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

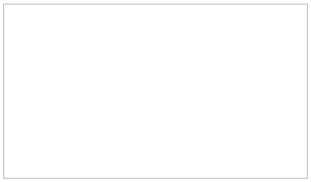
For the fiscal year ended December 31, 2021

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 Global 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. ☐

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: $229,001,120.

The number of shares of the registrant's common stock outstanding as of March 22, 2022 was 25,371,781.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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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.

RISK FACTOR SUMMARY

Our business is subject to numerous risks and uncertainties, including those described in Item 1A Risk Factors in this Annual Report on Form 10-K. These risks include, but are not limited to the following:

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.

We expect 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 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 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 may be adversely affected by the recent COVID-19 outbreak.

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.

We will 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.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

Our business operations could suffer in the event of information technology systems' failures 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, results of operations and damage our brand and reputation.

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.

Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues.

Any product candidates we develop that incorporate CBD will be subject to U.S. controlled substance laws and regulations and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition.

The passage of the 2018 Farm Bill will impact our development of a dry powder version of CBD.

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.

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.

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.

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.

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 have not paid dividends in the past and have no immediate plans to pay dividends.

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. We were formed by Lung Therapeutics, Inc., or LTI, an early-stage biotechnology company focused on the development of certain technologies in the pulmonary field. In March 2018, we completed a Series A preferred stock financing with third-party investors, at which time we acquired certain of LTI's non-core intellectual property rights and other assets, all of which relate to our TFF technology, for 4,000,000 shares of our common stock. On February 14, 2022, LTI reported that it owned 2,235,000 shares of our common stock, or approximately 8.8% of our capital stock. We are no longer a subsidiary of LTI.

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. Unless otherwise indicated, the terms "TFF Pharmaceuticals," "Company," "we," "us," and "our" refer to TFF Pharmaceuticals, Inc. and its wholly-owned subsidiaries.

Since our organization in 2018, we have engaged in several capital raising transactions, which are summarized below in "Management's Discussion and Analysis of Financial Condition and Results of Operations – General."

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. We believe, and early testing confirms, that our TFF platform can significantly improve the solubility of poorly water-soluble drugs, a class of drugs that makes up approximately 33% of the major pharmaceuticals worldwide, thereby improving the pharmacokinetic effect 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.

As of the date of this report, we have two product candidates under development, TFF Voriconazole

Inhalation Powder, or TFF Vori, and TFF Tacrolimus Inhalation Powder, or TFF Tac-Lac. In July 2020, we completed Phase I human clinical trials of our lead product, TFF Vori, and completed the enrollment of a Phase 1b clinical trial of TFF Vori in asthma patients in December 2021. Dosing of TFF Vori in patients with invasive pulmonary aspergillosis in a Phase 2 clinical trial will begin in the first half of 2022. In September 2021, we completed Phase 1 human clinical trials of our TFF Tac-Lac product in Australia. Dosing of TFF Tac-Lac in lung transplant patients in a Phase 2 clinical trial will begin in the first half of 2022. In November 2021, we commenced dosing of TFF Niclosamide in a Phase 1 human clinical trial in Canada. We have not progressed the development of any other of our drug candidates to human clinical trials and our efforts have focused on the formulation, early-stage animal testing and formal toxicology studies of our initial drug candidates in preparation for our first clinical trials.

We also focused on 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 engaged in the joint development of an inhaled SARS-CoV2 Monoclonal Antibody in collaboration with Augmenta BioWorks and a dry powder formulation of niclosamide in collaboration agreement with UNION therapeutics A/S. We are also actively engaged in the analysis and testing of dry powder formulations of several drugs and vaccines through topical, ocular and nasal applications pursuant to 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, especially to the deep lung, which is an area of extreme interest in respiratory medicine. We believe that our TFF platform can significantly increase the number of pulmonary drug products that can be delivered by way of breath-actuated inhalers, which are generally considered to be the most effective and patient-friendly means of delivering medication directly to the lungs. Our dry powder drug products 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 inhaled dry powder formulations of existing off-patent drugs intended for lung diseases and conditions, which we believe includes dozens of potential drug candidates, many of which have a potential market ranging from $100 million to over $500 million.

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, 40% of newly discovered drugs have little or no water solubility, and in some therapeutic areas this number can reach 90%, which in most cases will 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. 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 prevent them from being delivered by way of a breath-actuated inhaler and can only be given orally or intravenously. Breath actuated inhalers include dry powder inhalers, metered dose inhalers and nebulizers. A dry powder inhaler (such as the Advair Diskus) 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 (such as the Symbicort asthma inhaler) uses

propellant to push medication to the lungs. A nebulizer (such as the Aeroneb Pro) 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. In addition, it has been shown that dosing directly to the lungs requires a much lower dose of drug, sometimes as little as 10%, 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 be formulated for use with a breath-actuated inhaler. We believe there are dozens of off-patent drugs targeting lung conditions and diseases that are currently not eligible for delivery by way of breath-actuated inhalers, many of which have a potential market of $100 million to over $500 million. 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 drugs generally, the researchers at UT found that the technology was particularly useful in generating dry powder particles with properties suitable for inhalation delivery, especially to the deep lung, an area of extreme interest in respiratory medicine. It was found that the TFF platform yields particles that are particularly well suited to dry powder inhaler delivery. The process results in a “Brittle Matrix Particle,” which possess low bulk density, high surface area, and typically an amorphous morphology, allowing them to supersaturate when contacting the target site, such as lung tissue. The aerodynamic properties of the particles are such that the portion of drug deposited to the deep lung may reach as high as 75% or greater of the administered dose, compared to 10% or less when given orally or intravenously.

