform in all fields of use. We continue to work with Dr. Williams and his UT team through a series of Sponsored Research Agreements, or SRAs, with UT. Our SRAs with UT are industry standard sponsored research agreements pursuant to which UT provides to us certain product formulation, characterization and evaluation services regarding potential product candidates incorporating our TFF technology in exchange for our payment of UT's expenses and reasonable overhead. The services conducted by UT were carried out under the direction of Dr. Williams, who is the principal inventor of the TFF technology. The current SRA expires in July 2025 and is subject to renewal upon mutual agreement of the parties. The SRAs includes customary provisions concerning confidentiality, indemnification and intellectual property rights, including each party's exclusive ownership of all intellectual property developed solely by them and the parties' joint ownership of all intellectual property developed jointly. All patented intellectual property rights relating to the TFF technology developed solely or jointly by UT are subject to our patent license agreement with UT and are included among our licensed patent rights. Pursuant to those SRAs, Dr. Williams and his team, together with their labs and collaborators, provide expertise and initial development work, including:

- the preliminary development and in vitro evaluation of our drug candidates;
- the determination of the key characteristics influencing performance of our product candidates;
- the determination of the formulation and manufacturing parameters that influence the key characteristics of our product candidates;
- supply of bulk dry powders for initial good laboratory practice, or GLP, and non-GLP toxicity studies;
- supportive stability for future GLP and GMP studies; and
- the evaluation of the in vivo performance of our product candidates in various animal models.

In June 2022, we established our own laboratory in Austin, Texas where we undertake certain product formulation, characterization and evaluation services with regard to potential product candidates. We established our own laboratory to obtain direct ownership over all intellectual property developed within our laboratory and to address concerns on the part of our partners over potential conflicts with UT.

Our Internal Product Candidates

We intend to initially focus on the development of inhaled dry powder drugs for the treatment of pulmonary diseases and conditions. Our dry powder drug product candidates will be designed for use with dry powder inhalers, which are generally considered to be the most effective of all breath-actuated inhalers. We plan to focus on developing dry powder drugs intended for lung diseases and conditions that are off-patent, which we believe includes dozens of potential drug candidates, many of which have a potential market of over $1 billion. As of the date of this report, we have identified and are focusing on two initial drug candidates, each of which are in ongoing Phase 2 clinical trials.

Tacrolimus Inhalation Powder, TFF TAC — For Prophylaxis of Lung Transplant Rejection

We are developing Tacrolimus Inhalation Powder, TFF TAC, an inhaled dry powder formulation of tacrolimus, for the prophylaxis of organ rejection in patients receiving lung transplants, in combination with other immunosuppressants. Prograf (tacrolimus) is currently the first-line calcineurin inhibitor used in the maintenance regimen to prevent rejection after lung transplantation despite its many significant systemic toxicities. Prograf can be administered as oral capsules, injection or an oral suspension.

According to product labeling and prescribing information for Prograf, serious and otherwise important adverse drug reactions associated with Prograf include lymphoma and other malignancies, serious infections, new onset diabetes after transplant, nephrotoxicity, neurotoxicity, hyperkalemia, hypertension, anaphylactic reaction after injection, myocardial hypertrophy, pure red cell aplasia, and thrombotic microangiopathy, including hemolytic uremic syndrome and thrombotic thrombocytopenic purpura. Of particular concern is nephrotoxicity, which was reported in approximately 52% of kidney transplantation patients and in 40% and 36% of liver transplantation patients receiving Prograf in the U.S. and European randomized trials, respectively, and in 59% of heart transplantation patients in a European randomized trial.

Prograf is an off-patent drug and we have developed TFF TAC to be administered with an oral dry powder inhaler. Because our dry powder version would provide for a high local lung concentration, it is expected that oral tacrolimus can be stopped or weaned to minimize systemic toxicities while maintaining local lung immune suppression to prevent rejection. We believe our TFF TAC may have a high likelihood of success in competing in the immunosuppressant market for lung and heart/lung transplants. TFF TAC has been awarded orphan drug status.

To date, we have completed a Phase 1 study in healthy volunteers to assess the safety, tolerability and pharmacokinetics of TFF TAC. As of the date of this report, a Phase 2 clinical trial of TFF TAC in patients in lung transplant patients is underway. In December 2023, we released positive initial data from this trial. We expect to conclude our Phase 2 clinical trial of TFF TAC in the second half of 2024.

Voriconazole Inhalation Powder, TFF VORI — For the Treatment and Prophylaxis of Invasive Pulmonary Aspergillosis

We are developing Voriconazole Inhalation Powder, or TFF VORI, an inhaled dry powder formulation of voriconazole, for the treatment and prophylaxis of invasive pulmonary aspergillosis, or IPA, a severe fungal pulmonary disease with an overall 84-day all-cause mortality rate of approximately 30% despite use of standard of care therapy. IPA occurs primarily in patients with severe immunodeficiency, such as bone marrow and solid organ transplant recipients, and patients with chemotherapy-induced immunodeficiency, hematologic malignancy, or HIV. To date, the approved antifungals used to treat IPA have been delivered orally or intravenously, where doses required to achieve efficacy have been associated with systemic toxicities and drug-drug interaction issues, which places a premium on any formulation that can improve the drugs' efficacy and/or safety and tolerability. Due to the nature of these drugs, it has not been possible to make formulations for breath-actuated inhalers that might maximize lung concentration while limiting side effects.

Voriconazole is an off-patent, first-line drug for the treatment of IPA. It is also used off-label for the prophylaxis of IPA. We believe TFF VORI represents an opportunity for the treatment and prophylaxis of IPA and other voriconazole responsive pulmonary fungal infections. Direct delivery of TFF VORI to the lungs has the potential to put the drug exactly where it is needed, while minimizing off target toxic effects. Voriconazole is currently marketed in Australia, Canada, Europe and the U.S. as VFEND, and is available in several strengths and presentations for oral delivery or IV infusion. As of the date of this report, the Clinical Practice Guidelines released by the Infectious Diseases Society of America recommend voriconazole as first-line monotherapy for IPA. However, since the registration of VFEND in Europe and the U.S. in 2002, several studies have examined the exposure-response relationship with voriconazole. Those studies have identified a relationship between low voriconazole exposure and higher rates of treatment failure and high voriconazole exposure and higher propensity for neurotoxicity. Studies have also shown that voriconazole delivered orally or intravenously is associated with a high degree of exposure variability. In the case of oral delivery, the high degree of variability can be partly explained by the effect of food as high-fat meals decrease maximum concentrations by 34% to 58%. In addition, voriconazole when delivered orally or intravenously has many serious adverse reactions, including hepatic toxicity, arrhythmias and QT prolongation, infusion related reactions,

visual disturbances, severe cutaneous adverse reactions, photosensitivity and renal toxicity. Hepatic toxicity, arrythmias and severe cutaneous adverse reactions have been associated with fatalities. These studies confirm that when administered orally or intravenously, voriconazole provides a narrow therapeutic window between treatment success and unacceptable treatment toxicity.

We believe TFF VORI could be used for the treatment or prophylaxis of IPA and would benefit patients by providing the drug at the site of invasive fungal infections, while reducing or eliminating the potential serious side effects and fatal toxicities associated with oral and parenteral voriconazole. We believe the potential enhanced efficacy and/or improved safety and tolerability offered by TFF VORI may decrease the rate of voriconazole treatment failures and the need for later line therapies with their associated toxicities. We also believe that the administration of TFF VORI directly to the lungs will remove the variability in exposures due to the effects of food. In addition, animal and in vitro studies have shown that our TFF prepared dry powder formulation will improve the solubility of voriconazole compared to oral or intravenous delivery. We believe that the combination of improved solubility and direct-to-lung administration of TFF VORI will increase exposures in the lung while decreasing systemic exposures and minimizing systemic toxicities and drug-drug interactions.

To date, we have completed a Phase 1 study in healthy volunteers and a Phase 1b study in patients with asthma to assess the safety, tolerability and pharmacokinetics of TFF VORI. As of the date of this report, a Phase 2 clinical trial of TFF VORI in patients with IPA is underway. In December 2023, we released positive initial data from this trial, along with clinical data from our ongoing TFF VORI Expanded Access Program. In March 2024, we announced our decision to prioritize clinical development of TFF TAC based on positive Phase 2 data and to evaluate strategic options for TFF VORI. We expect to conclude our Phase 2 clinical trial of TFF VORI in the first half of 2024.

Other Potential Dry Powder Products

Our business model is to develop proprietary innovative drug product candidates that offer functional or commercial advantages, or both, to currently available alternatives. In our initial evaluation of the market, we have identified a number of potential drug candidates that show promise upon initial assessment, including:

Vaccines. Vaccines containing aluminum salts make up approximately 35% of all vaccines. Aluminum salts are incorporated into many vaccine formulations as an adjuvant, which is a substance added to vaccines to enhance the immune response of vaccinated individuals. A major limitation with these vaccines is that they are fragile and to maintain their efficacy they must be formulated as liquid suspensions and kept in a cold chain (2 – 8 °C) during transport and storage, which is burdensome and expensive. Also, exposure of the liquid vaccines to either ambient or freezing temperatures will cause a loss of efficacy, including particle aggregation in the case of freezing. Alternatives to cold chain have been examined, including the introduction of stabilizing agents in vaccines to prevent aggregation during freezing and the application of novel freezing and drying techniques; however, we believe that to date none of these techniques have led to an acceptable alternative to cold chain.

We have conducted characterization analyses of certain TFF formulated aluminum salt containing vaccines. Our evaluations suggest that aluminum salt containing vaccines can be successfully converted from liquid suspension into dry powder using our TFF platform and that the dry powder can later be reconstituted at the time of use without causing particle aggregation or a decrease in immunogenicity. In addition, the dry powder vaccine did not aggregate after repeated dry-freezing-and-thawing. We believe that the TFF platform may be used to formulate new vaccines, or to reformulate existing vaccines, that are adjuvanted with aluminum salts into dry vaccine powder without an appreciable decline in immunogenicity.

Furthermore, we have formulated candidate vaccines with non-aluminum adjuvants, including Addavax, and toll-like receptor, or TLR, agonist to boost the immune response. The exploration of TLR agonist adjuvants with universal influenza antigens was the basis of our June 2023 award of a $2.8 million Direct to Phase II Small Business Innovation Research, or SBIR, grant from the National Institute of Allergy and Infectious Diseases to continue development of a novel, pan-flu multivariant mucosal vaccine.

We have engaged pharmaceutical companies in the vaccine space in discussions concerning a potential joint development of TFF formulated vaccines. However, we do not intend to pursue the development of our dry powder formulation of vaccines beyond performance characterization and efficacy data through early animal testing until such time, if ever, as we obtain a development partner. There can be no assurance, however, that our early testing and development will lead to a commercial dry powder formulation of vaccines.

Other Potential Product Candidates. We have identified a number of additional promising drug candidates for dry powder formulation. Many of these potential drug candidates are off-patent drugs for which we would directly pursue the development of a dry powder formulation through the FDA's 505(b)(2) regulatory pathway. We have not commenced meaningful development activities for any of these product candidates at this time and there can be no assurance that we will pursue any of the product candidates below.

Candidate	Intervention	Indication
Rapamycin	Acute Treatment	Lymphangioleiomyomatosis
Alpha-1-antitrypsin	Chronic Treatment	Alpha-1antitrypsin deficiency
GM-CSF (filgrastim)	Treatment	Autoimmune pulmonary alveolar proteinosis
Treprostinil	Treatment	Pulmonary Arterial Hypertension
Pembrolizumab (Keytruda)	Acute Treatment	Cancer: Non-Small Cell Lung Cancer, Liver, brain, melanoma, metastatic
Cisplatin	Acute Treatment	Lung or esophageal cancer
Gemcitabine	Acute Treatment	Lung or esophageal cancer
Isoniazid/Rifampicin	Acute Treatment	Tuberculosis
Amphotericin B	Acute Treatment	Antifungal
Palivizumab	Prophylaxis	Tuberculosis
Ciprofloxacin	Acute Treatment	Infection
Tobramycin	Acute Treatment	Infection
Azithromycin	Acute Treatment	Infection
Calcium channel blockers	Acute Treatment	Raynaud's disease
Sumatriptin	Acute Treatment	Migraine
Stem cells	Lung remodeling	Pneumococcal pneumonia; cardiomyopathy

We believe that our TFF technology provides a diverse and effective way to develop solutions for lung specific disorders. Many potentially beneficial drugs for lung diseases and disorders are unable to be dosed in high enough concentrations to provide therapeutic benefit to the lung due to the systemic nature (oral or IV dosing) of the drug leading to systemic toxicities before the drug reaches therapeutic levels in the lung. We believe our TFF platform has the potential to take these difficult to formulate drugs and develop products to be delivered directly to the lung for treatment of lung disorders. This direct dosing to the lung may reduce plasma levels and has the potential to increase efficacy while reducing side effects.

Our Initial Intended Regulatory Pathway

The 505(b)(2) pathway is intended for developing drugs that are based on products that have been previously approved by the FDA or have already been proven to be safe and effective. A 505(b)(2) product reformulates the known active pharmaceutical ingredient in a new strength or dosage form, or for a new route of administration. 505(b)(2) products have the advantage of potentially significantly lower development costs and shorter development timelines versus traditional new molecular entities. We intend to maximize our use of the 505(b)(2) pathway for our current product candidates.

A 505(b)(2) new drug application, or NDA, is an application that contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant. This regulatory pathway enables the applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of its application. A 505(b)(2) product candidate might rely on the clinical studies or literature of a previously FDA-approved drug or rely on the literature and physician usage of an FDA-approved drug for an unapproved use. The clinical requirements for a 505(b)(2) drug candidate can vary widely from product to product depending primarily on whether the product candidate claims a new indication or claims improved safety compared to the existing approved product, and may include bioequivalence trials, limited safety and efficacy trials, or full Phase I through III trials. Generally, the clinical requirement for a new product candidate is typically unknown until the drug sponsor has obtained FDA feedback during the development process. We believe there is a significant opportunity to pursue dry powder formulations of off-patent drugs using the 505(b)(2) regulatory pathway.

Because our 505(b)(2) dry powder drug candidates will represent a new formulation and a new route of administration of an existing drug, we will need to obtain FDA approval of the TFF prepared drug candidate before we can begin commercialization. However, because we begin our formulation with a drug that has the same active ingredient and that has previously received FDA approval in another form, we believe that in most cases we should qualify for the FDA's 505(b)(2) regulatory pathway, which potentially will take less time and expense than the standard FDA approval process. We have obtained the FDA's agreement that the 505(b)(2) regulatory pathway is applicable for our two initial dry powder drug candidates, TFF TAC and TFF VORI.

TFF TAC has been awarded orphan drug designation. We also believe that in some cases our other dry powder drug products may qualify for the FDA's orphan drug designation. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the United States, or in other limited cases. Orphan drug designation provides for seven years of marketing exclusivity, independent of patent protection, to the company for the product in that designated orphan disease upon approval. In addition, companies developing orphan drugs are eligible for certain incentives, including tax credits for qualified clinical testing. Furthermore, an NDA for a product that has received orphan drug designation is not subject to a prescription drug user fee unless the application includes an indication other than the rare disease or condition for which the drug was designated.

Manufacturing

We have entered into short-term contract manufacturing agreements with Societal CDMO and Experic, LLC for their provision of certain product testing, development and preclinical and clinical manufacturing services for our TFF TAC and TFF VORI product candidates. Our agreements with Societal CDMO and Experic include customary provisions concerning confidentiality, indemnification and intellectual property rights, including our exclusive ownership of all intellectual property developed severally or jointly relating to our TFF technology. We have not entered into agreements with any contract manufacturers for commercial supply; however, we believe that Societal CDMO and Experic, among several other manufacturers, have the experience and the capacity to serve as a commercial contract manufacturer. We believe we will be able to engage a commercial contract manufacturer for our product candidates in a timely manner at competitive pricing.

Each of Societal CDMO's and Experic's facilities and services are conducted in accordance with the FDA's current good manufacturing practices, or cGMPs, regulations. Pursuant to the agreements with Societal CDMO and Experic, they will support clinical supplies and provide release and stability testing of the respective TFF drug product candidate. Specific tasks will include:

- Engineering review and TFF technology installation;
- Familiarization with TFF technology, including powder processing and handling;
- Analytical method transfer, development, and validation;
- Conducting process development trials and short-term supportive stability analysis;
- Scale-up and demonstration batches of the product candidate;
- Manufacture and analytical characterization of materials to support toxicology studies, both placebo and active;
- Process train qualification for cGMP manufacturing;
- Manufacturing and release of cGMP batches for clinical trials; and
- Conducting formal stability study under the guidelines of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, or ICH.

Licenses and Intellectual Property Rights

We hold rights to our TFF technology pursuant to a patent license agreement with the University of Texas at Austin, or UT. UT is the owner of 141 U.S. and international patents and patent applications with claims covering the TFF platform. Pursuant to the patent license agreement, we hold an exclusive worldwide, royalty-bearing license

to the rights to all current and future patents held by UT relating to the TFF technology, including any divisionals, continuations and extensions, in all fields of use. The patent license agreement also provides us with a non-exclusive license to all know-how related to the TFF technology. We have also filed four US and foreign patent applications relating to certain elements of the thin film freezing platform.

We are required to pay royalties to UT in the amount of 2% of net sales received by us from the sale of products covered by the licensed patent rights. We will also be required to make certain milestone payments to UT in connection with the certain regulatory submissions and approvals and pay fees in connection with any assignments or sublicenses, including:

- $50,000 upon each approval of an IND for the first indication of each product candidate;
- $100,000 upon submission of a final Phase II report (or a foreign equivalent) on the first product candidate;
- $250,000 upon submission of a final Phase III report (or a foreign equivalent) on the first product candidate;
- $500,000 upon regulatory approval in the U.S. (or a foreign equivalent) on the first product candidate; and
- $500,000 upon regulatory approval in the U.S. (or a foreign equivalent) on the second product candidate or on the second indication of the first product candidate.

Pursuant to the UT patent license agreement, UT has agreed to consult with us concerning the development and implementation of a strategy for the prosecution and maintenance of the licensed patent rights, including any infringement of the licensed patents rights by third parties. However, UT has retained control and final decision-making authority over such matters. We are responsible for the payment of all fees and expenses involved in the prosecution and maintenance of the licensed patent rights and are obligated to negotiate in good faith with UT over the funding and allocation of any recovery involved in any patent infringement action brought to enforce the licensed patent rights, which are presently scheduled to expire over a period of time commencing in 2023 and ending in 2035.

The term of the UT patent license agreement is co-terminus with the licensed patent rights. However, UT has the right to terminate the patent license agreement, or any part of the licensed patent rights or field of use, in the event of our breach of any provision of the patent license agreement that remains uncured after UT's written notice of breach and an applicable cure period or in the event we initiate any proceeding to challenge the validity or scope of the licensed patent rights. The agreement also contains customary representations, warranties, covenants and indemnities by the parties.

In addition to the licensed patent rights, we also rely on our trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position. We will vigorously defend our intellectual property to preserve our rights and gain the benefit of our technological investments.

Government Regulations and Funding

Pharmaceutical companies are subject to extensive regulation by foreign, federal, state and local agencies, such as the U.S. FDA, and various similar agencies in most countries worldwide. The manufacture, distribution, marketing and sale of pharmaceutical products are subject to government regulation in the U.S. and various foreign countries. Additionally, in the U.S., we must follow rules and regulations established by the FDA requiring the presentation of data indicating that our product candidates are safe and efficacious and are manufactured in accordance with cGMP regulations. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our product candidates, and we may be criminally prosecuted. We, our manufacturers and clinical research organizations, may also be subject to regulations under other foreign, federal, state and local laws, including, but not limited to, the U.S. Occupational Safety and Health Act, the Resource Conservation and Recovery Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries. The U.S. government has increased its enforcement activity regarding illegal marketing practices domestically and internationally. As a result, pharmaceutical companies must ensure their compliance with the Foreign Corrupt Practices Act and federal healthcare fraud and abuse laws, including the False Claims Act.

These regulatory requirements impact our operations and differ from one country to another, so that securing the applicable regulatory approvals of one country does not imply the approval of another country. The approval procedures involve high costs and are manpower intensive, usually extend over many years and require highly skilled and professional resources.

FDA Market Approval Process

The steps usually required to be taken before a new drug may be marketed in the U.S. generally include:

- completion of pre-clinical laboratory and animal testing;
- completion of required chemistry, manufacturing and controls testing;
- the submission to the FDA of an IND, which must be evaluated and found acceptable by the FDA before human clinical trials may commence;
- performance of adequate and well-controlled human clinical trials to establish the safety, pharmacokinetics and efficacy of the proposed drug for its intended use;
- submission and approval of an NDA;
- successful pre-approval inspection of the manufacturer and analytical testing facilities; and
- agreement with FDA of the label language, including the prescribing information insert.

Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND process.

Clinical trials are usually conducted in three phases. Phase I clinical trials are normally conducted in small groups of healthy volunteers to assess safety and tolerability of various dosing regimens and pharmacokinetics. After a safe dose has been established, in Phase II clinical trials the drug is administered to small populations of patients to look for initial signs of efficacy via dose ranging studies in treating the targeted disease or condition and to continue to assess safety and the effective doses to be studied in larger trials in Phase III. In the case of vaccines, the participants are healthy and the signs of efficacy can be obtained in early Phase I, therefore this Phase is defined as Phase I/II. Phase III clinical trials are usually multi-center, double-blind controlled trials in hundreds or even thousands of subjects at various sites to assess as fully as possible both the safety and effectiveness of the drug.

Clinical trials must be conducted in accordance with the FDA's good clinical practice, or GCP, requirements. The FDA may order the temporary or permanent discontinuation of a clinical study at any time or impose other sanctions if it believes that the clinical study is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. An institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at study sites that the IRB oversees and also may halt a study, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group recommends whether or not a trial may move forward at designated check points based on access to certain data from the study. The clinical study sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

As a product candidate moves through the clinical testing phases, manufacturing processes are further defined, refined, controlled and validated. The level of control and validation required by the FDA increases as clinical studies progress. We and the third-party manufacturers on which we rely for the manufacture of our product candidates and their respective components (including the API) are subject to requirements that drugs be manufactured, packaged and labeled in conformity with cGMPs. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, recordkeeping and other requirements.

Assuming completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the product candidate is submitted to the FDA in the form of an NDA, requesting approval to market the product for one or more indications, together with payment of a user fee, unless waived. An NDA includes all relevant data available from pertinent nonclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information on the chemistry, manufacture, controls and proposed labeling, among other things. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product candidate for its intended use to the satisfaction of the FDA. The FDA also conducts a pre-approval inspection of the manufacturer and laboratory prior to approval of the NDA.

If an NDA submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Prescription Drug User Fee Act, or PDUFA, the FDA's goal is to complete its initial review and respond to the applicant within ten months of submission, unless the application relates to an unmet medical need, or is for a serious or life-threatening indication, in which case the goal may be within six months of NDA submission. However, PDUFA goal dates are not legal mandates and the FDA response often occurs several months beyond the original PDUFA goal date. Further, the review process and the target response date under PDUFA may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the NDA. The NDA review process can, accordingly, be very lengthy. During its review of an NDA, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. Data from clinical studies are not always conclusive and the FDA and/or any advisory committee it appoints may interpret data differently than the applicant.

After the FDA evaluates the NDA and inspects manufacturing facilities where the drug product and/or its API will be produced and tested, it will either approve commercial marketing of the drug product with prescribing information for specific indications or issue a complete response letter indicating that the application is not ready for approval and stating the conditions that must be met in order to secure approval of the NDA. If the complete response letter requires additional data and the applicant subsequently submits that data, the FDA nevertheless may ultimately decide that the NDA does not satisfy its criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing. Such post-marketing testing may include Phase IV clinical trials and surveillance to further assess and monitor the product's safety and efficacy after approval. Regulatory approval of products for serious or life-threatening indications may require that participants in clinical studies be followed for long periods to determine the overall survival benefit of the drug.

If the FDA approves one of our product candidates, we will be required to comply with a number of post-approval regulatory requirements. We would be required to report, among other things, certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling for any of our product candidates. Also, quality control and manufacturing procedures must continue to conform to cGMPs after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMPs, which imposes extensive procedural, substantive and record keeping requirements. If we seek to make certain changes to an approved product, such as certain manufacturing changes, we may need FDA review and approval before the change can be implemented.

While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all.

The FDA may also require post-marketing testing, or Phase IV testing, as well as risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions or an approval that could otherwise restrict the distribution or use of the product.

Section 505(b)(2) New Drug Applications

We intend to submit applications for both of our lead therapeutic candidates via the 505(b)(2) regulatory pathway. As an alternate path for FDA approval of new indications or new formulations of previously-approved products, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA. Section 505(b)(2) of the FDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drugs that have a new dosage form, strength, route of administration, formulation or indication.

The Hatch-Waxman Amendments permit the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved product or the FDA's conclusions from prior review of such studies. The FDA may require companies to perform additional studies or measurements to support any changes from the approved product. The FDA may then approve the new product for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication supported by the Section 505(b)(2) application. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification and validation data related to the manufacturing and quality of the new product must be included in an NDA submitted under Section 505(b)(2).

To the extent that the Section 505(b)(2) applicant is relying on the FDA's conclusions regarding studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or 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 Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the reference product has expired. If the Orange Book certifications outlined above are not accomplished, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition affecting fewer than 200,000 individuals in the United States, or in other limited cases. Orphan drug designation (ODD) provides for seven years of market exclusivity in the orphan designated disease, independent of patent protection, to the company with ODD that brings a particular product to market. In addition, companies developing orphan drugs are eligible for certain incentives, including tax credits for qualified clinical testing. In addition, an NDA for a product that has received orphan drug designation is not subject to a prescription drug user fee unless the application includes an indication other than the rare disease or condition for which the drug was designated.

To gain exclusivity, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to the orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same active moiety for the same indication for seven years, except in limited circumstances, such as another drug's showing of clinical superiority over the drug with orphan exclusivity. Competitors, however, may receive approval of different active moieties for the same indication or obtain approval for the same active moiety for a different indication. In addition, doctors may prescribe products for off-label uses and undermine our exclusivity. Orphan drug exclusivity could block the approval of one of our product candidates for seven years if a competitor obtains approval for the same active moiety for the same indication before we do, unless we are able to demonstrate that our product is clinically superior.

We may plan to pursue orphan drug designation and exclusivity for some of our product candidates in the United States, European Union, and other geographies of interest for specific products. We cannot guarantee that we will obtain orphan drug designation for any products in any jurisdiction. Even if we are able to obtain orphan drug designation for a product, we cannot be sure that such product will be approved, that we will be able to obtain orphan drug exclusivity upon approval, if ever, or that we will be able to maintain any exclusivity that is granted.

Continuing Regulatory Compliance

After a drug is approved for marketing and enters the marketplace, numerous regulatory requirements continue to apply. These include, but are not limited to:

- the FDA's cGMP regulations require manufacturers, including third party manufacturers, to follow stringent requirements for the methods, facilities and controls used in manufacturing, processing and packing of a drug product;
- labeling regulations and the FDA prohibitions against the promotion of drugs for unapproved uses (known as off-label uses), as well as requirements to provide adequate information on both risks and benefits during promotion of the drug;
- approval of product modifications or use of a drug for an indication other than approved in an NDA;
- adverse drug experience regulations, which require us to report information on adverse events during pre-market testing and post-approval safety reporting;
- NDA quarterly reporting for the first three years, then annual reporting thereafter, of changes in chemistry, manufacturing and control or CMC, labeling, clinical studies and findings, and toxicology studies from the data submitted in the NDA;
- post-market testing and surveillance requirements, including Phase IV trials, when necessary to protect the public health or to provide additional safety and effectiveness data for the drug; and
- the FDA's recall authority, whereby it can ask, or under certain conditions order, drug manufacturers to recall from the market a product that is in violation of governing laws and regulation. After a drug receives approval, any modification in conditions of use, active ingredient(s), route of administration, dosage form, strength or bioavailability, will require a new approval, for which it may be possible to submit a 505(b)(2), accompanied by additional clinical data necessary to demonstrate the safety and effectiveness of the product with the proposed changes. Additional clinical studies may be required for proposed changes.

Other U.S. Healthcare Laws and Compliance Requirements

For products distributed in the United States, we will also be subject to additional healthcare regulation and enforcement by the federal government and the states in which we conduct our business. Applicable federal and state healthcare laws and regulations include the following:

- The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- The Ethics in Patient Referrals Act, commonly referred to as the Stark Law, and its corresponding regulations, prohibit physicians from referring patients for designated health services (including outpatient drugs) reimbursed under the Medicare or Medicaid programs to entities with which the physicians or their immediate family members have a financial relationship or an ownership interest, subject to narrow regulatory exceptions, and prohibits those entities from submitting claims to Medicare or Medicaid for payment of items or services provided to a referred beneficiary;
- The federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- Health Insurance Portability and Accountability Act of 1996, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of

individually identifiable health information. This statute also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services; and

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government.

Reimbursement

Sales of our product candidates in the United States may depend, in part, on the extent to which the costs of the product candidates will be covered by third-party payers, such as government health programs, commercial insurance and managed health care organizations. These third-party payers are increasingly challenging the prices charged for medical products and services. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payers do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our product candidates on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposes new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries and includes a major expansion of the prescription drug benefit under Medicare Part D. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for product candidates for which we receive marketing approval. However, any negotiated prices for our product candidates covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payers.

On February 17, 2009, the American Recovery and Reinvestment Act of 2009 was signed into law. This law provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes of Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payers, it is not clear how such a result could be avoided and what if any effect the research will have on the sales of our product candidates, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payer to not cover our product candidates could reduce physician usage of the product candidates and have a material adverse effect on our sales, results of operations and financial condition.

Employees and Human Capital Resources

As of the date of this report, we have 19 employees, including our executive officers, and several consultants providing technical, financial and general administrative services.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of stock-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Available Information

Our website is located at *www.tffpharma.com*. The information on or accessible through our website is not part of this annual report on Form 10-K. A copy of this annual report on Form 10-K is located at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an internet site that contains reports and other information regarding our filings at *www.sec.gov*.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Before purchasing our common stock, you should read and consider carefully the following risk factors as well as all other information contained in this report, including our financial statements and the related notes. Each of these risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock. There may be additional risks that we do not presently know of or that we currently believe are immaterial, which could also impair our business and financial position. If any of the events described below were to occur, our financial condition, our ability to access capital resources, our results of operations and/or our future growth prospects could be materially and adversely affected and the market price of our common stock could decline. As a result, you could lose some or all of any investment you may make in our common stock.

Risks Related to Our Business

We will need additional financing to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all. Our consolidated financial statements have been prepared assuming that we will continue as a going concern. Our ability to continue as a going concern will require us to obtain additional capital to fund our operations over the twelve months from the date of this report. As of December 31, 2023, we had total assets of approximately $12.0 million and working capital of approximately $5.2 million. As of December 31, 2023, our liquidity included approximately $5.5 million of cash and cash equivalents. In addition to our cash on hand at year end, on March 22, 2024, we completed a registered direct offering of 147,500 shares of our common stock for the gross proceeds of approximately $1.2 million before deducting placement agent fees and other offering expenses. We intend to seek additional funds through various financing sources, including the sale of our equity and debt securities, licensing fees for our technology and co-development and joint ventures with industry partners, with a preference toward licensing fees for our technology and co-development and joint ventures with industry partners. In addition, we will consider alternatives to our current business plan that may enable to us to achieve revenue producing operations and meaningful commercial success with a smaller amount of capital. However, there can be no guarantees that such funds will be available on commercially reasonable terms, if at all. If such financing is not available on satisfactory terms, we may be unable to further pursue our business plan and we may be unable to continue operations, in which case you may lose your entire investment.