The TFF process, outlined in the figures below, involves dissolving 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” typically with amorphous drug morphology. 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, lung-approved excipients, a custom-made TFF drum and conventional process equipment.

We believe our TFF platform is a breakthrough platform technology for making dry powders from drugs which 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 10% of the drug reaches the lungs, and these drugs may cause unwanted and even deadly side effects. We believe that our TFF platform for the first time will allow many of these medications to be formulated into the convenient, direct-to-lung dry powder inhaler format, thereby enhancing efficacy, reducing or eliminating side effects and providing for delivery of drug direct to the target site.

Biologics. Biopharmaceuticals (or biologics) are by far the fastest growing sector in the pharmaceutical industry today. According to Mordor Intelligence, the market for biologics was valued at approximately $302.6 billion in 2020 and is expected to reach $509.2 billion by 2026. 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 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 salt containing vaccines, which we believe may provide significant advantages over the traditional method of handling vaccines through 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.

UT initially licensed the TFF technology to The Dow Chemical Company, or Dow, and Dow researchers pursued the development of the TFF platform until Dow's decision to divest its pharmaceutical assets in 2007. While at Dow, the technology was scaled from laboratory (milligrams) to pilot/commercial quantities (kilos). In addition, the Dow team showed that the scaling process did not alter the morphology or other properties of particles made using TFF. More than a dozen drugs, including both small molecules and biologics, were processed by Dow researchers and UT collaborators using the technology, and the benefits were quantified using both in vivo and analytical techniques. In a report published by Dow researchers in 2008, they reported that in several drugs tested by them, there was evidence of enhanced dissolution rates using the TFF platform compared to bulk drugs. In one instance, the researchers measured that a TFF prepared drug was able to reach 96% dissolution in two minutes compared to 60% dissolution in 30 minutes by the same drug in bulk form.

Following its decision to divest its pharmaceutical assets in 2007, Dow's license rights to the TFF platform were terminated. In July 2015, UT granted to our former parent, LTI, an exclusive worldwide, royalty bearing license to the patent rights for the TFF platform in all fields of use, other than vaccines, for which LTI was granted a non-exclusive worldwide, royalty bearing license to the patent rights for the TFF platform. In January 2018, we entered into a Contribution and Subscription Agreement with LTI, pursuant to which we agreed to acquire from LTI certain intellectual property rights and other assets, including the UT patent license agreement, all of which relate to our TFF platform. We closed on the acquisition of the LTI assets in March 2018. In November 2018, we and UT amended the UT patent license agreement pursuant to which, among other things, our exclusive patent rights to the TFF platform were expanded to all fields of use.

We continue to work with the inventors of the TFF platform 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 with regard to our product candidates incorporating our TFF technology in exchange for our payment of UT's expenses and reasonable overhead. The services conducted by UT are to be carried out under the direction of a principal investigator at UT who is the principal inventor of the TFF technology. The current SRA expires in April 2022 and is subject to renewal upon mutual agreement of the parties. As of the date of this report, we are engaged in talks with UT to extend the SRA. 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, the research scientists, 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.

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 intend to develop dry powder drugs that can be used with existing dry powder inhalers that are commercially available without licensing. 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 ranging from

$100 million to over $1 billion. As of the date of this report, we have identified and are focusing on three initial drug candidates and with each we are in the early stages of formulation and testing.

TFF Voriconazole Inhalation Powder, Vori – For the Treatment of Invasive Pulmonary Aspergillosis

We are developing an inhaled dry powder drug intended to treat invasive pulmonary aspergillosis, or IPA, a severe fungal pulmonary disease with a mortality rate that can reach 90% in some patient populations. IPA occurs primarily in patients with severe immunodeficiency, such as bone marrow transplant recipients, other transplant patients, patients with chemotherapy-induced immunodeficiency, and HIV patients. To date, the antifungals used to treat IPA have been delivered orally or intravenously. However, these delivery methods have resulted in low drug concentrations in the lung due to poor bioavailability. We believe these antifungals have serious side effects and drug interaction issues, which places a premium on any solution that can provide effective treatment in more limited dosages. 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.

We believe, and our preclinical studies and clinical trials to date confirm, that our TFF platform can be used to formulate a dry powder version of Voriconazole, generally considered to be one of the best antifungal drugs used in the treatment of IPA. Voriconazole is an off-patent drug and our TFF prepared version of Voriconazole would represent the first inhaled antifungal medication for the treatment of IPA, which has the potential to put the drug exactly where it is needed while minimizing off target effects.

Voriconazole is currently marketed in Australia, 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, identifying a relationship between low Voriconazole exposure and higher rates of treatment failure, as well as a higher propensity for neurotoxicity at higher exposures. Studies have shown that when delivered orally or intravenously Voriconazole can have differing bioavailability, and therefore differing concentration of the drug available to the lungs, based on whether the patient recently had food. In addition, Voriconazole when delivered orally or intravenously has been shown to have various side effects including nausea and headaches, and adverse events including optic neuritis and papilledema, hepatic toxicity, galactose intolerance, arrhythmias and QT prolongation. These studies confirm that when administered orally or intravenously, Voriconazole provides a narrow therapeutic window between treatment failure and unacceptable treatment toxicity.