The report of our independent registered public accounting firm for the year ended December 31, 2023 states that due to our lack of revenue from commercial operations, significant losses and need for additional capital, there is substantial doubt about our ability to continue as a going concern.

We are a clinical-stage biopharmaceutical company with limited operating history. We are a biopharmaceutical company, formed in January 2018, and have limited operating history. We have not commenced revenue-producing operations. In 2020 and 2021, we completed Phase I human clinical trials for our TFF TAC and TFF VORI product candidates and as of the date of this report we have Phase 2 clinical trials underway for both product candidates.

To date, our operations have otherwise consisted of preliminary research and development, drug formulation and characterization and testing of our initial product candidates. Our limited operating history makes it difficult for potential investors to evaluate our technology or prospective operations. As a development stage biopharmaceutical company, we are subject to all the risks inherent in the organization, financing, expenditures, complications and delays involved with a new business. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical-stage biopharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we may be unable to:

- successfully implement or execute our business plan, or ensure that our business plan is sound;
- successfully complete pre-clinical and clinical trials and obtain regulatory approval for the marketing of our product candidates;
- successfully demonstrate a favorable differentiation between our dry powder candidates and the current products on the market;
- our ability to commercially license our TFF platform to other pharmaceuticals companies;
- successfully contract for the manufacture of our clinical drug products and establish a commercial drug supply;
- secure market exclusivity and/or adequate intellectual property protection for our product candidates;
- attract and retain an experienced management and advisory team; and
- raise sufficient funds in the capital markets to effectuate our business plan, including product and clinical development, regulatory approval and commercialization for our product candidates.

Investors should evaluate an investment in us in light of the uncertainties encountered by developing companies in a competitive environment. There can be no assurance that our efforts will be successful or that we will ultimately be able to attain profitability. If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected. You must be prepared to lose all of your investment.

We have a history of significant operating losses and anticipate continued operating losses for the foreseeable future. For the fiscal years ended December 31, 2023 and 2022, we incurred a net loss of $21.2 million and $31.8 million, respectively. As of December 31, 2023, we had an accumulated deficit of $118.3 million. We expect to continue to incur substantial expenses without any corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize at least one of our product candidates or enter into one or more commercial license agreements for our TFF platform. However, there can be no assurance we will be able to obtain regulatory approval for any of our product candidates or enter into a commercial license. Even if we are able to obtain regulatory approval and subsequently commercialize our product candidates or successfully license our TFF platform, there can be no assurance that we will generate significant revenues or ever achieve profitability.

We expect to have significant research, regulatory and development expenses as we advance our product candidates toward commercialization. As a result, we expect to incur substantial losses for the foreseeable future, and these losses will be increasing. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable may impair our ability to sustain operations and adversely affect our business and our ability to raise capital. If we are unable to generate positive cash flow within a reasonable period of time, we may be unable to further pursue our business plan or continue operations, in which case you may lose your entire investment.

Our business model is entirely dependent on certain patent rights licensed to us from the University of Texas at Austin, and the loss of those license rights would, in all likelihood, cause our business, as presently contemplated, to fail. We hold an exclusive worldwide, royalty bearing license to the patent rights for the TFF platform in all fields of use granted by the University of Texas at Austin, or UT. Our current business model, which focuses exclusively on the development of drugs using the TFF technology, is based entirely on the availability of the patent rights licensed to us by UT under the patent license agreement. The patent license agreement requires us to pay royalties and milestone payments and conform to a variety of covenants and agreements, and in the event of our breach of the agreement,

UT may elect to terminate the agreement. As of the date of this report, we believe we are in compliance with the patent license agreement and consider our relationship with UT to be excellent. However, in the event of our breach of the patent license agreement for any reason, and our inability to cure such breach within any cure period or obtain a waiver from UT, we could lose the patent license agreement, which would result in our loss of all rights to the TFF technology.

Our business model includes the licensing of our TFF Platform to other pharmaceutical companies, however, technology licensing in the pharmaceutical industry is a lengthy process and subject to several risks and factors outside of our control, and we cannot forecast our ability to successfully license our technology or the length of time it takes to establish a new licensing relationship. Our business model includes the joint development of dry powder formulations of proprietary drugs owned or licensed by other pharmaceutical companies. As of the date of this report, we are at various stages of feasibility studies of proprietary drugs owned by multiple U.S. and international pharmaceutical companies. Our involvement with these pharmaceuticals companies typically begins with our formulation of dry powder versions of one or more proprietary drugs owned by the pharmaceutical company, followed by a period of feasibility testing and evaluation of the dry powder formulations by our potential licensee. Assuming the feasibility study is successful, and our dry powder formulation appears to provide the expected benefits, our ability to convert the successful test into a commercial license of our TFF platform is dependent on a number of risks and factors, many of which are outside our control, including:

- the rate of adoption and incorporation of new technologies, including our TFF platform by members of the pharmaceutical industry generally;
- our potential licensee's internal evaluation of the economic benefits of marketing a dry powder version of a drug that may be currently marketed by the potential licensee, regardless of the benefits or advantages of the dry powder version;
- our potential licensee's internal budgetary and product development issues, including their ability to commit the capital and human resources towards the development and of the dry powder product candidate;
- our potential licensee's willingness to accept our requirements for upfront fees and ongoing royalties; and
- the other risks relating to the adoption of our TFF platform discussed through this "Risk Factor" section.

In addition, we believe that in many cases our potential licensee engages with us in the early-stage feasibility testing as part of their evaluation of multiple drug and drug delivery options and prior to making any decision or commitment to the development of a dry powder version of their proprietary drug product. Consequently, even if our TFF platform is successful in early feasibility studies, our potential licensee may decide, for reasons unrelated to the performance of our TFF platform, not to enter into a license agreement with us. Therefore, we are unable to predict the degree to which our proposed licensing model will be successful.

Unfavorable geopolitical and macroeconomic developments could adversely affect our business, financial condition or results of operations. Our business could be adversely affected by conditions in the U.S. and global economies, the United States and global financial markets and adverse geopolitical and macroeconomic developments, including rising inflation rates, the Ukrainian/Russian and Israeli/Palestinian conflicts and related sanctions, bank failures, and economic uncertainties related to these conditions.

For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In response to rising inflation, the U.S. Federal Reserve has raised, and may again raise, interest rates, which, coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks.

Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022 and the eruption of the Israeli/Palestinian conflict in October 2023, including as a result of economic sanctions and export controls against Russia and countermeasures taken by Russia. The full economic and social impact of these sanctions and countermeasures, in addition to the ongoing military conflicts in Ukraine and Gaza, which could conceivably expand, remains uncertain; however, both the conflicts and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, and/or

supply chain continuity, in both Europe and globally, and has introduced significant uncertainty into global markets. While we do not currently operate in Russia, Ukraine or the Middle East, as the adverse effects of these conflicts continue to develop our business and results of operations may be adversely affected.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs. Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. 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 disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data 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 were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and study subjects, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyberattack. The number and complexity of these threats continue to increase over time. If a material breach of, or accidental or intentional loss of data from, our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices.

Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

We currently have no sales and marketing organization. If we are unable to establish satisfactory sales and marketing capabilities or secure a third-party sales and marketing relationship, we may not be able to successfully commercialize any of our product candidates. At present, we have no sales or marketing personnel. Upon and subject to initial receipt of the requisite regulatory approvals for one or more of our drug products, we intend to commercialize our drug products through a combination of our internal direct sales force, third-party marketing and distribution relationships. In some cases, such as involving the development of combination drugs or the development of dry powder formulations of patented drugs, we intend to pursue the licensing of our TFF technology or enter into a joint development arrangement. If we are not successful in recruiting sales and marketing personnel and building a sales and marketing infrastructure or entering into appropriate collaboration arrangements with third parties, we will have difficulty successfully commercializing our product candidates, which would adversely affect our business, operating results and financial condition.

Even if we enter into third-party marketing and distribution arrangements, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. In terms of establishing a sales and marketing infrastructure, we will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to build an internal sales organization or enter into collaboration arrangements with third parties include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any of our product candidates;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an internal sales and marketing organization.

We plan to be completely dependent on third parties to manufacture our product candidates, and the commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices. We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture our drug candidates for use in our clinical trials or for commercial sales, if any. As a result, we will be obligated to rely on contract manufacturers, if and when any of our product candidates are approved for commercialization. We have entered into short-term contract manufacturing agreements with Soceital CDMO and Experic for their provision of certain product testing, development and clinical manufacturing services for our TFF TAC and TFF VORI product candidates, respectively, and we are currently in discussion with several contract manufacturers for the commercial supply of any drug candidates we are able to bring to market. However, we have not entered into agreements with any contract manufacturers for commercial supply and may not be able to engage contract manufacturers for commercial supply of any of our product candidates on favorable terms to us, or at all, should the need arise.

The facilities used by our current and future contract manufacturers to manufacture our product candidates must be approved by the FDA or comparable foreign regulatory authorities. Such approvals are subject to inspections that will be conducted after we submit a New Drug Application, or NDA, or Biologics License Application, or BLA, to the FDA or their equivalents to other relevant regulatory authorities. We will not control the manufacturing process of our product candidates, and will be completely dependent on our contract manufacturing partners for compliance with Current Good Manufacturing Practices, or cGMPs, for manufacture of both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control, storage, distribution and record keeping relating to our product candidates. If our contract manufacturers do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure or maintain regulatory approval for product made at their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, manufacture, obtain regulatory approval for or market our product candidates, if approved. Likewise, we could be negatively impacted if any of our contract manufacturers elect to discontinue their business relationship with us.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our product candidates, delays, suspensions or withdrawals of approvals, inability to supply product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, manufacture, obtain regulatory approval for or market any of our product candidates, if approved.

If, for any reason, these third parties are unable or unwilling to perform we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our active pharmaceutical ingredients, or APIs, or finished products or should cease doing business with us for any reason, we could experience significant interruptions in the supply of any of our product candidates or may not be able to create a supply of our product candidates at all. Were we to encounter manufacturing difficulties, our ability to produce a sufficient supply of any of our product candidates might be negatively affected. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity available at our third-party manufacturing partners, could impair our ability to supply any of our product candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk drug substance or finished product manufacturer, if we face these or other difficulties with our then current manufacturing partners, we could experience significant interruptions in the supply of any of our product candidates if we decided to transfer the manufacture of any of our product candidates to one or more alternative manufacturers in an effort to deal with such difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in development delays and lost sales. Additionally, we will rely on third parties to supply the raw materials needed to manufacture our product candidates. Any such reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to the operation of one of our contract manufacturers caused by problems with suppliers could delay shipment of any of our product candidates, increase our cost of goods sold and result in lost sales.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. We will face a potential risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk of such liability if we commercialize any of our product candidates. For example, we may be sued if any product we develop, including any of our product candidates, or any materials that we use in our product candidates allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. In the U.S., claims could also be asserted against us under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense of these claims would require us to employ significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our product candidates or any future products that we may develop;
- injury to our reputation;
- failure to obtain regulatory approval for our product candidates;
- withdrawal of participants in our clinical trials;
- costs associated with our defense of the related litigation;
- a diversion of our management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize some or all of our product candidates; and
- a decline in the value of our stock.

As of the date of this report, we have procured insurance coverage for our human clinical trials, which we consider adequate for our current level of clinical testing and development, however we do not carry product liability insurance. We intend to obtain product liability insurance at the time we commence commercial sale of our initial product. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against

potential product liability claims could prevent or inhibit the commercialization of products we develop. Although we will endeavor to obtain and maintain such insurance in coverage amounts we deem adequate, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies would also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. As a result, we may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our business operations could suffer in the event of information technology systems' failures or security breaches. While we believe that we have implemented adequate security measures within our internal information technology and networking systems, our information technology systems may be subject to security breaches, damages from computer viruses, natural disasters, terrorism, and telecommunication failures. Any system failure or security breach could cause interruptions in our operations in addition to the possibility of losing proprietary information and trade secrets. To the extent that any disruption or security breach results in inappropriate disclosure of our confidential information, our competitive position may be adversely affected and we may incur liability or additional costs to remedy the damages caused by these disruptions or security breaches.

Sales of counterfeit versions of our product candidates, as well as unauthorized sales of our product candidates, may have adverse effects on our revenues, business and results of operations and damage our brand and reputation. Our product candidates may become subject to competition from counterfeit pharmaceutical products, which are pharmaceutical products sold under the same or very similar brand names and/or having a similar appearance to genuine products, but which are sold without proper licenses or approvals. Such products divert sales from genuine products, often are of lower cost and quality (having different ingredients or formulations, for example), and have the potential to damage the reputation for quality and effectiveness of the genuine product. Obtaining regulatory approval for our product candidates is a complex and lengthy process. If during the period while the regulatory approval is pending illegal sales of counterfeit products begin, consumers may buy such counterfeit products, which could have an adverse impact on our revenues, business and results of operations. In addition, if illegal sales of counterfeits result in adverse side effects to consumers, we may be associated with any negative publicity resulting from such incidents. Although pharmaceutical regulation, control and enforcement systems throughout the world have been increasingly active in policing counterfeit pharmaceuticals, we may not be able to prevent third parties from manufacturing, selling or purporting to sell counterfeit products competing with our product candidates. Such sales may also be occurring without our knowledge. The existence and any increase in production or sales of counterfeit products or unauthorized sales could negatively impact our revenues, brand reputation, business and results of operations.

Risks Related to Product Regulation

Our success is entirely dependent on our ability to obtain the marketing approval for our product candidates by the FDA and the regulatory authorities in foreign jurisdictions in which we intend to market our product candidates, of which there can be no assurance. We are not permitted to market our product candidates as prescription pharmaceutical products in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are eventually approved for commercialization. As of the date of this report, we have not submitted an NDA to the FDA or comparable applications to other regulatory authorities for any of our product candidates.

Because our initial dry powder drug candidates, TFF TAC and TFF VORI, contain active pharmaceutical ingredients from established drugs that are off-patent, we have gained FDA agreement on the 505(b)(2) regulatory pathway for these product candidates. We believe that our initial drug product candidates will qualify for FDA approval through the FDA's 505(b)(2) regulatory pathway and through similar regulatory paths in other foreign jurisdictions. The clinical requirements for a 505(b)(2) drug candidate can vary widely from product to product depending primarily on whether the product candidate claims a new indication, provides for a different route of administration, or claims improved safety compared to the existing approved product, and may include bioequivalence trials, limited safety and efficacy trials, or full Phase I through III trials. To the extent we claim that our drug product candidates target a

new indication or offer improved safety compared to the existing approved products, and it is our present expectation that we will do so in many cases, it is likely that we will be required to conduct additional clinical trials, potentially including a full Phase I through Phase III development program, in order to obtain marketing approval.

Our business model is to pursue the development of off-patent drugs for which we would directly pursue the development of a dry powder formulation through the FDA's 505(b)(2) regulatory pathway; however, not all of our product candidates will target off-patent drugs. For novel product candidates, we expect to require a full NDA through the FDA's 505(b)(1) regulatory pathway.

Our success depends on our receipt of the regulatory approvals described above, and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following:

- the demonstration of phase appropriate chemistry, manufacturing, and controls testing;
- the results of toxicology studies may not support the filing of an IND and/or NDA for our product candidates;
- the FDA or comparable foreign regulatory authorities or Institutional Review Boards, or IRB, may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of our product candidates' safety and efficacy;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, European Medicines Agency, or EMA, or other regulatory agencies for us to receive marketing approval for any of our product candidates;
- the dosing of our product candidates in a particular clinical trial may not be at an optimal level to demonstrate safety and/or efficacy of the product;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our product candidates;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval of our product candidates.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory approval for our product candidates for the foregoing, or any other reasons, will prevent us from commercializing our product candidates, and our ability to generate revenue will be materially impaired.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Our business model depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. In 2020 and 2021, we completed Phase I human clinical trials for our TFF TAC and TFF VORI product candidates, and in 2022 we initiated Phase 2 clinical trials for both product candidates. In March 2024, we announced our decision to prioritize clinical development of TFF TAC based on positive Phase 2 data and to evaluate strategic options for TFF VORI, however, there can be no

assurance that the Phase 2 trial for TFF TAC will be successful, we will be successful in finding a strategic option for TFF VORI or that we will continue clinical development of TFF TAC in support of an approval from the FDA or comparable foreign regulatory authorities for any indication. We note that most product candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials for TFF TAC and TFF VORI can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. Therefore, our business currently depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur.

Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited. If approved for marketing, the commercial success of our product candidates will depend upon each product's acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance for any of our product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies;
- efficacy of our product candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates in applicable therapeutic and vaccine guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidates not commercially viable. For example, regulatory

authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for any of our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the drug. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates.

Even if we obtain marketing approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates. Even if we obtain regulatory approval for any of our product candidates for an indication, the FDA or foreign equivalent may still impose significant restrictions on their indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase IV clinical trials, and post-market surveillance to monitor safety and efficacy. Our product candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current cGMPs, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

With respect to sales and marketing activities related to our product candidates, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if any of our product candidates are approved for a particular indication, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for our product candidates, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. If we or a regulatory agency discover

previously unknown problems with a product candidate, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. If we fail to comply with the regulatory requirements in international markets and/or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even though we may apply for orphan drug designation for a product candidate, we may not be able to obtain orphan drug marketing exclusivity. We believe that in some cases our dry powder drug products may qualify for the FDA's orphan drug status. There is no guarantee that the FDA will grant any future application for orphan drug designation for any of our product candidates, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation

does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for any of our product candidates in the indications for which we think they might qualify, if we elect to seek such applications.

Current and future legislation 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. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our product candidates and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or, collectively, the Health Care Reform Law, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposed a significant annual fee on companies that manufacture or import branded prescription drug products.

The Health Care Reform Law remains subject to legislative efforts to repeal, modify or delay the implementation of the law. If the Health Care Reform Law is repealed or modified, or if implementation of certain aspects of the Health Care Reform Law are delayed, such repeal, modification or delay may materially adversely impact our business, strategies, prospects, operating results or financial condition. We are unable to predict the full impact of any repeal, modification or delay in the implementation of the Health Care Reform Law on us at this time. Due to the substantial regulatory changes that will need to be implemented by Centers for Medicare & Medicaid Services, or CMS, and

others, and the numerous processes required to implement these reforms, we cannot predict which healthcare initiatives will be implemented at the federal or state level, the timing of any such reforms, or the effect such reforms or any other future legislation or regulation will have on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce or eliminate our profitability.

Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of any of our product candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA or a comparable foreign regulatory authority failing to grant permission to proceed and placing the clinical study on hold;
- subjects for clinical testing failing to enroll or remain enrolled in our trials at the rate we expect;
- a facility manufacturing any of our product candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing our product candidates, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports from clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGMP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA, comparable foreign regulatory authorities, or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;
- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- adding new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason; and
- government or regulatory delays or "clinical holds" requiring suspension or termination of a trial.

Product development costs for any of our product candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA, comparable foreign regulatory authorities, and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of any of our product candidates, its commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring competing products to market before we do, and the commercial viability of any of our affected product candidates could be significantly reduced.

Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues. Our ability to successfully market our product candidates will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our product candidates and related treatments. Countries in which any of our product candidates are sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell our product candidates profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope. Increasingly, third-party payors attempt to contain health care costs in ways that are likely to impact our development of products including:

- failing to approve or challenging the prices charged for health care products;
- introducing reimportation schemes from lower priced jurisdictions;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

Risks Relating to Our Intellectual Property Rights

We are dependent on rights to certain technologies licensed to us. We do not have complete control over these technologies and any loss of our rights to them could prevent us from selling our product candidates. As noted above, our business model is entirely dependent on certain patent rights licensed to us by the University of Texas at Austin, or UT. See, "*Risk Factors — Risks Relating to Our Business — Our business model is entirely dependent on certain patent rights licensed to us from the University of Texas at Austin, and the loss of those license rights would, in all likelihood, cause our business, as presently contemplated, to fail.*" Because we will hold those rights as a licensee, we have limited control over certain important aspects of those patent rights. Pursuant to the patent license agreement, UT has reserved the right to control all decisions concerning the prosecution and maintenance of all U.S. and foreign patents, as well as all decisions concerning the enforcement of any actions against potential infringers of the patent rights. We believe that UT shares a common interest in these matters with us, and UT has agreed to consult with us on the prosecution and enforcement of possible infringement claims as well as other matters for which UT has retained control. However, there can be no assurance that UT will agree with our views as to how best to prosecute, maintain and defend the patent rights subject to the patent license agreement.

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights. Our commercial success will depend, in part, on our ability to successfully defend the patent rights subject to our patent license agreement with UT against third-party challenges and successfully enforcing these patent rights against third party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in the patent applications subject to the UT patent license agreement. The patents and patent applications relating to our TFF platform and related technologies may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies.

The degree of future protection afforded by the patent rights licensed to us is uncertain because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. We cannot be certain that any patent application owned by a third party will not have priority over patent applications in which we hold license rights or that we will not be involved in interference, opposition or invalidity proceedings before United States or foreign patent offices.

Additionally, if UT were to initiate legal proceedings against a third party to enforce a patent covering any of our product candidates, the defendant could counterclaim that such patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office, or the U.S. PTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g. opposition proceedings. Such proceedings could result in revocation or amendment of UT's patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which UT and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on any of our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

In the future, we may rely on know-how and trade secrets to protect technology, especially in cases in which we believe patent protection is not appropriate or obtainable. However, know-how and trade secrets are difficult to protect. While we intend to require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we fail to obtain or maintain patent protection or trade secret protection for our product candidates or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts. Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third-party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we

may be required to license in order to research, develop or commercialize any of our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Third parties may hold proprietary rights that could prevent any of our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to any of our product candidates or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market any of our product candidates or any future product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidates or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing any of our product candidates or a future product candidate, which could harm our business, financial condition and operating results.

We expect that there are other companies, including major pharmaceutical companies, working in the areas competitive to our product candidates which either has resulted, or may result, in the filing of patent applications that may be deemed related to our activities. If we were to challenge the validity of these or any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we were to challenge the validity of these or any issued United States patent in an administrative trial before the Patent Trial and Appeal Board in the U.S. PTO, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity or enforceability. Even if we are successful, litigation could result in substantial costs and be a distraction to management.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is commonplace in our industry, we will employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our business could be adversely affected by conditions in the U.S. and global economies. The United States and global financial markets and adverse geopolitical and macroeconomic developments, including high inflation, the conflicts in Ukraine and the Middle East and related sanctions, bank failures, and economic uncertainties related to these conditions could adversely affect our business.

Risks Related to Owning Our Common Stock

The market price of our shares may be subject to fluctuation and volatility. You could lose all or part of your investment. The market price of our common stock is subject to wide fluctuations in response to various factors, some of which are beyond our control. Since shares of our common stock were sold in our initial public offering in October 2019 at a price of $125.00 per share, the reported high and low sales prices of our common

stock have ranged from $5.15 to $528.50 through March 22, 2024. The market price of our shares on the NASDAQ Capital Market may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated variations in our and our competitors' results of operations and financial condition;
- market acceptance of our product candidates;
- changes in earnings estimates or recommendations by securities analysts, if our shares are covered by analysts;
- development of technological innovations or new competitive products by others;
- announcements of technological innovations or new products by us;
- publication of the results of preclinical or clinical trials for our product candidates;
- failure by us to achieve a publicly announced milestone;
- delays between our expenditures to develop and market new or enhanced products and the generation of sales from those products;
- developments concerning intellectual property rights, including our involvement in litigation brought by or against us;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products;
- changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses;
- changes in our expenditures to promote our product candidates;
- our sale or proposed sale, or the sale by our significant stockholders, of our shares or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our shares; and
- general economic and market conditions and other factors, including factors unrelated to our operating performance.

If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline. In addition, independent industry analysts may provide reviews of our product candidates and our TFF platform's capabilities, as well as those of our competitors, and perception of our offerings in the marketplace may be significantly influenced by these reviews. We have no control over what these industry analysts report, and because industry analysts may influence current and potential customers, our brand could be harmed if they do not provide a positive review of our products and platform capabilities or view us as a market leader.

Future capital raises may dilute your ownership and/or have other adverse effects on our operations. If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced and these stockholders may experience substantial dilution. If we raise additional funds by issuing debt securities,

these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our intellectual property or candidate products, or to grant licenses on terms that are not favorable to us.

We are an "emerging growth company" under the JOBS Act of 2012 and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors. We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements;
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments; and
- extended transition periods available for complying with new or revised accounting standards.

We have chosen to take advantage of all of the benefits available under the JOBS Act, including the exemptions discussed above. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an "emerging growth company" for up to five years, although we will lose that status sooner if our revenues exceed $1.07 billion, if we issue more than $1 billion in non-convertible debt in a three year period, or if the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30 in any future year.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. We are required to provide a report on management's assessment of our internal control over financial reporting. Once we are neither an emerging growth company nor a non-accelerated filed, we will be required to obtain an attestation from our independent registered public accounting firm on our internal control report. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retrospective changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common shares. There is also a risk that neither we nor our independent registered public accounting firm (when applicable in the future) will be able to conclude within the prescribed timeframe that internal controls over financial reporting is effective as required by Section 404. As a result, investors could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

We have not paid dividends in the past and have no immediate plans to pay dividends. We plan to reinvest all of our earnings, to the extent we have earnings, to cover operating costs and otherwise become and remain competitive. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend. Therefore, you should not expect to receive cash dividends on our common stock.

We may be at an increased risk of securities class action litigation. Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable. The provisions of our second amended and restated certificate of incorporation, or Certificate, and amended and restated bylaws and applicable provisions of Delaware law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. The provisions in our Certificate and amended and restated bylaws:

- limit who may call stockholder meetings;
- do not provide for cumulative voting rights; and
- provide that all board vacancies may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum.

In addition, Section 203 of the Delaware General Corporation Law may limit our ability to engage in any business combination with a person who beneficially owns 15% or more of our outstanding voting stock unless certain conditions are satisfied. This restriction lasts for a period of three years following the share acquisition. These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

Our Certificate and amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees. Provisions in our Certificate and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed to us or our stockholders by any of our directors, officers or other employees;
- any action asserting a claim against us or any of our directors, officers or other employees arising pursuant to any provision of Delaware law or our charter documents; or
- any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine, but excluding actions to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

These exclusive forum provisions do not apply to claims under the Securities Act or the Exchange Act. These exclusive forums provisions, however, do provide that if no state court located in the State of Delaware has jurisdiction, the federal district court for the District of Delaware shall be the exclusive forum. By becoming a stockholder in our company, you will be deemed to have notice of and have consented to the provisions of our Certificate and amended and restated bylaws related to choice of forum, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. The choice of forum provisions in our Certificate and amended and restated bylaws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or any of our directors, officers or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in our Certificate and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

Risk Management and Strategy. We employ processes for assessing, identifying, and managing material risks from cybersecurity threats that are incorporated into our overall risk management system. These items are designed to help protect our information assets from internal and external threats and protect the integrity and confidentiality of our data. Our system includes procedural and technical safeguards, response plans, and reviews of our policies. We engage various external entities, including consultants, to improve and enhance our cybersecurity oversight. We provide all employees and consultants with cybersecurity and prevention training including timely and relevant topics covering social engineering, phishing, mobile security, and data protection and the need for reporting incidents and suspicious events immediately. With respect to third parties that assist in our cybersecurity oversight, we obtain reports to assess the security of their systems and processes. We engage in ongoing monitoring of all third-party providers to ensure compliance with our cybersecurity standards.

Although we develop and maintain systems and controls designed to prevent cybersecurity threats from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with service providers and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

As of the date of this report, we are not aware of any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition.

Governance. Our senior management team conducts the regular assessment and management of material risks from cybersecurity threats, including review with our IT team and third-party service providers. All employees and consultants are directed to report to our senior management any irregular or suspicious activity that could indicate a cybersecurity threat or incident. The Audit Committee of our Board of Directors evaluates our cybersecurity assessment and management policies, including quarterly interviews with our senior officers and independent registered accounting firm.

Item 2. Properties

We lease approximately 1,000 square feet of office space in Fort Worth, Texas at the rate of $4,100 per month. The lease has no term and is on a month-to-month basis. We also lease approximately 3,750 square feet of lab space in Austin, Texas at a current rate of $7,163 per month. The lease agreement is for three years and expires on May 31, 2025. The lease has an additional three-year option for renewal.

Item 3. Legal Proceedings

As of the date of this report, there are no legal proceedings to which we or our properties are subject. We may be involved, from time to time, in legal proceedings and claims arising in the ordinary course of its business. Such matters are subject to many uncertainties and outcomes and are not predictable with assurance.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Repurchases of Equity Securities

Market Information

Our common stock has traded on the NASDAQ Stock Market under the symbol "TFFP."

Holders of Record

As of March 22, 2024, there were six holders of record of our common stock.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We presently intend to retain earnings to finance the operation and expansion of our business.

Equity Compensation Plan Information

We have adopted the TFF Pharmaceuticals, Inc. 2018 Stock Incentive Plan ("2018 Plan") providing for the grant of non-qualified stock options and incentive stock options to purchase shares of our common stock and for the grant of restricted and unrestricted share grants. We reserved 131,379 shares of our common stock under the 2018 Plan. All officers, directors, employees and consultants to our company are eligible to participate under the 2018 Plan. The purpose of the 2018 Plan is to provide eligible participants with an opportunity to acquire an ownership interest in our company.

In September 2021, we adopted the TFF Pharmaceuticals, Inc. 2021 Stock Incentive Plan ("2021 Plan"), which was also approved by our stockholders at our annual meeting of stockholders held on November 4, 2021. The 2021 Plan provides for the grant of non-qualified stock options and incentive stock options to purchase shares of our common stock, the grant of restricted and unrestricted share awards and grant of restricted stock units. We reserved 168,000 shares of our common stock under the 2021 Plan. All of our employees and any subsidiary employees (including officers and directors who are also employees), as well as all of our nonemployee directors and other consultants, advisors and other persons who provide services to us will be eligible to receive incentive awards under the 2021 Plan.

The following table sets forth certain information as of December 31, 2023 about our stock plans under which our equity securities are authorized for issuance.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options	(b) Weighted-Average Exercise Price of Outstanding Options	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected In Column (a))
Equity compensation plans approved by security holders	233,340	$ 74.63	46,007
Equity compensation plans not approved by security holders	—	—	—
Total	233,340	$ 74.63	46,007

Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 6. Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

General

We were formed as a Delaware corporation on January 24, 2018 for the purpose of developing and commercializing innovative drug products based on our patented Thin Film Freezing, or TFF, technology platform". Since our formation, we have focused on the development of our initial drug candidates, the establishment of strategic relationships with established pharmaceutical companies for the licensing of our TFF technology platform and the pursuit of additional working capital. We have not commenced revenue-producing operations.

Except as otherwise indicated, all share and share price this report gives effect to a reverse stock split effected on December 19, 2023 at a ratio of one for 25.

Since January 1, 2022, we have engaged in the following financing transactions:

ATM Offering. On June 10, 2022, we entered into an Open Market Sale Agreement with Jefferies LLC, as agent, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $35.0 million in an "at-the-market" offering, to or through the agent. From July 2022 through September 30, 2022, we sold 4,160 shares of our common stock at average price of $149.00 per share resulting in net proceeds of approximately $405,000, after deducting sales agent commissions and offering expenses. During 2023, we sold 7,062 shares of its common stock through the ATM offering at an average price of $8.80 per share resulting in net proceeds of approximately $60,000. We terminated our Open Market Sale Agreement with Jefferies LLC in March 2024.