We believe a TFF prepared dry powder formulation of Voriconazole can maximize both the prophylactic value to the lungs for immunocompromised patients susceptible to IPA and the treatment value of patients suffering from chronic IPA. We also believe our dry powder drug would benefit patients by providing the drug at the "port of entry" of invasive fungal infections, while also reducing or eliminating the unpleasant and potentially fatal side effects associated with Voriconazole and other last line antifungals. We also believe that the administration of our TFF prepared dry powder formulation directly to the lungs will significantly reduce any potential differences in bioavailability due to the effects of eating or fasting. 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 our TFF prepared dry powder formulation will allow for a lower dose directly to the lungs and thereby reduce the high systemic exposure of oral administration and associated side effects, including optic neuritis and papilledema, hepatic toxicity, galactose intolerance, arrhythmias and QT prolongation.

Through our work with UT, we successfully conducted preclinical testing of a TFF formulation of Voriconazole in 2018. In February 2019, we participated in a pre-IND meeting with the FDA for purposes of discussing our proposed regulatory pathway for TFF Vori and obtaining guidance from the FDA on the pre-clinical plan leading to

the filing and acceptance of an IND application for TFF Vori. We were successful in gaining agreement that a 505(b)(2) approach would be appropriate for TFF Vori. In October 2019, we submitted to the FDA an IND for our TFF Vori and initiated our Phase I human clinical trials in November 2019. We completed the clinical portion of our Phase 1 trial in July 2020 and progressed to a Phase 1b clinical trial in asthma patients in November 2020, which completed dosing in December 2021. We have initiated activities to gain regulatory approval for a Phase 2 clinical trial of TFF Vori and we expect to begin enrolling patients in the first half of 2022. We believe that subject to a successful completion of a single well-controlled and adequately powered study, we will be able to file FDA marketing approval. However, there can be no assurance that the FDA will not ask for additional clinical data. We also believe that our dry powder formulation may qualify as an orphan drug, as there are an estimated 50,000 transplant patients and an additional 30,000 or more acute leukemia patients in the U.S. each year that are at risk of developing IPA, as well as approximately 50,000 patients suffering with IPA.

TFF Tacrolimus Inhalation Powder, Tac-Lac — For Immunosuppression to Prevent Organ Transplant Rejection

We are developing TFF Tac-Lac, a dry powder version of Tacrolimus, an immunosuppressive drug used in transplant medicine. Prograf Tacrolimus is currently the second most commonly administered immunosuppressive agent in solid organ transplantation despite what we believe to be the many challenges for patients and physicians when used for extended periods. Prograf Tacrolimus can cause nephrotoxicity, particularly when used in high doses. According to product labeling and prescribing information for Prograf Tacrolimus, nephrotoxicity 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.

Although Tacrolimus has been shown via animal models to be beneficial for a number of immunological diseases that affect the lung, systemic toxicity (including renal failure, hypertension, hirsutism, diabetes) has limited its use. In addition, Tacrolimus when delivered orally or intravenously has been shown to have side effects including nausea, indigestion, stomach pain and headaches. Adverse events associated with Tacrolimus when delivered orally or intravenously include increase in cancer, increase in infections, anemia, kidney problems, nervous system problems (including seizures, coma, tremors, confusion, headaches), high blood pressure, QT prolongation, high level of potassium in the blood, myocardial hypertrophy, diabetes, damage to the brain, high level of fats or lipids or phosphates in the blood, constipation, diarrhea, bronchitis, inability to sleep, low magnesium levels, reduction in white blood cells, lack of energy, damage to the peripheral nerves, and fluid around the heart.

Tacrolimus is an off-patent drug and we intend to develop a dry powder version suitable for use with a dry powder inhaler. Because our dry powder version would provide for a high local lung concentration without the typical systemic toxicity frequently experienced with oral dosage form immunosuppressants, we believe our drug candidate should have a high likelihood of success in competing in the immunosuppressant market for lung and heart/lung transplants.

Through our partners at UT, we successfully conducted preclinical testing of our dry powder formulation of Tacrolimus in 2018. In September 2019, we participated in a pre-IND meeting with the FDA for purposes of discussing our proposed regulatory pathway for TFF Tac-Lac and obtaining guidance from the FDA on the pre-clinical plan leading to the filing and acceptance of an IND application for TFF Tac-Lac. We were successful in gaining agreement that a 505(b)(2) approach would be appropriate for TFF Tac-Lac. In September 2021, we completed a Phase 1 human clinical trial of TFF Tac-Lac. We have initiated activities to gain regulatory approval for a Phase 2 clinical trial of TFF Tac-Lac and we expect to begin enrolling patients in the first half of 2022. As of the date of this report, we intend to submit to the FDA an IND for TFF Tac-Lac when we initiate Phase 2 clinical trials.

Other Potential Dry Powder Products

Our business model is to develop proprietary innovative drug product candidates that offer commercial or

functional 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, for two of which we have conducted meaningful development activities, including dry powder formulations of:

Cannabidiol, or CBD, a controlled substance as defined in the federal Controlled Substances Act of 1970, or CSA, that is reported to be used by some for the treatment of various epilepsy syndromes as well as anxiety, insomnia, and different types of pain. We are in the early stages of developing an inhaled dry powder drug that could be used to support or to treat a variety of health issues that may benefit from CBD administration. Researchers have explored using the broader class of cannabinoids for inflammation, symptoms of multiple sclerosis, anorexia, schizophrenia, and other conditions. The FDA has approved Epidiolex for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients two years of age or older. The Epidiolex product is an oral solution containing 100 mg/mL of CBD.