November 2022 Public Offering. In November 2022, we completed a public offering, selling 371,304 shares of common stock and warrants to purchase up to 185,652 shares of common stock at an offering price of $28.75 per share. We received gross proceeds of approximately $10,675,000. In addition, we granted the underwriter a 45-day option to purchase an additional 15% of the number of shares of common stock and warrants at the public offering price, less underwriting discounts and commissions. The option was exercised in November 2022 and the underwriter purchased an additional 55,696 shares of common stock and warrants to purchase up to 27,848 shares of common stock and we received additional gross proceeds of approximately $1,601,251. We received net proceeds of $11,235,626, after deducting underwriting discounts and offering-related expenses.

August 2023 Public Offering. On August 17, 2023, we completed a public offering, selling 915,216 shares of common stock, including 119,376 shares of common stock issued pursuant to the full exercise by the underwriter of its over-allotment option, at an offering price of $6.25 per share. The Company received gross proceeds of approximately $5.7 million. The Company received net proceeds of approximately $5.1 million, after deducting underwriting discounts and offering-related expenses.

March 2024 Registered Direct Offering. On March 22, 2024, we completed a registered direct offering, selling 147,500 shares of common stock and warrants to purchase up to 147,500 shares of common stock at an offering price of $8.00 per share. The warrants are immediately exercisable upon issuance at an exercise price of $8.00 per share and will expire five and one-half years following the date of issuance. We received gross proceeds of approximately $1.2 million before deducting placement agent fees and other offering expenses.

Results of Operations

We were formed in January 2018 and have not commenced revenue-producing operations. To date, our operations have consisted of the development and early-stage testing, Phase 1 human clinical trials of our initial product candidates and the current Phase 2 clinical trials of our TFF TAC and TFF VORI. In March 2024, we announced our decision to prioritize clinical development of TFF TAC based on positive Phase 2 data and to evaluate strategic options for TFF

VORI. We do not expect that our deemphasis of the development of TFF VORI will materially impact the trend in our expenditures on clinical development. We have generated limited grant revenue and non-recurring revenue under feasibility and material transfer agreements.

The following table summarizes our results of operations with respect to the items set forth below for the fiscal years ended December 31, 2023 and 2022 together with the percentage change for those items.

	Years ended December 31,			
	2023	2022	Increase (Decrease)	Change
Revenue	$ 733,871	$ 495,805	$ 238,066	48%
Research and development expense	$ 12,061,422	$ 18,496,340	$ (6,434,918)	(35)%
General and administrative expense	10,567,111	13,796,255	(3,229,144)	(23)%
Total operating expense	$ 22,628,533	$ 32,292,595	$ (9,664,062)	(30)%

We have entered into feasibility and material transfer agreements with third parties that provide us with funds in return for certain research and development activities. On June 23, 2023, we were awarded a Direct to Phase II Small Business Innovation Research, or SBIR, grant of approximately $2.8 million to continue development of a novel, pan-flu multivariant mucosal vaccine. During the years ended December 31, 2023 and 2022, we recognized $733,871 and $495,805, respectively, of revenue from the feasibility and material transfer agreements and the SBIR grant. The costs associated with the feasibility and material transfer agreements and SBIR grant are expensed as incurred and are reflected as a component of research and development expense.

Research and development expense was as follows for the years indicated:

	Years ended December 31,			
	2023	2022	Increase (Decrease)	Change
Manufacturing and related	$ 4,756,145	$ 7,870,281	$ (3,114,136)	(40)%
Clinical and preclinical	2,647,397	7,509,857	(4,862,460)	(65)%
Payroll, stock-based compensation and related	3,679,251	2,244,889	1,434,362	64%
Other	978,629	871,313	107,316	12%
Total research and development expense	$ 12,061,422	$ 18,496,340	$ (6,434,918)	(35)%

Research and development expense decreased during the year ended December 31, 2023 compared to the year ended December 31, 2022 due to a $4.9 million reduction in clinical and preclinical expenses and a $3.1 million reduction in manufacturing and related expenses, offset by increases of $1.4 million payroll expense and $0.1 million other research and development expenses. Research and development expenses during the year ended December 31, 2022 were impacted by the initial set-up costs for the Phase 2 trial of TFF VORI, completion of the Phase 1 trial of TFF Niclosamide and the suspension of the joint development and collaboration agreement with Augmenta Bioworks, Inc.

General and administrative expense was as follows for the years indicated:

	Years ended December 31,			
	2023	2022	Increase (Decrease)	Change
Payroll, stock-based compensation and related	$ 4,901,101	$ 5,495,343	$ (594,242)	(11)%
Insurance and office expense	2,035,540	2,856,559	(821,019)	(29)%
Professional fees and patent expense	2,009,770	2,482,158	(472,388)	(19)%
Market research	624,274	1,207,569	(583,295)	(48)%
Consulting	562,625	1,333,541	(770,916)	(58)%
Other	433,801	421,085	12,716	3%
Total general and administrative expense	$ 10,567,111	$ 13,796,255	$ (3,229,144)	(23)%

General and administrative expense decreased during the year ended December 31, 2023 compared to the year ended December 31, 2022 due to decreases of $0.8 million in insurance and office expenses, $0.8 million in consulting expenses, $0.6 million in payroll related expense, $0.6 million in market research expenses and $0.5 million in professional fees and patent expenses. The decrease in general and administrative expenses was due in part to strategic cost reduction efforts implemented by management.

The following table summarizes our other income and interest income, net for the years ended December 31, 2023 and 2022 together with the percentage change for those items.

	Years ended December 31,			
	2023	2022	Increase (Decrease)	Change
Interest income, net	$ 266,188	$ 26,728	$ 239,460	896%
Change in fair value of note receivable	$ 385,243	$ —	$ 385,243	100%

Interest income increased during fiscal 2023 due to the interest accrued on the note receivable and increased interest earned on cash equivalents. Other income during fiscal 2023 is the change in the fair value of the note receivable.

We incurred a net loss of $21.2 million and $31.8 million for the fiscal years ended December 31, 2023 and 2022, respectively.

Financial Condition

As of December 31, 2023, we had total assets of approximately $12.0 million and working capital of approximately $5.2 million. As of December 31, 2023, our liquidity included approximately $5.5 million of cash and cash equivalents. In addition to our cash on hand at year end, on March 22, 2024, we completed a registered direct offering of 147,500 shares of our common stock for the gross proceeds of approximately $1.2 million before deducting placement agent fees and other offering expenses.

As of the date of this report, we will need additional capital to fund our operations over the 12 months following the date of this report. We intend to seek additional funding through various financing sources, including the sale of our equity and/or debt securities, and/or licensing fees for our technology and co-development and joint ventures with industry partners. In addition, we will consider alternatives to our current business plan that may enable us to achieve our product development goals with a smaller amount of capital. However, there can be no guarantees that such funds, including any potential funds through the sale of our equity securities, it will be available on commercially reasonable terms, if at all. If such financing is not available on satisfactory terms, we may be unable to further pursue our business plan and we may be unable to continue operations, in which case you may lose your entire investment. Accordingly, management believes that there is substantial doubt regarding our ability to continue as a going concern through the next 12 months from the date of this filing.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended December 31, 2023 and 2022:

	2023	2022
Net cash used in operating activities	$ (16,038,195)	$ (27,342,160)
Cash used in investing activities	(94,750)	(1,551,326)
Cash flows provided by financing activities	5,013,412	11,751,003
Effect of exchange rate changes	(14,669)	(39,874)
Net change in cash and cash equivalents	$ (11,134,202)	$ (17,182,357)

The decrease in cash used in operating activities is primarily a result of a lower net loss during 2023 compared to 2022. The decrease in cash used in investing activities is related to reduced purchases of property and equipment during 2023 compared to 2022. The financing activities for 2023 consist of the August 2023 public offering and proceeds from the ATM offering, offset by costs incurred related to the ATM. The financing activities for 2022 primarily consist of the November 2022 public offering and proceeds from the ATM offering.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are 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. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to our consolidated financial statements included herein, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Critical Accounting Policies

Research and Development Expenses and Related Prepaid and Accrued Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our research and development expenses as of each balance sheet date based on facts and circumstances known to us at that time. The significant estimates in our research and development expenses include the costs incurred for services performed by our vendors in connection with services for which we have not yet been invoiced. We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows.

For the majority of our service providers, payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Critical Accounting Estimates

Stock-Based Compensation

We compute stock-based compensation in accordance with authoritative guidance. We use the Black-Scholes-Merton option-pricing model to determine the fair value of its stock options. The Black-Scholes-Merton option-pricing model includes various assumptions, including the fair market value of our common stock, expected life of stock options, the expected volatility and the expected risk-free interest rate, among others. These assumptions reflect our best estimates, but they involve inherent uncertainties based on market conditions generally outside our control.

As a result, if other assumptions had been used, stock-based compensation cost, as determined in accordance with authoritative guidance, could have been materially impacted. Furthermore, if we use different assumptions on future grants, stock-based compensation cost could be materially affected in future periods.

For grants of our common stock, we use the closing stock price on the date of grant as the fair value of the common stock.

Fair Value Option — Convertible Note Receivable

We have elected to measure our convertible note receivable using the fair value option as permitted under applicable accounting guidance. Under the fair value option, bifurcation of an embedded derivative is not necessary, and all related gains and losses on the host contract and derivative due to change in the fair value will be reflected in other income (expense), net in the consolidated statements of operations. Interest accrues on the unpaid principal balance on a quarterly basis and is recognized in interest income in the consolidated statements of operations.

The decision to elect the fair value option is determined on an instrument-by-instrument basis and must be applied to an entire instrument and is irrevocable once elected. Pursuant to this guidance, assets and liabilities are measured at fair value based, in part, on general economic and stock market conditions and those characteristics specific to the underlying investments. The carrying value is adjusted to estimated fair value at the end of each quarter, required to be reported separately in our consolidated balance sheets from those instruments using another accounting method.

To estimate the fair value of the convertible note receivable requires management to utilize unobservable inputs, such as the equity value of Augmenta, the timing and probability of future financing events, optional conversion to common stock, and repayment at maturity. If these estimates were changed, our change in fair value of the convertible note receivable could differ materially.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
TFF Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of TFF Pharmaceuticals, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and 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 "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of 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 accounting principles generally accepted in the United States of America.

Explanatory Paragraph — Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has not generated revenue from commercial operations since inception, has incurred significant losses and needs to raise additional capital to fund its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. 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 audits 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.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2018.

New York, NY
March 28, 2024

TFF PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,478,113	$ 16,612,315
Research and development tax incentive receivable	433,852	186,507
Prepaid assets and other current assets	1,678,353	2,226,344
Total current assets	7,590,318	19,025,166
Operating lease right-of use asset, net	119,529	196,044
Property and equipment, net	1,999,781	3,078,342
Note receivable – Augmenta	2,310,000	1,812,975
Other assets	7,688	7,688
Total assets	$ 12,027,316	$ 24,120,215
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 958,442	$ 919,607
Accrued liabilities	1,285,586	4,430
Deferred research grant revenue	101,000	126,000
Current portion of operating lease liability	83,512	80,625
Total current liabilities	2,428,540	1,130,662
Operating lease liability, net of current portion	31,742	110,094
Total liabilities	2,460,282	1,240,756
Commitments and contingencies (see Note 5)		
Stockholders' equity:		
Common stock; $0.001 par value, 180,000,000 shares and 45,000,000 authorized as of December 31, 2023 and 2022, respectively; 2,370,000 and 1,447,722 shares issued and outstanding as of December 31, 2023 and 2022, respectively	2,370	1,448
Additional paid-in capital	128,044,509	120,105,728
Accumulated other comprehensive loss	(148,192)	(139,295)
Accumulated deficit	(118,331,653)	(97,088,422)
Total stockholders' equity	9,567,034	22,879,459
Total liabilities and stockholders' equity	$ 12,027,316	$ 24,120,215

The accompanying notes are an integral part of these consolidated financial statements.

TFF PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years Ended December 31,	
	2023	**2022**
CONSOLIDATED STATEMENTS OF OPERATIONS		
Revenue	$ 733,871	$ 495,805
Operating expenses:		
Research and development	12,061,422	18,496,340
General and administrative	10,567,111	13,796,255
Total operating expenses	22,628,533	32,292,595
Loss from operations	(21,894,662)	(31,796,790)
Other income (expense):		
Interest income, net	266,188	26,728
Change in fair value of note receivable	385,243	—
Total other income, net	651,431	26,728
Net loss	$ (21,243,231)	$ (31,770,062)
Net loss per share, basic and diluted	$ (11.85)	$ (26.49)
Weighted average common shares outstanding, basic and diluted	1,792,551	1,199,191
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS		
Net loss	$ (21,243,231)	$ (31,770,062)
Other comprehensive loss:		
Foreign currency translation adjustments	(8,897)	(90,374)
Comprehensive loss	$ (21,252,128)	$ (31,860,436)

The accompanying notes are an integral part of these consolidated financial statements.

TFF PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2022	1,014,870	$ 1,015	$ 104,103,325	$ (48,921)	$ (65,318,360)	$ 38,737,059
Sale of common stock, net of offering costs	4,160	4	404,551	—	—	404,555
Sales of common stock and warrants through public offering, net of offering costs	427,000	427	11,235,199	—	—	11,235,626
Issuance of common stock for stock option exercises	1,692	2	110,820	—	—	110,822
Stock-based compensation	—	—	4,251,833	—	—	4,251,833
Foreign currency translation adjustment	—	—	—	(90,374)	—	(90,374)
Net loss	—	—	—	—	(31,770,062)	(31,770,062)
Balance, December 31, 2022	1,447,722	1,448	120,105,728	(139,295)	(97,088,422)	22,879,459
Sales of common stock through the at-the-market offering	7,062	7	60,258	—	—	60,265
Costs related to the at-the-market offering	—	—	(108,700)	—	—	(108,700)
Sales of common stock and in public offering, net of offering costs	915,216	915	5,063,807	—	—	5,064,722
Cash paid for fractional shares resulting from reverse stock split	—	—	(2,875)	—	—	(2,875)
Stock-based compensation	—	—	2,926,291	—	—	2,926,291
Foreign currency translation adjustment	—	—		(8,897)	—	(8,897)
Net loss	—	—	—	—	(21,243,231)	(21,243,231)
Balance, December 31, 2023	2,370,000	$ 2,370	$ 128,044,509	$ (148,192)	$ (118,331,653)	$ 9,567,034

The accompanying notes are an integral part of these consolidated financial statements.

TFF PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (21,243,231)	$ (31,770,062)
Adjustment to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,926,291	4,251,833
Interest accrued on note receivable	(111,782)	—
Change in fair value of note receivable	(385,243)	—
Write-off of construction-in-process	747,348	—
Depreciation and amortization	502,480	388,221
Changes in operating assets and liabilities:		
Receivable due from collaboration agreement	—	(184,272)
Research and development tax incentive receivable	(259,797)	751,403
Prepaid assets and other current assets	1,480,729	181,604
Accounts payable	38,382	(577,105)
Accrued liabilities	367,093	(412,480)
Deferred revenue	(25,000)	76,000
Operating lease obligation	(75,465)	(47,302)
Net cash used in operating activities	(16,038,195)	(27,342,160)
Cash flows from investing activities:		
Purchases of property and equipment	(94,750)	(1,551,326)
Net cash used in investing activities	(94,750)	(1,551,326)
Cash flows from financing activities:		
Sales of common stock through ATM, net of offering costs	60,265	404,555
Payment of offering costs in connection with ATM	(108,700)	—
Sale of common stock in public offering, net of offering costs	5,064,722	—
Net proceeds from issuances of common stock and warrants	—	11,235,626
Proceeds from issuance of common stock for stock option exercises	—	110,822
Payments to settle fractional shares resulting from reverse stock split	(2,875)	—
Net cash provided by financing activities	5,013,412	11,751,003
Effect of exchange rate changes on cash and cash equivalents	(14,669)	(39,874)
Net change in cash and cash equivalents	(11,134,202)	(17,182,357)
Cash and cash equivalents at beginning of year	16,612,315	33,794,672
Cash and cash equivalents at end of year	$ 5,478,113	$ 16,612,315
Supplemental disclosure of non-cash investing and financing activities:		
Financing obtained for insurance premiums	$ 914,063	$ —
ROU asset obtained for new operating lease	$ —	$ 238,021
Conversion of collaboration receivable to note receivable	$ —	$ 1,812,975
Purchases of equipment included in accounts payable	$ —	$ 13,400

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1 — ORGANIZATION AND DESCRIPTION OF BUSINESS

TFF Pharmaceuticals, Inc. (the "Company") was incorporated in the State of Delaware on January 24, 2018. The Company's initial focus is on the development of inhaled dry powder drugs to enhance the treatment of pulmonary diseases and conditions. In December 2019, the Company established a wholly owned Australian subsidiary, TFF Pharmaceuticals Australia Pty Ltd ("TFF Australia"), in order to conduct clinical research. TFF Pharmaceuticals, Inc., along with TFF Australia, are collectively referred to as the "Company". The Company is in the development stage and is devoting substantially all of its efforts toward technology research and development and the human clinical trials of its initial product candidates.

ATM Offering

On June 10, 2022, the Company entered into an Open Market Sale Agreement with Jefferies LLC, as agent, under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to $35.0 million in an "at-the-market" ("ATM") offering, to or through the agent. From July 2022 through September 30, 2022, the Company sold 4,160 shares of its common stock at an average price of $149.00 per share resulting in net proceeds of approximately $0.4 million, after deducting sales agent commissions and offering expenses. During 2023, the Company sold 7,062 shares of its common stock through the ATM offering at an average price of $8.80 per share resulting in net proceeds of approximately $60,000. The Company terminated the Open Market Sale Agreement with Jefferies LLC in March 2024.

November 2022 Public Offering

In November 2022, the Company completed a public offering ("November 2022 Offering"), selling 371,304 shares of common stock and warrants to purchase up to 185,652 shares of common stock at an offering price of $28.75 per share. The Company received gross proceeds of approximately $10.7 million. In addition, the Company granted the underwriter a 45-day option to purchase an additional 15% of the number of shares of common stock and warrants at the public offering price, less underwriting discounts and commissions. The option was exercised in November 2022 and the underwriter purchased an additional 55,696 shares of common stock and warrants to purchase up to 27,848 shares of common stock and the Company received additional gross proceeds of approximately $1.6 million. The Company received net proceeds of approximately $11.2 million, after deducting underwriting discounts and offering-related expenses.

August 2023 Public Offering

On August 17, 2023, the Company completed an underwritten public offering ("August 2023 Offering"), selling 915,216 shares of common stock, including 119,376 shares of common stock issued pursuant to the full exercise by the underwriter of its over-allotment option, at an offering price of $6.25 per share. The Company received gross proceeds of approximately $5.7 million. The Company received net proceeds of approximately $5.1 million, after deducting underwriting discounts and offering-related expenses.

Reverse Stock Split

Effective December 19, 2023, the Company effected a one-for-25 reverse stock split of its issued and outstanding common shares. Accordingly, all common share, stock option, per common share and warrant amounts for all periods presented in the consolidated financial statements and notes thereto have been adjusted retrospectively to reflect this reverse stock split.

NOTE 2 — GOING CONCERN AND MANAGEMENT'S PLANS

The accompanying consolidated financial statements have been prepared under the assumption the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

For the years ended December 31, 2023 and 2022, the Company reported a net loss of $21.2 million and $31.8 million, respectively, and negative cash from operations of $16.0 million and $27.3 million, respectively. As of December 31, 2023, the Company had cash and cash equivalents of approximately $5.5 million, a working capital surplus of approximately $5.2 million and an accumulated deficit of $118.3 million. The Company has not generated revenues from commercial operations since inception and expects to continue incurring losses for the foreseeable future and needs to raise additional capital to continue the pursuit of its product development.

Management believes that the Company does not have sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing. Additionally, in view of the Company's expectation to incur significant losses for the foreseeable future it will be required to raise additional capital resources in order to fund its operations, although the availability of, and the Company's access to such resources, is not assured. Accordingly, management believes that there is substantial doubt regarding the Company's ability to continue operating as a going concern through the next twelve months from the date of this filing.

NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The Company's consolidated financial statements are presented in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC") and reflect the financial position, results of operations and cash flows for all periods presented.

Principles of Consolidation

The consolidated financial statements include the accounts of TFF Pharmaceuticals, Inc. and its wholly owned subsidiary, TFF Australia. All material intercompany accounts and transactions have been eliminated in consolidation.

Foreign Currency

The currency of TFF Australia, the Company's international subsidiary, is in Australian dollars. Foreign currency denominated assets and liabilities are translated into U.S. dollars using the exchange rates in effect at each balance sheet date. Results of operations and cash flows are translated using the average exchange rates throughout the period. The effect of exchange rate fluctuations on translation of assets and liabilities is included as a separate component of stockholders' equity in accumulated other comprehensive income (loss).

Geographic Concentrations

The Company conducts business in the U.S. and Australia. As of December 31, 2023 and 2022, the Company maintained 100% of its net property and equipment in the U.S.

Cash and Cash Equivalents

The Company maintains its operating accounts in financial institutions in the U.S. and in Australia. The balances are insured up to specified limits. The Company's cash is maintained in checking accounts and money market funds with maturities of less than three months when purchased, which are readily convertible to known amounts of cash,

NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

and which in the opinion of management are subject to insignificant risk of loss in value. As of December 31, 2023 and 2022, the Company had cash in Australia of AUD$285,827 (US$194,734) and AUD$1,028,616 (US$699,977), respectively.

Property and Equipment, net

Property and equipment are stated at cost less accumulated depreciation and amortization. The Company calculates depreciation using the straight-line method over the estimated useful lives of the assets, which range from two to five years for furniture, fixtures, lab and computer equipment and software. Assets held within construction in progress are not depreciated. Construction in progress is related to the construction or development of property and equipment that have not yet been placed in service for its intended use. As of December 31, 2023 and 2022, approximately $0.7 million and $1.5 million, respectively, of the Company's property and equipment consisted of lab equipment that are considered construction in progress. Expenditures for repairs and maintenance of assets are charged to expense as incurred.

Leases

At the inception of an arrangement, the Company determines whether an arrangement is or contains a lease based on the facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Leases with a term greater than one year are recognized on the consolidated balance sheets as operating lease right-of-use assets and current and long-term operating lease liabilities, as applicable. The Company has elected not to recognize on the consolidated balance sheets leases with terms of 12 months or less. The Company typically only includes the initial lease term in its assessment of a lease arrangement. Options to extend a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued rent. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

Fair Value Option — Convertible Note Receivable

The guidance in Accounting Standards Codification ("ASC") 825, *Financial Instruments*, provides a fair value option election that allows entities to make an irrevocable election of fair value as the initial and subsequent measurement attribute for certain eligible financial assets and liabilities. The Company has elected to measure its convertible note receivable using the fair value option. Under the fair value option, bifurcation of an embedded derivative is not necessary, and all related gains and losses on the host contract and derivative due to change in the fair value will be reflected in other income (expense), net in the consolidated statements of operations. Interest accrues on the unpaid principal balance on a quarterly basis and is recognized in interest income in the consolidated statements of operations.

The decision to elect the fair value option is determined on an instrument-by-instrument basis and must be applied to an entire instrument and is irrevocable once elected. Pursuant to this guidance, assets and liabilities are measured at fair value based, in part, on general economic and stock market conditions and those characteristics specific to the underlying investments. The carrying value is adjusted to estimated fair value at the end of each quarter, required to be reported separately in our consolidated balance sheets from those instruments using another accounting method.

NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

Fair Value of Financial Instruments

Authoritative guidance requires disclosure of the fair value of financial instruments. The Company measures the fair value of certain of its financial assets and liabilities on a recurring basis. A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value which is not equivalent to cost will be classified and disclosed in one of the following three categories:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets and liabilities.

Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as unadjusted quoted prices for similar assets and liabilities, unadjusted quoted prices in the markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Income Taxes

In accordance with authoritative guidance, deferred tax assets and liabilities are recorded for temporary differences between the financial reporting and tax bases of assets and liabilities using the current enacted tax rate expected to be in effect when the differences are expected to reverse. A valuation allowance is recorded on deferred tax assets unless realization is considered more likely than not.

The Company evaluates its tax positions taken or expected to be taken in the course of preparing the Company's tax returns to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority. Tax positions not deemed to meet the "more-likely-than-not" threshold are not recorded as a tax benefit or expense in the current year. The Company recognizes interest and penalties, if any, related to uncertain tax positions in interest expense. No interest and penalties related to uncertain tax positions were accrued at either December 31, 2023 or 2022.

The Company follows authoritative guidance which requires the evaluation of existing tax positions. The Company files in the federal and various state jurisdictions. Management has analyzed all open tax years, as defined by the statute of limitations, for all major jurisdictions. Open tax years are those that are open for examination by taxing authorities. The Company's tax years since its incorporation in 2019 and forward are subject to examination by tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

Revenue Recognition

Feasibility Agreements

The Company has entered into feasibility and material transfer agreements ("Feasibility Agreements") with third parties that provide the Company with funds in return for certain research and development activities. Revenue from the Feasibility Agreements is recognized in the period during which the related qualifying services are rendered and costs are incurred, provided that the applicable conditions under the Feasibility Agreements have been met.

The Feasibility Agreements are on a best-effort basis and do not require scientific achievement as a performance obligation. All fees received under the Feasibility Agreements are non-refundable. The costs associated with the Feasibility Agreements are expensed as incurred and are reflected as a component of research and development expense in the accompanying consolidated statements of operations.

Funds received from the Feasibility Agreements are recorded as revenue as the Company is the principal participant in the arrangement because the activities under the Feasibility Agreements are part of the Company's development programs. In those instances where the Company first receives consideration in advance of providing

NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

underlying services, the Company classifies such consideration as deferred revenue until (or as) the Company provides the underlying services. In those instances where the Company first provides the underlying services prior to its receipt of consideration, the Company records a grant receivable.

Grants

The Company accounts for grants awarded from a government-sponsored entity for research and development related activities that provide for payments for reimbursed costs, which includes overhead and general and administrative costs, as well as an administrative fee. The Company recognizes revenue from grants as it performs services under the arrangements. Associated expenses are recognized when incurred as research and development expense. Revenue and related expenses are presented gross in the consolidated statements of operations.

Collaborative Arrangements

The Company considers the nature and contractual terms of arrangements and assesses whether an arrangement involves a joint operating activity pursuant to which the Company is an active participant and is exposed to significant risks and rewards dependent on the commercial success of the activity. If the Company is an active participant and is exposed to significant risks and rewards dependent on the commercial success of the activity, the Company accounts for such arrangement as a collaborative arrangement under Accounting Standards Codification ("ASC") 808, *Collaborative Arrangements*. ASC 808 describes arrangements within its scope and considerations surrounding presentation and disclosure, with recognition matters subjected to other authoritative guidance, in certain cases by analogy.

For arrangements determined to be within the scope of ASC 808 where a collaborative partner is not a customer for certain research and development activities, the Company accounts for payments received for the reimbursement of research and development costs as a contra-expense in the period such expenses are incurred. This reflects the joint risk sharing nature of these activities within a collaborative arrangement. The Company classifies payments owed or receivables recorded as other current liabilities or prepaid expenses and other current assets, respectively, in the Company's consolidated balance sheets. Please refer to Note 5, "Joint Development Agreement" for additional details regarding the Company's joint development agreement ("JDA") with Augmenta Bioworks, Inc. ("Augmenta"), which was suspended as of January 1, 2023.

If payments from the collaborative partner to the Company represent consideration from a customer in exchange for distinct goods and services provided, then the Company accounts for those payments within the scope of ASC 606, *Revenue from Contracts with Customers*. The Company does not currently have any collaborative arrangements that are accounted for under ASC 606.

Research and Development Expenses and Related Prepaid and Accrued Expenses

Research and development ("R&D") expenses consist of costs incurred for R&D of its product candidate and are recorded to operating expenses when incurred. The Company's R&D expenses consist primarily of costs incurred in performing R&D activities, including personnel-related expenses such as salaries, stock-based compensation and benefits, as well as facilities costs, dues and subscriptions and external costs of outside vendors engaged as contract research organization, contract manufacturers, consultants and other third parties to conduct and support our clinical trials. The Company accrues expenses related to development activities performed by third parties based on an evaluation of services received and efforts expended pursuant to the terms of the contractual arrangements. Payments under some of these contracts depend on clinical trial milestones. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of expenses. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual or prepaid expense accordingly.

NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

Research and Development Tax Incentive

The Company is eligible to obtain a cash refund from the Australian Taxation Office for eligible research and development expenditures under the Australian R&D Tax Incentive Program (the "Australian Tax Incentive"). The Company recognizes the Australian Tax Incentive when there is reasonable assurance that the cash refund will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured.

As the Company has determined that it has reasonable assurance that it will receive the cash refund for eligible research and development expenditures, the Company records the Australian Tax Incentive as a reduction to research and development expenses as the Australian Tax Incentive is not dependent on the Company generating future taxable income, the Company's ongoing tax status, or tax position. At each period end, management estimates the refundable tax offset available to the Company based on available information at the time. This percentage of eligible research and development expenses reimbursable under the Australian Tax Incentive is 43.5% for the years ended December 31, 2023 and 2022. In addition, the Company is also eligible to receive amounts from the United States Internal Revenue Service ("IRS") related to research and development tax credits for expenditures.

The research and development incentive receivable represents an amount due in connection with the Australian Tax Incentive and from the IRS. The Company has recorded a research and development tax incentive receivable of $433,852 and $186,507 as of December 31, 2023 and 2022, respectively, in the consolidated balance sheets. The Company recorded a reduction to research and development expenses of $259,797 and $274,863 during the years ended December 31, 2023 and 2022, respectively.

Basic and Diluted Earnings per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and dilutive share equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. Since the Company has had net losses for all periods presented, all potentially dilutive securities are anti-dilutive.

For the years ended December 31, 2023 and 2022, the Company had the following potential common stock equivalents outstanding which were not included in the calculation of diluted net loss per common share because inclusion thereof would be anti-dilutive:

	Years Ended December 31,	
	2023	2022
Stock Options	233,340	116,362
Warrants	248,216	230,069
	481,556	346,431

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates include the fair value of the convertible note receivable, stock-based compensation and warrants and the valuation allowance against deferred tax assets. Actual results could differ from those estimates.

NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

Common Stock Warrants

The Company classifies as equity any warrants that (i) require physical settlement or net-share settlement or (ii) provide the Company with a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the Company's control), (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement) or (iii) that contain reset provisions that do not qualify for the scope exception. The Company assesses classification of its common stock warrants and other freestanding derivatives at each reporting date to determine whether a change in classification between assets and liabilities is required. The Company evaluated these warrants to assess their proper classification and determined that the common stock warrants meet the criteria for equity classification in the consolidated balance sheet. The warrants issued for services provided to the Company are measured at fair value, which the Company determines using the Black-Scholes-Merton option-pricing model.

Stock-Based Compensation

The Company computes stock-based compensation in accordance with authoritative guidance. The Company uses the Black-Scholes-Merton option-pricing model to determine the fair value of its stock options. The Black-Scholes-Merton option-pricing model includes various assumptions, including the fair market value of the common stock of the Company, expected life of stock options, the expected volatility and the expected risk-free interest rate, among others. These assumptions reflect the Company's best estimates, but they involve inherent uncertainties based on market conditions generally outside the control of the Company.

As a result, if other assumptions had been used, stock-based compensation cost, as determined in accordance with authoritative guidance, could have been materially impacted. Furthermore, if the Company uses different assumptions on future grants, stock-based compensation cost could be materially affected in future periods.