We believe, and early in-vitro research confirms, that our TFF platform can be used to formulate a dry powder version of CBD. Through our work with UT, early animal model testing of TFF formulations of CBD administered via inhalation have been completed. The inhaled CBD showed more sustained pharmacokinetic blood levels compared to the IV delivery method in the animal studies.

We intend to engage pharmaceutical and non-pharmaceutical companies in the CBD space in discussions concerning a potential joint development of our dry powder formulation of CBD, which may target a CBD drug product subject to FDA regulation or a non-drug CBD product that may not be subject to FDA approval. We do not intend to pursue the development of our dry powder formulation of a CBD drug product beyond performance characterization and efficacy data through early animal testing until such time, if ever, as we obtain a drug development partner. There can be no assurance that our early testing and development will lead to a commercial dry powder formulation of a CBD drug product.

The 2018 Farm Bill, which was signed into law on December 20, 2018, liberalized to some degree the regulation of hemp and hemp-derived products, such as CBDs, under the CSA. However, the 2018 Farm Bill did not alter the FDA's authority to regulate products containing cannabis or cannabis-derived compounds, including CBD, under the Federal Food, Drug, and Cosmetic Act, or the FDCA. Following passage of the 2018 Farm Bill, the FDA reaffirmed its enforcement authority and reiterated the requirement that a CBD product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, be approved by the FDA for its intended use before it may be introduced into interstate commerce. However, we believe that CBD products that are not marketed with a claim of therapeutic benefit, or with any other disease claim, and meet the requirements of a dietary supplement, may not require FDA pre-marketing approval. Hemp products, including CBDs, that qualify as drugs, food, dietary supplements, veterinary products, and cosmetics will continue to be regulated by the FDA under the applicable regulatory frameworks. As of the date of this report, we believe that Epidiolex is the only CBD-based product that has received market approval from the FDA

Vaccines containing aluminum salts, which 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 very 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 drug and performance characterization activities of certain TFF formulated salt containing vaccines. Our activities suggest that the salt containing vaccines can be successfully converted from liquid suspension into dry powder using our TFF platform using a relatively low concentration of trehalose as an excipient,

and that the dry powder can later be reconstituted at the time of use without causing particle aggregation or decrease in efficacy. In addition, the dry vaccine powder 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 significant loss of efficacy.

We intend to engage pharmaceutical companies in the vaccine space in discussions concerning a potential joint development of TFF formulated salt containing vaccines and, in the meantime, we do not intend to pursue the development of our dry powder formulation of salt containing 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 salt containing vaccines.

Other Potential Product Candidates. We have identified a number of additional drug candidates that show promise upon initial evaluation. In each case, these are drugs for which we would directly pursue the development of a dry powder formulation for use through a dry powder inhaler. 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	Vitamin A 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 very 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 concentration to provide therapeutic benefit to the lung due to the systemic nature (oral or IV dosing) of the drug leading to toxicity of the kidney, lungs and other systemic safety concerns. 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 diseases and disorders. This direct dosing may reduce plasma levels and has the potential to increase efficacy while reducing side effects.

We believe that all of the above 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. However, not all of our drug product candidates will target off-patent drugs. For example, we do not expect our proposed dry powder formulation of CBD to be off-patent and our proposed dry powder formulation of aluminum salt vaccines may not be off-patent. We also expect that our dry powder formulation of a CBD drug product will likely require a full NDA through the FDA's 505(b)(1) regulatory pathway and that our dry powder formulation of aluminum salt vaccines

will require a biological license application, or BLA, which is very similar to a full NDA through the FDA's 505(b)(1) regulatory pathway.

Our business model includes the development proprietary innovative drug product candidates that offer commercial or functional advantages, or both, to currently available alternatives. Because our initial dry powder drug candidates, TFF Vori and TFF Tac-Lac, will be established drugs that are off-patent, we believe that our initial drug product candidates will qualify for approval by the U.S. Food and Drug Administration, or FDA, through the FDA's 505(b)(2) regulatory pathway and in corresponding regulatory paths in other foreign jurisdictions. The 505(b)(2) pathway sometimes does not require clinical trials other than a bioequivalence trial. However, to the extent we claim that our 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 in many cases, it is likely that we will be required to conduct additional clinical trials in order to obtain marketing approval. For example, and as more fully described below, based on a February 2019 pre-Investigational New Drug Application, or IND, meeting with the FDA concerning TFF Vori, we believe we will need to conduct Phase I and Phase II studies prior to filing for marketing approval for TFF Vori. In addition, based on a September 2019 pre-IND meeting with the FDA concerning TFF Tac-Lac, we also believe we will require Phase I and Phase IIb/IIIa studies prior to filing for marketing approval for TFF Tac-Lac. However, there can be no assurance that the FDA will not ask for additional clinical data for either TFF Vori or TFF Tac-Lac.

While we intend to target 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, not all of our product candidates will target off-patent drugs and, at least in the case of a dry powder formulation of cannabidiol, or CBD, our product candidate may not be a drug. We do not expect our proposed dry powder formulation of CBD drug product to be off-patent and our proposed dry powder formulation of aluminum salt vaccines may not be off-patent. We also expect that our dry powder formulation of a CBD drug product will likely require a full New Drug Application, or NDA, through the FDA's 505(b)(1) regulatory pathway; however, a non-pharmaceutical CBD dry powder formulation, such as a dietary supplement, may not require FDA pre-market approval. We expect that our dry powder formulation of aluminum salt vaccines will require a biological license application, or BLA, which is very similar to a full NDA through the FDA's 505(b)(1) regulatory pathway.

We also believe that in some cases our dry powder drug products may qualify for the FDA's orphan drug status. Upon and subject to receipt of the requisite approvals, we intend to commercialize our drug product candidates through a combination of our internal direct sales and third-party marketing and distribution partnerships. In some cases, such as the development of combination drugs or the development of dry powder formulations of patented drugs, we intend to pursue the licensing of our TFF platform or a joint development arrangement.

Our Intended Regulatory Pathway

The 505(b)(2) pathway is intended for molecules 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 molecule in a new strength or dosage form. 505(b)(2) products have the advantage of potentially significantly lower development costs and shorter development timelines versus traditional new molecular entities. We expect to utilize the 505(b)(2) pathway for all of our current product candidates.

A 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies not conducted by or for the applicant. This alternate 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-unapproved, or DESI, drug. The clinical requirements for a 505(b)(2) drug candidate can vary widely from product to product and may include new clinical trials, bioequivalence trials, limited safety and efficacy trials, or full Phase I through III trials. Unless the FDA has released a guidance document, the clinical

requirement for a new product candidate is typically not known until the drug sponsor has a Pre-IND meeting with the FDA. We believe there is a significant opportunity to pursue dry powder formulations of off-patent drugs using the 505(b)(2) regulatory pathway.

We also believe that in some cases the indication for some of our dry powder drug product candidates may qualify for the FDA's orphan drug status. 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 exclusivity, independent of patent protection, to the company that brings a particular orphan drug 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.

Our Joint Development Collaborations and Licensing Activities

We also focused on 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 engaged in the joint development of an inhaled SARS-CoV2 Monoclonal Antibody in collaboration with Augmenta BioWorks and a dry powder formulation of niclosamide in collaboration agreement with UNION therapeutics A/S. We are also actively engaged in the analysis and testing of dry powder formulations of several drugs and vaccines through topical, ocular and nasal applications pursuant to feasibility studies and material transfer agreements with U.S. and international pharmaceutical companies and certain government agencies.

Inhaled SARS-CoV2 Monoclonal Antibody (Joint development with Augmenta BioWorks)

On November 2, 2020, we entered into a Joint Development Agreement with Augmenta BioWorks pursuant to which we and Augmenta agreed to work jointly to develop one or more dry powder formulations of Augmenta's human derived monoclonal antibody for the treatment of patients with COVID-19. Initially, we and Augmenta are working jointly to develop an inhaled dry powder form of a sars-cov2 monoclonal, or mAb, using our proprietary TFF process. The proprietary mAb in this formulation was identified by Augmenta and has demonstrated potent binding and neutralization activity against the SARS-CoV2 virus that causes the COVID-19 disease. Recent Emergency Use Authorizations of anti-SARS-CoV2-mAbs delivered by intravenous infusion have been achieved by Regeneron and Eli Lilly. Early testing confirmed that our TFF platform can be used to formulate a dry powder mAb for inhalation delivery. We believe a TFF prepared anti-SARS-CoV2-mAb administered directly to the lungs can maximize the early outpatient treatment of patients with COVID-19 infections who are at risk for serious disease complications while minimizing the amount of antibody required to achieve efficacious dose.

Pursuant to the Joint Development Agreement, or JDA, we and Augmenta 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 experiences a default on its required payment, Augmenta will have the one-time right to elect to require us to purchase Augmenta's interest in the JDA for a one-time fee of $500,000. Upon exercise of the put right and payment by us, Augmenta will grant us an exclusive, worldwide, royalty-free, transferable, sublicensable license to the Augmenta antibody and Augmenta's rights to the property developed under the JDA.

Niclosamide Inhalation Powder (Joint Development with UNION therapeutics A/S)

On August 12, 2020, we entered into a licensing and collaboration agreement with UNION therapeutics A/S in which UNION acquired an option to obtain a worldwide exclusive license for the TFF technology in combination with

niclosamide. Pursuant to the terms of the license agreement, UNION can exercise its option to obtain the license within 45 days after the complete data has been received by UNION from investigator-initiated trials. Upon exercise of the option, UNION shall be responsible to pay all expenses incurred in the development of any licensed product. We will be eligible to receive milestone payments upon the achievement of certain milestones in the development the licensed products, based on completion of clinical trials, pre-marketing approvals and/or the receipt of at least $25,000,000 of grant funding. We will receive a single-digit tiered royalty on net sales, and will also be entitled to receive sales-related milestone payments based on the commercial success of the licensed products.

Niclosamide has been used to treat tapeworm infections in humans since the 1960s and was recently reported to be one of the most potent approved drugs in screens for antiviral activity against the SARS-CoV2 virus that causes the COVID-19 disease. Early testing confirmed that our TFF platform can be used to formulate a dry powder version of Niclosamide, which is no longer subject to patent protection. We believe a TFF prepared dry powder formulation of Niclosamide administered directly to the lungs can maximize both the early outpatient treatment of patients with COVID-19 infections who are at risk for serious disease complications and for prophylactic use for persons exposed to COVID-19. Under the license agreement, we are responsible for the conduct of investigator-initiated clinical studies of the TFF dry powder formulation of niclosamide and in November 2021 we commenced dosing in a Phase 1 human clinical trial of the TFF Niclosamide product in Canada

Manufacturing

We have entered into short-term contract manufacturing agreements with IriSys, Inc. CoreRx, Inc. and Experic for their provision of certain product testing, development and preclinical and clinical manufacturing services for our TFF Vori and TFF Tac-Lac product candidates, respectively. Our agreements with IriSys, CoreRx 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 the commercial supply, however, we believe that IriSys, CoreRx 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 CoreRx's, IriSys' 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 CoreRx, IriSys and Experic, they will generate 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.