Recent Accounting Standards

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2020-06, *Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity' Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity' Own Equity* ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU also removes certain settlement conditions that are required for equity-linked contracts to qualify for the derivative scope exception, and it simplifies the diluted earnings per share calculation in certain areas. The provisions of ASU 2020-06 are applicable for fiscal years beginning after December 15, 2023, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. The Company adopted ASU 2020-06 on January 1, 2023, which did not result in a material impact on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments — Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments*. The ASU amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that aren't measured at fair value through net income (loss). For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction in carrying value of the asset. Entities will no longer be permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses should be recognized. This new guidance is effective in the first quarter of 2023 for calendar-year SEC filers that are smaller reporting companies as of the one-time determination date. Early adoption is permitted beginning in 2019. The Company has adopted the new guidance as of January 1, 2023, and it did not have a material impact on its consolidated financial statements and related disclosures.

NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements, Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*, that adds 14 of the 27 identified disclosure or presentation requirements to the Codification, each amendment in the ASU will only become effective if the SEC removes the related disclosure or presentation from its existing regulations by June 30, 2027. The Company currently complies with these disclosure requirements as applicable under Regulation S-X or Regulation S-K and will adopt these new standards depending on timing of when they become effective, which is not expected to have a material impact on its financial position and results of operations.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. This amended guidance applies to all public entities and aims to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses, to enable investors to develop more decision-useful financial analyses. This guidance is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently analyzing the impact that ASU No. 2023-07 will have on its consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. This amended guidance applies to all entities and broadly aims to enhance the transparency and decision usefulness of income tax disclosures. For public business entities, the amendments in this ASU are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted for any annual periods for which financial statements have not been issued or made available for issuance. The Company is currently analyzing the impact that ASU No. 2023-09 will have on its consolidated financial statements.

The Company's management does not believe that any other recently issued, but not yet effective, accounting standards if currently adopted would have a material effect on the consolidated financial statements.

NOTE 4 — SUPPLEMENTAL FINANCIAL INFORMATION

Accrued Liabilities

Accrued liabilities consisted of the following:

	December 31,	
	2023	**2022**
Accrued compensation	568,689	4,430
Insurance premium financing	716,897	—
	1,285,586	4,430

In October 2023, the Company entered into a short-term note payable of $914,063 for the financing of insurance premiums. The note bears interest at 9.95% and monthly principal and interest payments of $105,819 are paid over a 9-month period. The Company recorded interest expense of $14,475 related to the short-term note payable during the year ended December 31, 2023.

NOTE 5 — COMMITMENTS AND CONTINGENCIES

Operating Leases

In October 2018, the Company entered into a lease agreement for office space in Doylestown, Pennsylvania. The lease commenced on October 15, 2018 and expired on October 31, 2023, as amended. The lease had an additional one-year option for renewal, and the base rent was $37,080 per year. The Company determined that the lease agreement was considered a short-term lease under ASC 842 and did not record a right-of-use asset or liability. The Company did not renew the lease upon its expiration. The Company rents another office space on a month-to-month basis with

NOTE 5 — COMMITMENTS AND CONTINGENCIES (cont.)

no long-term commitment, which is considered a short-term lease as well. In May 2022, the Company entered into a lease agreement for lab space in Austin, Texas. The lease commenced on June 1, 2022 and expires on May 31, 2025. The lease has an additional three-year option for renewal, which the Company has determined it is not reasonably certain to exercise.

Supplemental balance sheet information related to leases was as follows:

	December 31,	
	2023	2022
Operating leases:		
Operating lease right-of-use assets	$ 119,529	$ 196,044
Operating lease liability – current portion	$ 83,512	$ 80,625
Operating lease liability – long-term portion	31,742	110,094
Total operating lease liabilities	$ 115,254	$ 190,719

Supplemental lease expense related to leases was as follows:

		For The Years Ended December 31,	
Lease	Statement of Operations Classification	2023	2022
Operating lease cost	Research and development	$ 89,100	$ 51,975
Short-term lease cost.	Research and development	—	20,815
Short-term lease cost.	General and administrative	77,210	83,870
Total lease expense		$ 166,310	$ 156,660

Other information related to operating leases:

	December 31, 2023	December 31, 2022
Weighted-average remaining lease term	1.4 years	2.4 years
Weighted-average discount rate	8%	8%

Supplemental cash flow information related to operating leases was as follows:

	For The Years Ended December 31,	
	2023	2022
Cash paid for operating lease liabilities	$ 88,050	$ 57,300

Approximate future minimum lease payments under non-cancellable leases (including short-term leases) are as follows:

Fiscal Year Ending December 31,	
2024.	$ 91,000
2025.	38,000
Total minimum lease payments.	129,000
Less: Imputed interest	(14,000)
Total	$ 115,000

NOTE 5 — COMMITMENTS AND CONTINGENCIES (cont.)

Legal

The Company may be involved, from time to time, in legal proceedings and claims arising in the ordinary course of its business. Such matters are subject to many uncertainties and outcomes and are not predictable with assurance. While management believes that such matters are currently insignificant, matters arising in the ordinary course of business for which the Company is or could become involved in litigation may have a material adverse effect on its business and financial condition. To the Company's knowledge, neither the Company nor any of its properties are subject to any pending legal proceedings.

NOTE 6 — JOINT DEVELOPMENT AGREEMENT

On November 2, 2020, the Company and Augmenta entered into the JDA pursuant to which the Company and Augmenta (collectively the "Parties") agreed to work jointly to develop one or more novel commercial products incorporating Augmenta's human derived monoclonal antibody for the treatment of patients with COVID-19 and the Company's patented Thin Film Freezing technology platform. Each party retains full ownership over its existing assets.

The Parties will share development costs with each party funding its fifty-percent-share at specified times. In the event that one of the Parties fails to make its pro rata share payment, the other party may terminate the JDA. In lieu of terminating the JDA, the non-defaulting party may elect to continue the JDA by paying the delinquent amount and each party's pro rata share of the JDA will automatically adjust by the amount paid. In addition, in the event Augmenta experienced a default on its required payment, Augmenta had the one-time right to elect to require the Company to purchase Augmenta's interest in the JDA ("Put Right") for a one-time fee of $500,000. Upon exercise of the Put Right and payment by the Company, Augmenta would grant the Company an exclusive, worldwide, royalty-free, transferable, sublicensable license to the Augmenta antibody and Augmenta's rights to the property developed under the JDA. The Company determined that the likelihood of the Put Right being exercised to be remote. The Put Right was eliminated in connection with a convertible note purchase agreement (see below and Note 7).

The JDA is within the scope of ASC 808 as the Company and Augmenta are both active participants in the research and development activities and are exposed to significant risks and rewards that are dependent on commercial success of the activities of the arrangement. The research and development activities are a unit of account under the scope of ASC 808 and are not promises to a customer under the scope of ASC 606.

The Company records its portion of the research and development expenses as the related expenses are incurred. All payments received or amounts due from Augmenta for reimbursement of shared costs are accounted for as an offset to research and development expense. During the years ended December 31, 2023 and 2022, the Company recorded research and development expenses of $0 and $341,840, respectively.

Effective January 1, 2023, the Company and Augmenta entered into a convertible note purchase agreement ("Augmenta Note") in which the receivable due from Augmenta was converted into a convertible note receivable (see Note 7). The Augmenta Note satisfies Augmenta's requirement to fund its fifty-percent-share of the development costs under the JDA. In addition, the Company and Augmenta agreed to suspend the development work under the JDA. The Augmenta Note has a maturity date of January 1, 2026; therefore, the Company has reflected the amount due under the Augmenta Note as a long-term note receivable as of December 31, 2023 and 2022.

NOTE 7 — CONVERTIBLE NOTE RECEIVABLE — AUGMENTA

Effective January 1, 2023, the Company and Augmenta entered into the Augmenta Note pursuant to which a receivable due from Augmenta in connection with the JDA was converted into a convertible note receivable (see Note 5). Under the terms of the Augmenta Note, Augmenta agreed to pay the principal amount of $1,812,975 to the Company. The Augmenta Note accrues interest at a rate of 6% per annum and has a maturity date of the earlier of (i) January 1, 2026 ("Maturity Date"), or (ii) upon the occurrence and during the continuance of an event of default. Accrued interest shall be payable at maturity.

NOTE 7 — CONVERTIBLE NOTE RECEIVABLE — AUGMENTA (cont.)

The Company has the following optional conversion rights under the Augmenta Note:

- The Company may convert, at any time and at its option, all outstanding principal and accrued and unpaid interest into shares of Augmenta common stock at a price per share equal to an amount obtained by dividing $15 million by the number of outstanding shares of Augmenta common stock on a fully diluted basis ("Conversion Price").
- If Augmenta completes a private placement sale of its preferred stock in the amount less than $15 million, the Company may convert, at its option, all outstanding principal and accrued and unpaid interest into shares of the same security in such financing at a per share price equal to the lower of the Conversion Price or the price per share sold in the financing.

In addition, the outstanding principal and accrued and unpaid interest under the Augmenta Note will automatically convert in the following scenarios:

- If Augmenta completes a financing with gross proceeds of at least $15 million ("Qualified Financing") on or before the Maturity Date, then the outstanding principal and accrued and unpaid interest shall automatically convert into the same security at a price per share equal to the lower of the Conversion Price or the price per share sold in the Qualified Financing.
- If Augmenta completes an underwritten public offering with gross proceeds of at least $35 million ("Qualified IPO") on or before the Maturity Date, then the outstanding principal and accrued and unpaid interest shall automatically convert into the same security at a price per share equal to the lower of the Conversion Price or the price per share sold in the Qualified IPO.
- If a change of control occurs prior to the payment in full of the principal amount of the Augmenta Note, then the Company will be paid all outstanding principal and accrued and unpaid interest, plus a premium of 100% of the outstanding principal.

The Company has elected to measure the Augmenta Note at fair value in accordance with ASC 825 (see Note 8).

NOTE 8 — FAIR VALUE OF FINANCIAL ASSETS AND LIABILITIES

The carrying value of cash and cash equivalents, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The Augmenta Note is held at fair value.

The following table presents the Company's assets and liabilities that are measured at fair value as of December 31, 2023:

	Fair value measured as of December 31, 2023			
	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets				
Augmenta Note at fair value	$ 2,310,000	$ —	$ —	$ 2,310,000

NOTE 8 — FAIR VALUE OF FINANCIAL ASSETS AND LIABILITIES (cont.)

Level 3 Measurement

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial assets that are measured at fair value on a recurring basis:

	Fair Value of Level 3 Augmenta Note
Beginning balance, January 1, 2023	$ 1,812,975
Accrued interest receivable	111,782
Change in fair value	385,243
Ending balance, December 31, 2023	$ 2,310,000

The fair value of the Augmenta Note is measured using Level 3 (unobservable) inputs. The Company determined the fair value for the Augmenta Note using a probability weighted-scenario valuation model with the assistance of a third-party valuation specialist. The unobservable inputs include estimates of the equity value of Augmenta and the timing and probability of future financing events, optional conversion to common stock, and repayment at maturity. The conversion upon a qualified financing scenario valued the Augmenta Note based on a bond plus call option model. The optional conversion to common stock valued the Augmenta Note based on the present value of common stock, determined using an adjusted net assets method and option-pricing model, and implied number of common shares upon conversion. The repayment upon maturity is based on the total principal and accrued interest through the maturity date.

NOTE 9 — STOCKHOLDERS' EQUITY

Common Stock

ATM Offering

From July 2022 through September 30, 2022, the Company sold 4,160 shares of its common stock through the ATM offering at average price of $149.00 per share resulting in net proceeds of approximately $0.4 million, after deducting sales agent commissions and offering expenses.

In 2023, the Company sold 7,062 shares of its common stock through the ATM offering at average price of $8.80 per share resulting in net proceeds of approximately $60,000.

November 2022 Public Offering

In November 2022, the Company completed the November 2022 Offering, selling 371,304 shares of common stock and warrants to purchase up to 185,652 shares of common stock at an offering price of $28.75 per share. The Company received gross proceeds of approximately $10.7 million. In addition, the Company granted the underwriter a 45-day option to purchase an additional 15% of the number of shares of common stock and warrants at the public offering price, less underwriting discounts and commissions. The option was exercised in November 2022 and the underwriter purchased an additional 55,696 shares of common stock and warrants to purchase up to 27,848 shares of common stock and the Company received additional gross proceeds of approximately $1.6 million. The Company received net proceeds of approximately $11.2 million, after deducting underwriting discounts and offering-related expenses.

August 2023 Offering

On August 17, 2023, the Company completed the August 2023 Offering, selling 915,216 shares of common stock, including 119,376 shares of common stock issued pursuant to the full exercise by the underwriter of its over-allotment option, at an offering price of $6.25 per share. The Company received gross proceeds of approximately

NOTE 9 — STOCKHOLDERS' EQUITY (cont.)

$5.7 million. The Company received net proceeds of approximately $5.1 million, after deducting underwriting discounts and offering-related expenses. In connection with the August 2023 Offering, the Company issued to the underwriter a warrant to purchase 18,304 shares of common stock, exercisable at $7.81 per share, commencing on the 180th day following the closing date of the August 2023 Offering and expiring five years from the closing date of the August 2023 Offering. The classification of the warrants was evaluated and the Company concluded they are considered equity instruments. The warrants were considered offering costs and netted against additional paid-in capital.

Stock Option Exercises

During the year ended December 31, 2022, 1,692 shares of common stock were issued in connection with the exercise of stock options for total proceeds of approximately $0.1 million.

NOTE 10 — WARRANTS

In connection with the November 2022 Offering, the Company issued warrants to purchase 213,500 shares of common stock. Each warrant is immediately exercisable on the date of issuance at an exercise price of $32.25 per share and expires five years from the date of issuance. The Company evaluated these warrants to assess their proper classification and determined that the warrants meet the criteria for equity classification in the consolidated balance sheet.

In connection with the August 2023 Offering, the Company issued warrants to purchase 18,304 shares of common stock. Each warrant is exercisable commencing on the 180th day following the closing date of the August 2023 Offering at an exercise price of $7.81 per share and expires five years from the closing date of the August 2023 Offering. The classification of the warrants was evaluated and the Company concluded they are considered equity instruments. The warrants were considered offering costs and netted against additional paid-in capital.

A summary of warrant activity for the years ended December 31, 2023 and 2022 is as follows:

	Number of Shares	Range of Exercise Prices	Weighted-Average Exercise Prices	Weighted-Average Remaining Life
Outstanding at January 1, 2022	15,569	$ 62.50 – 397.50	144.75	4.4
Issued	214,500	32.25 – 142.50	32.75	—
Exercised	—	—	—	—
Outstanding at December 31, 2022	230,069	32.25 – 397.50	40.25	4.4
Issued	18,304	7.81	7.81	—
Expired	(157)	62.50	62.50	—
Exercised	—	—	—	—
Outstanding at December 31, 2022	248,216	$ 7.81 – $397.50	$ 42.38	4.4

The warrants outstanding at December 31, 2023 had an aggregate intrinsic value of approximately $0.

NOTE 11 — STOCK BASED COMPENSATION

In January 2018, the Company's board of directors approved its 2018 Stock Incentive Plan ("2018 Plan"). The 2018 Plan provides for the grant of non-qualified stock options and incentive stock options to purchase shares of the Company's common stock, the grant of restricted and unrestricted share awards and grant of restricted stock units. There are 131,379 shares of common stock reserved for issuance under the 2018 Plan. All of the Company's employees and any subsidiary employees (including officers and directors who are also employees), as well as all of the Company's nonemployee directors and other consultants, advisors and other persons who provide services to the Company will be eligible to receive incentive awards under the 2018 Plan.

NOTE 11 — STOCK BASED COMPENSATION (cont.)

In September 2021, the Company's board of directors approved its 2021 Stock Incentive Plan ("2021 Plan"), which was also approved by the stockholders of the Company at the Company's annual meeting of stockholders held on November 4, 2021. The 2021 Plan provides for the grant of non-qualified stock options and incentive stock options to purchase shares of the Company's common stock, the grant of restricted and unrestricted share awards and grant of restricted stock units. The Company has 168,000 shares of its common stock reserved under the 2021 Plan. All of the Company's employees and any subsidiary employees (including officers and directors who are also employees), as well as all of the Company's nonemployee directors and other consultants, advisors and other persons who provide services to the Company will be eligible to receive incentive awards under the 2021 Plan.