Because our dry powder drug candidates will represent a new formulation 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 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 investment than the standard FDA approval process.

Licenses and Intellectual Property Rights

We hold rights to our TFF technology pursuant to a patent license agreement entered into in July 2015, between University of Texas at Austin, or UT, and our former parent, LTI, which LTI assigned to us in March 2018, as amended by UT and us on November 30, 2018. UT is the owner of 127 U.S. and international patents and patent applications with claims covering the TFF platform. Pursuant to the amended patent license agreement, we hold an exclusive worldwide, royalty bearing license to the rights to the aforementioned patents, including any divisionals, continuations and extensions, in all fields of use. 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;

$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; and

Our issuance to UT of one percent (1%) of our outstanding common stock, calculated on a fully-diluted basis, upon and as of our first IND approval for a 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 sick 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, 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 Regulation

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 [ ] 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 are a clinical-stage biopharmaceutical company with limited operating history. We are a biopharmaceutical company, newly-formed in January 2018, and have limited operating history. We have not commenced revenue-producing operations. In 2021, we completed Phase I human clinical trials for our TFF Vori and TFF Tac-Lac product candidates, and in November 2021 we commenced dosing in a Phase 1 human clinical trial of the TFF Niclosamide product in Canada, however, 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, 2021 and 2020, we incurred a net loss of $31.0 million and $18.6 million, respectively. As of December 31, 2021, we had an accumulated deficit of $65.3 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 towards 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.

We expect 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. As of December 31, 2021, we had total assets of approximately $40.7 million and working capital of approximately $36.9 million. As of December 31, 2021, our liquidity included approximately $33.8 million of cash and cash equivalents. We believe that our cash on-hand as of the date of this report is sufficient to fund our proposed operating plan for, at least, the 12 months following the date of this report. However, as of the date of this report, we believe that we will need additional capital to fund our operations through to the marketing approval for TFF Vori and TFF Tac-Lac, assuming such approval can be obtained at all, and to engage in the substantial development of any other of our drug candidates, such as formulation, early stage animal testing and formal toxicology studies. 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 towards 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.

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. In July 2015, the University of Texas at Austin, or UT, granted to our former parent, LTI, an exclusive worldwide, royalty bearing license to the patent rights for the TFF platform in all fields of use, other than vaccines. In March 2018, LTI assigned to us all of its interest to the TFF platform, including the patent license agreement with UT. In November 2018, we and UT amended the patent license agreement such that our exclusive patent rights to the TFF platform were expanded to all fields of use. 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 new chemical entities with 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.

Our business may be adversely affected by the recent COVID-19 outbreak. In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. In January 2020, this coronavirus spread to other countries, including the United States, and efforts to contain the spread of COVID-19 have included lock-downs and self-isolation procedures, which have, at times. significantly limited business operations and restricted internal and external meetings. As of the date of this report, the COVID-19 pandemic has had a relatively insignificant impact on our operations. During 2020, we experienced a temporary suspension of dosing in the Phase I clinical trial for our TFF Tac-Lac due to the COVID-19 pandemic and the pandemic has otherwise caused minor slowing in the timing of certain non-clinical and clinical activities by us and our collaborators and service providers during 2020 and 2021. However, the COVID-19 pandemic has not caused us to forego, abandon or materially delay any proposed activities. While we believe we have been able to effectively manage the disruption caused by the COVID-19 pandemic to date, there can be no assurance that our operations, including the development of our drug candidates, will not be disrupted or materially adversely affected in the future by the COVID-19 pandemic or an epidemic or outbreak of an infectious disease like the outbreak of COVID-19. Further, the outbreak and any preventative or protective actions that our customers may take in respect of COVID-19 may result in a period of disruption to other work in progress. Our customers' businesses could be disrupted, and our future costs and potential revenues and technology evaluations could be negatively affected. Any resulting financial impact cannot be reasonably estimated at this time but may materially affect our business and financial condition. The extent to which COVID-19 impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

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 will 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 IriSys, Inc., CoreRx, Inc. and Experic for their provision of certain product testing, development and clinical manufacturing services for our TFF Vori and TFF Tac-Lac 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, 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 Vori and TFF Tac-Lac, will be established drugs that are off-patent, we believe that our initial drug product candidates will qualify for FDA approval through the FDA's 505(b)(2) regulatory pathway and in corresponding regulatory paths in other foreign jurisdictions. The 505(b)(2) pathway sometimes does not require clinical trials other than a bioequivalence trial; however, 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 in order to obtain marketing approval. For example, based on separate pre-IND meetings with the FDA concerning TFF Vori and TFF Tac-Lac, we believe we will need to conduct Phase I and Phase II studies prior to filing for marketing approval for TFF Vori and Phase I and Phase IIb/IIIa studies prior to filing for marketing approval for TFF Tac-Lac. However, there can be no assurance that the FDA will not ask for additional clinical data for either TFF Vori or TFF Tac-Lac.

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 and, at least in the case of a dry powder formulation of CBD, our product candidate may not be a drug. We do not expect any dry powder formulation of a CBD drug product to be off-patent and our proposed dry powder formulation of aluminum salt vaccines may not be off-patent. We also expect that our dry powder formulation of a CBD drug product will likely require a full NDA through the FDA's 505(b)(1) regulatory pathway; however, a non-pharmaceutical CBD dry powder formulation may not require FDA approval. We expect that our dry powder formulation of aluminum salt vaccines will require a biological license application, or BLA, which is very similar to 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 results of toxicology studies may not support the filing of an IND 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;
- 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 approvalof 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 2021, we completed Phase I human clinical trials for our TFF Vori and TFF Tac-Lac product candidates, and in November 2021 we commenced dosing in a Phase 1 human clinical trial of the TFF Niclosamide product in Canada. However, as of the date of this report, we have not otherwise progressed any of our product candidates beyond performance characterization and animal testing. We may not be successful in obtaining approval from the FDA or comparable foreign regulatory authorities to start clinical trials for any other of our product candidates. If we do not obtain such approvals as presently planned, the time in which we expect to commence clinical programs for any product candidate will be extended and such extension will increase our expenses, delay our potential receipt of any revenues, and increase our need for additional capital. Moreover, there is no guarantee that we will receive approval to commence human clinical trials or, if we do receive approval, that our clinical trials will be successful or that we will continue clinical development 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 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 4 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.

Any product candidates we develop that incorporate CBD will be subject to U.S. controlled substance laws and regulations and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition. We believe that our TFF platform could be used to formulate a dry powder version of cannabidiol, or CBD, and we are in the early stages of developing a dry powder form of CBD. CBD is a controlled substance as defined in the federal Controlled Substances Act of 1970, or CSA. Controlled substances are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the federal Drug Enforcement Agency, or DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have no currently "accepted medical use" in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the United States. Pharmaceutical products approved for use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription.

While cannabis and certain of its derivatives, including CBD, are Schedule I controlled substances, products approved for medical use in the United States that contain cannabis or cannabis extracts must be placed in Schedules II through V, since approval by the FDA satisfies the "accepted medical use" requirement. In 2018, the FDA approved Epidiolex, a sesame oil oral solution of CBD, and the DEA scheduled Epidiolex to Schedule V. To our knowledge, Epidiolex is the only CBD-based drug to have received FDA marketing approval. If we are able to develop a CBD-based dry powder drug candidate, and the FDA provides market approval for such drug candidate, of which there can be no assurance, the DEA will make a scheduling determination and place our dry powder CBD-based drug candidate in a schedule other than Schedule I in order for it to be prescribed to patients in the United States. If we are able to develop a CBD-based dry powder drug candidate, we would be able to favorably cite Epidiolex for purposes of DEA scheduling; however, there can be no assurance that any CBD-based drug candidate we develop will be listed by the DEA as a Schedule V controlled substance. Furthermore, if the FDA, DEA or any foreign regulatory authority determines that any of our CBD-based drug candidates may have potential for abuse, it may require us to generate more clinical data than would otherwise be required, which could increase the cost or delay the launch of such drug candidate.

Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining the necessary registrations may result in delay of the importation, manufacturing or distribution of any CBD-based drug candidates we may develop. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states have also established controlled substance laws and regulations. Though state-controlled substance laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our product candidates as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial

sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

The passage of the 2018 Farm Bill will impact our development of a dry powder version of CBD. The Agriculture Improvement Act of 2018, or the 2018 Farm Bill, was signed into law on December 20, 2018. This new law excludes hemp from the definition of marijuana for purposes of the CSA, and legalizes the cultivation and commercial sale of hemp in the United States, subject to state regulation and continuing oversight by federal regulatory agencies. However, the 2018 Farm Bill does not legalize hemp-derived CBDs. CBDs generally remain a Schedule I controlled substance under the CSA and the 2018 Farm Bill provides that a CBD will be removed from Schedule I status if, among other requirements, the CBD is derived from hemp produced by a licensed grower in a manner consistent with the 2018 Farm Bill and associated federal and state regulations.

In addition, the 2018 Farm Bill did not alter the FDA's authority to regulate products containing cannabis or cannabis-derived compounds, including CBD, under the Federal Food, Drug, and Cosmetic Act. Hemp products, including CBDs, that qualify as drugs, food, dietary supplements, veterinary products, and cosmetics will continue to be regulated by the FDA under the applicable regulatory frameworks. Following passage of the 2018 Farm Bill, the FDA reaffirmed its enforcement authority and reiterated the requirement that a CBD product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, be approved by the FDA for its intended use before it may be introduced into interstate commerce. However, we believe that hemp-derived CBD products that are not marketed with a claim of therapeutic benefit, or with any other disease claim, may not require FDA pre-marketing approval. While we believe that recent legislation, most notably the 2018 Farm Bill, has reduced the amount of DEA regulation of CBDs, this is a rapidly evolving area of law and there remains some uncertainty surrounding future state regulation of CBDs. In addition, as of the date of this report, the FDA has approved for marketing only one CBD-based drug product, Epidiolex, and there can be no assurance that we will not encounter increased costs or delays in pursuing FDA market approval of a CBD-based dry powder formula, assuming we can obtain approval at all.

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.

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 $5.00 per share, the reported high and low sales prices of our common stock have ranged from $3.44 to $21.14 through March 11, 2022. The market price of our shares on the NASDAQ Global 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.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our shares and result in substantial losses being incurred by our investors. In the past, following periods of market volatility, public company stockholders have often instituted securities class action litigation. If we were involved in securities litigation, it could impose a substantial cost upon us and divert the resources and attention of our management from our business.

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. Commencing with our annual report on Form 10-K for the fiscal year ended December 31, 2020, 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 directorsthen 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 2. Properties

We lease approximately 1,000 square feet of office space in Fort Worth, Texas at the rate of $3,900 per month. The lease has an initial term ending May 1, 2023 and thereafter shall extend on a month-to-month basis. . We also lease 1,500 square feet of office space in Doylestown, Pennsylvania. The lease agreement is for one year and expires October 31, 2022, subject to our option to renew for an additional year. The monthly lease rate is $3,000.