The following table summarizes the stock-based compensation expense recorded in the Company's results of operations during the years ended December 31, 2023 and 2022 for stock options and warrants:

	Years Ended December 31,	
	2023	2022
Research and development	$ 997,339	$ 908,712
General and administrative	1,928,952	3,343,121
	$ 2,926,291	$ 4,251,833

As of December 31, 2023, there was approximately $3.8 million of total unrecognized compensation expense related to non-vested share-based compensation arrangements that are expected to vest. This cost is expected to be recognized over a weighted-average period of 1.9 years.

The Company records compensation expense for awards with graded vesting using the straight-line method. The Company recognizes compensation expense over the requisite service period applicable to each individual award, which generally equals the vesting term. The Company estimates the fair value of each option award using the Black-Scholes-Merton option pricing model. Forfeitures are recognized when realized.

The Company estimated the fair value of stock options using the Black-Scholes option pricing model. The fair value of stock options issued was estimated using the following assumptions:

	Years Ended December 31,	
	2023	2022
Weighted average exercise price	$ 22.92	$ 92.75
Weighted average grant date fair value	$ 15.42	$ 71.00
Assumptions		
Expected volatility	92 – 102%	90 – 97%
Expected term (in years)	6.3 – 10.0	5.3 – 10.0
Risk-free interest rate	3.44 – 4.81%	2.41 – 4.20%
Expected dividend yield	0.00%	0.00%

The risk-free interest rate was obtained from U.S. Treasury rates for the applicable periods. The Company's expected volatility was based upon the historical volatility for industry peers and used an average of those volatilities. The expected life of the Company's options was determined using the simplified method as a result of limited historical data regarding the Company's activity for employee awards and the contractual term for nonemployee awards. The dividend yield considers that the Company has not historically paid dividends, and does not expect to pay dividends in the foreseeable future. The Company uses the closing stock price on the date of grant as the fair value of the common stock.

NOTE 11 — STOCK BASED COMPENSATION (cont.)

The following table summarizes stock option activity during the years ended December 31, 2023 and 2022:

	Number of Shares	Weighted-Average Exercise Prices	Weighted-Average Remaining Contractual Term (In Years)	Intrinsic Value
Outstanding at January 1, 2022	115,754	$ 162.00	8.05	$ 9,932,413
Granted	18,256	92.75	—	—
Exercised	(1,692)	65.50	—	—
Cancelled	(15,955)	188.25	—	—
Outstanding at December 31, 2022	116,363	$ 162.00	7.46	$ 24,279
Granted	138,837	22.92	—	—
Exercised	—	—	—	—
Cancelled	(21,860)	142.96	—	—
Outstanding at December 31, 2023	233,340	$ 74.63	7.66	$ —
Exercisable at December 31, 2023	107,752	$ 108.51	6.08	$ —

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had strike prices lower than the fair value of the Company's common stock.

Option Modifications

Effective March 21, 2022, one of the members of the Company's board of directors, Dr. Brian Windsor, resigned. As part of his resignation from the board of directors, modifications were made to Dr. Windsor's vested and non-vested stock option awards including acceleration of certain non-vested option awards and the extension of the post-termination exercise period of certain stock option awards. During the year ended December 31, 2022, in accordance with ASC Topic 718, *Compensation — Stock Compensation*, the Company recorded a one-time, non-cash incremental compensation expense net of the required reversal of previously recognized compensation attributed to non-vested shares in the amount of approximately $0.3 million, which is included in general and administrative expense in the accompanying consolidated statements of operations.

Effective December 4, 2022, the Company's CEO, Glenn Mattes, resigned. As part of his resignation, modifications were made to certain of Mr. Mattes' vested stock option awards to extend the post-termination exercise period of these stock option awards. During the year ended December 31, 2022, in accordance with ASC 718, the Company recorded a one-time, non-cash incremental compensation expense in the amount of approximately $0.2 million, which is included in general and administrative expense in the accompanying consolidated statements of operations.

NOTE 12 — INCOME TAXES

The Company had no income tax expense due to operating losses incurred for the years ended December 31, 2023 and 2022. The Company accounts for income taxes in accordance with ASC 740, which requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a full valuation allowance.

NOTE 12 — INCOME TAXES (cont.)

The Company's income tax expense for the years ended December 31, 2023 and 2022 are summarized below:

	December 31, 2023	December 31, 2022
Current:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total current	$ —	$ —
Deferred:		
Federal	$ (5,119,585)	$ (7,871,979)
State	(29,214)	—
Foreign	(25,908)	453,410
Change in valuation allowance	5,174,707	7,418,569
Total deferred	—	—
Income tax provision (benefit)	$ —	$ —

The Company's deferred tax assets are as follows:

	December 31, 2023	December 31, 2022
Deferred tax assets:		
Net operating loss carryforwards	$ 17,989,784	$ 15,321,270
Research and development tax credit	3,261,950	2,384,554
Section 174 amortization	4,454,248	3,437,763
Intangibles	375,916	175,334
Stock compensation	1,527,808	1,029,447
Accruals and other	(77,399)	(173)
Total deferred tax assets	27,532,307	22,348,195
Valuation allowances	(27,532,307)	(22,348,195)
Net deferred tax assets	$ —	$ —

The effective tax rate of the Company's provision (benefit) for income taxes differs from the federal statutory rate as follows:

	December 31, 2023	December 31, 2022
Statutory rate	21.00%	21.00%
State rate	0.00%	0.00%
Foreign	(0.38)%	(0.31)%
Permanent book/tax differences	(0.64)%	(0.94)%
Research and development credit	4.13%	5.03%
Changes in valuation allowance	(24.11)%	(24.78)%
Total	—	—

As of December 31, 2023 and 2022, the Company had gross federal income tax net operating loss ("NOL") carryforwards of $84,366,128 and $71,906,839, respectively, and federal research tax credits of $4,349,267 and $3,179,405, respectively. The Company has state NOL carryforwards of approximately $841,000, of which approximately $790,000 will carryforward indefinitely and the remainder will begin to expire in 2038. Additionally, the

NOTE 12 — INCOME TAXES (cont.)

Company had gross foreign income tax net operating loss carryforwards of $822,472 and $736,112 as of December 31, 2023 and 2022, respectively. The federal and foreign NOL have an indefinite life while the federal research tax credits can be carried forward and will expire in 2038 through 2043.

Utilization of U.S. net operating losses and tax credit carryforwards may be limited by "ownership change" rules, as defined in Sections 382 and 383 of the Code. Similar rules may apply under state tax laws. The Company is currently conducting a study to-date to assess whether a limitation would apply under Sections 382 and 383 of the Code as and when it starts utilizing its net operating losses and tax credits. The Company will continue to monitor activities in the future. In the event the Company previously experienced an ownership change, or should experience an ownership change in the future, the amount of net operating losses and research and development credit carryovers available in any taxable year could be limited and may expire unutilized. The consolidated financial statement impact of a limitation under Sections 382 and 383 would not be material as a result of the full valuation allowance.

The Inflation Reduction Act ("IRA") was enacted on August 16, 2022. The IRA introduced new provisions including a 15% corporate alternative minimum tax for certain large corporations that have at least an average of $1 billion adjusted financial statement income over a consecutive three-tax-year period and a 1% excise tax surcharge on stock repurchases. The IRA is applicable for tax years beginning after December 31, 2022 and had no benefit to the consolidated financial statements for any of the periods presented, and the Company does not expect it to have a direct material impact on its future results of operations, financial condition, or cash flows.

Due to the uncertainty surrounding the realization of the benefits of its deferred assets, including NOL carryforwards, the Company has provided a 100% valuation allowance on its deferred tax assets at December 31, 2023.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740, *Income Taxes*. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2023, the Company had a reserve for uncertain tax positions of $1,087,317, and no interest or penalties have been charged to the Company for the years ended December 31, 2023 and 2022. If incurred, the Company will classify any interest and penalties as a component of interest expense and operating expense, respectively. If recognized, $1,087,317 of the reserve for uncertain tax positions would favorably affect the Company's effective tax rate.

A reconciliation of the change in the unrecognized tax positions for the year ended December 31, 2023 is as follows:

	Federal and State
Balance at December 31, 2022	$ 794,851
Additions for tax positions related to current year	292,466
Decreases for tax positions related to prior years	—
Balance at December 31, 2023	$ 1,087,317

NOTE 13 — SBIR GRANT

On June 23, 2023, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, awarded the Company a Direct to Phase II Small Business Innovation Research ("SBIR") grant of approximately $2.84 million to continue development of a novel, pan-flu multivariant mucosal vaccine using the Company's Thin Film Freezing technology.

NOTE 13 — SBIR GRANT (cont.)

The purpose of the SBIR grant is to provide funding to support preclinical and IND enabling studies to advance the development of a shelf-stable dry powder formulation of a novel universal influenza virus vaccine, developed in the laboratory of Dr. Ted Ross at the Cleveland Clinic (previously of University of Georgia). Funding from the SBIR grant is expected to take place over three years.

Revenue from the SBIR grant will be recognized in the period during which the related qualifying services are rendered and costs are incurred, provided that the applicable conditions under the SBIR grant have been met. The costs associated with the SBIR grant will be expensed as incurred and will be reflected as a component of research and development expense in the accompanying consolidated statements of operations.

Funds received from the SBIR grant will be recorded as revenue as the Company is the principal participant in the arrangement because the activities under the SBIR grant are part of the Company's development programs. In those instances where the Company first receives consideration in advance of providing underlying services, the Company will classify such consideration as deferred revenue until (or as) the Company provides the underlying services. In those instances where the Company first provides the underlying services prior to its receipt of consideration, the Company will record a grant receivable.

During the year ended December 31, 2023, the Company recognized approximately $81,000 of revenue related to the SBIR grant. There were no amounts due to the Company related to the SBIR grant as of December 31, 2023.

NOTE 14 — SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to December 31, 2023 through the filing date of this Annual Report. Based on its evaluation, nothing other than the events described below need to be disclosed.

On March 22, 2024, the Company completed a registered direct offering, selling 147,500 shares of common stock and warrants to purchase up to 147,500 shares of common stock at an offering price of $8.00 per share. The warrants are immediately exercisable upon issuance at an exercise price of $8.00 per share and will expire five and one-half years following the date of issuance. The Company received gross proceeds of approximately $1.2 million before deducting placement agent fees and other offering expenses.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our chief executive officer and chief financial officer evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(e) under the Exchange Act. Based upon that evaluation, our management, including our chief executive officer and chief financial officer, concluded that our disclosure controls and procedures were effective as of December 31, 2023 in ensuring all material information required to be filed has been made known in a timely manner.

(b) Changes in internal control over financial reporting.

There were no changes to our internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act that occurred during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

(c) Management's report on internal controls over financial reporting.

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting, as defined under Rule 13a-15(f) under the Exchange Act. Our management has assessed the effectiveness of our internal controls over financial reporting as of December 31, 2023 based on the framework established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) ("COSO"). Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. An internal control material weakness is a significant deficiency, or aggregation of deficiencies, that does not reduce to a relatively low level the risk that material misstatements in financial statements will be prevented or detected on a timely basis by employees in the normal course of their work. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023, and based on that evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2023.

This 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 the rules of the Securities and Exchange Commission that permit us to provide only management's report in this Annual Report.

Item 9B. Other Information

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item will be contained in the 2024 Proxy Statement and is hereby incorporated by reference.

Item 11. Executive Compensation

The information required under this item will be contained in the 2024 Proxy Statement and is hereby incorporated by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required under this item will be contained in the 2024 Proxy Statement and is hereby incorporated by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required under this item will be contained in the 2024 Proxy Statement and is hereby incorporated by reference.

Item 14. Principal Accountant Fees and Services

The information required under this item will be contained in the 2024 Proxy Statement and is hereby incorporated by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Financial statements

Reference is made to the Index and Financial Statements under Item 8 in Part II hereof where these documents are listed.

(b) Financial statement schedules

Financial statement schedules are either not required or the required information is included in the consolidated financial statements or notes thereto filed under Item 8 in Part II hereof.

(c) Exhibits

The exhibits to this Annual Report on Form 10-K are set forth below. The exhibit index indicates each management contract or compensatory plan or arrangement required to be filed as an exhibit.

Number	Exhibit Description	Method of Filing
3.1	Second Amended and Restated Certificate of Incorporation of the Registrant	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
3.2	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation of the Registrant	Incorporated by reference from the Registrant's Report on Form 10-K filed on March 31, 2023.
3.3	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation of the Registrant	Incorporated by reference from the Registrant's Report on Form 8-K filed on November 22, 2023.
3.4	First Amended and Restated Bylaws of the Registrant	Incorporated by reference from the Registrant's Report on Form 8-K filed on April 6, 2023.
4.1	Specimen Certificate representing shares of common stock of Registrant	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on September 27, 2019.
4.2	Warrant dated October 29, 2019 issued to National Securities Corporation	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 27, 2020.
4.3	Warrant dated November 20, 2019 issued to National Securities Corporation	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 27, 2020.
4.4	Warrant dated August 17, 2023 issued to The Benchmark Company, LLC	Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q filed on November 14, 2023.
4.5	Description of Capital Stock	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 10, 2021
4.6	Form of Warrant issued to investors in November 2022 Follow-On Offering	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 31, 2023.
4.7	Form of Warrant issued to private placement investors in March 2024 private placement	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on March 22, 2024.
4.8	Form of Warrant dated March 22, 2024 issued to H.C. Wainwright & Co., LLC	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on March 22, 2024.
10.1*	TFF Pharmaceuticals, Inc. 2018 Stock Incentive Plan	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.2*	Employment Agreement dated February 15, 2019, by and between the Registrant and Kirk Coleman	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.3*	TFF Pharmaceuticals, Inc. 2021 Stock Incentive Plan	Incorporated by reference from the Registrant's Definitive Proxy Statement filed on September 23, 2021

Number	Exhibit Description	Method of Filing
10.4	Amended and Restated Patent License Agreement dated April 20, 2022 between the Registrant and The University of Texas at Austin, on behalf of the Board of Regents of the University of Texas System	Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q filed on May 11, 2022.
10.5*	Executive Employment Agreement Between Zamaneh Mikhak, M.D. and Registrant	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 31, 2023.
10.6*	Executive Employment Agreement Between Harlan Weisman, M.D. and Registrant	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 31, 2023.
21.1	List of Subsidiaries	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 27, 2020.
23.1	Consent of Marcum LLP	Filed electronically herewith
31.1	Certification under Section 302 of the Sarbanes-Oxley Act of 2002.	Filed electronically herewith.
31.2	Certification under Section 302 of the Sarbanes-Oxley Act of 2002.	Filed electronically herewith.
32.1	Certifications Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.	Filed electronically herewith.
97.1	TFF Pharmaceuticals, Inc. Executive Officer Clawback Policy	Filed electronically herewith.
101.INS	Inline XBRL Instance Document.	Filed electronically herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	Filed electronically herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Filed electronically herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	Filed electronically herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	Filed electronically herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	Filed electronically herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	Filed electronically herewith

* Indicates management compensatory plan, contract or arrangement.

Item 16. Form 10-K Summary

Not provided.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this annual report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

TFF PHARMACEUTICALS, INC.

Date: March 28, 2024

By: */s/ Harlan Weisman*
Harlan Weisman,
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/ *Harlan Weisman* Harlan Weisman	Chief Executive Officer and Director *(Principal Executive Officer)*	March 28, 2024
/s/ *Kirk Coleman* Kirk Coleman	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 28, 2024
/s/ *Robert S. Mills, Jr.* Robert S. Mills, Jr.	Director	March 28, 2024
/s/ *Stephen Rocamboli* Stephen Rocamboli	Director	March 28, 2024
/s/ *Brandi Roberts* Brandi Roberts	Director	March 28, 2024
/s/ Catherine Lee Catherine Lee	Director	March 28, 2024
/s/ Michael Patane Michael Patane	Director	March 28, 2024
/s/ *Thomas King* Thomas King	Director	March 28, 2024