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 11, 2022, there were seven 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 3,284,480 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 4,200,000 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, 2021 about our stock plans under which our equity securities are authorized for issuance.

	(a) Number of Securities to	(b) Weighted-	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation

Plan Category	be Issued Upon Exercise of Outstanding Options	Average Exercise Price of Outstanding Options	Plans (Excluding Securities Reflected In Column (a))
Equity compensation plans approved by security holders	2,893,839	$ 6.48	4,053,482
Equity compensation plans not approved by security holders	—	—	—
Total	2,893,839	$ 6.48	4,053,482

Unregistered Sales of Equity Securities and Use of Proceeds

During the year ended December 31, 2021, we issued an aggregate of 444,751 shares of our common stock, including 415,917 shares of common stock that were issued in connection with the cashless exercise of 424,288 common stock purchase warrants and 28,834 shares of common stock that were issued in connection with the exercise of common stock purchase warrants for total proceeds of $180,213. The issuances of our common shares to the warrant holders were exempt under Section 4(a)(2) of the Securities Act of 1933 and Rule 506 there under. All of the warrant holders were accredited investors, as such term is defined in Rule 501 under the Securities Act.

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.

Since our organization in 2018, we have engaged in the following financing transactions:

Series A Preferred Stock Placements. In March 2018, we conducted a private placement of 5,662,000 shares of our Series A preferred stock, at an offering price of $2.50 per share, for the gross proceeds of approximately $14.2 million, and in May 2019 we conducted a private placement of 3,268,000 shares of our Series A preferred stock, at an offering price of $2.50 per share, for the gross proceeds of approximately $8.2 million. The shares of our Series A preferred stock accumulated dividends at the rate of 6% per annum. The shares of Series A preferred stock, including all accrued but unpaid dividends on the Series A preferred stock, which totaled $1,603,709, automatically converted into 9,571,692 shares of our common stock concurrent with the completion of our initial public offering at the conversion price of $2.50.

Initial Public Offering. On October 25, 2019, we conducted an initial public offering of 4,400,000 shares of common stock at a public offering price of $5.00 per share. After the payment of underwriter discounts and offering expenses, and after giving effect to the underwriters' exercise of its overallotment option on November 20, 2019 to purchase an additional 479,300 shares of our common stock at the offering price of $5.00 per share, we received net proceeds of approximately $21.8 million.

August 2020 Private Placement. On August 13, 2020, we conducted a private placement of 3,048,654 shares of common stock, at a purchase price per share of $8.50, for aggregate gross proceeds of approximately $25,914,000,

before deducting selling commissions and other offering expenses. After deducting the placement agent commissions and offering expenses, we received net proceeds of approximately $24,280,000.

March 2021 Public Offering. On March 30, 2021, we conducted a public offering of 2,140,000 shares of common stock, at a purchase price per share of $14.00, for aggregate gross proceeds of approximately $30,000,000, before deducting underwriter discounts and offering expenses. After deducting the underwriter discounts and offering expenses, we received net proceeds of approximately $28,015,000.

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 and Phase 1 human clinical trials of our initial product candidates. In connection with our organization on January 24, 2018, we entered into a Contribution and Subscription Agreement with Lung Therapeutics, Inc., or LTI, our former parent, pursuant to which we agreed to acquire from LTI certain of LTI's non-core intellectual property rights and other assets, or the Acquired Assets, all of which relate to our Thin Film Freezing technology. We closed on the acquisition of the Acquired Assets concurrent with the close of the initial Series A preferred stock financing in March 2018.

In December 2019, we established a wholly-owned Australian subsidiary, TFF Pharmaceuticals Australia Pty Ltd. in order to conduct clinical research.

As of the date of this report, the COVID-19 pandemic has had a relatively insignificant impact on our operations. During 2020, we experienced a temporary suspension of dosing in the Phase I clinical trial for our TFF Tac-Lac due to the COVID-19 pandemic and the pandemic has otherwise caused minor slowing in the timing of certain non-clinical and clinical activities by us and our collaborators and service providers during 2020 and the first quarter of 2021. However, the COVID-19 pandemic has not caused us to forego, abandon or materially delay any proposed activities. While we believe we have been able to effectively manage the disruption caused by the COVID-19 pandemic to date, there can be no assurance that our operations, including the development of our drug candidates, will not be disrupted or materially adversely affected in the future by the COVID-19 pandemic or an epidemic or outbreak of an infectious disease like the outbreak of COVID-19.

The following table summarizes our results of operations with respect to the items set forth below for the fiscal years ended December 31, 2021 and December 31, 2020 together with the percentage change for those items.

	Year ended December 31,			
	2021	2020	Favorable (Unfavorable)	Change
Grant revenue	$ 88,161	$ —	$ 88,161	—%
Research and development expense	$21,300,865	$10,681,565	$ (10,619,300)	99%
General and administrative expense	10,573,954	8,012,085	(2,561,869)	32%
Total operating expense	$31,874,819	$18,693,650	$ (13,181,169)	71%

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. During the years ended December 31, 2021 and 2020, we recognized $88,161 and $0, respectively, of grant revenue.

During the fiscal years ended December 31, 2021 and 2020, we incurred $21.3 million and $10.7 million of research and development expenses and $10.6 million and $8.0 million of general and administrative expenses, respectively. The increase in research and development expenses during 2021 was mainly due to increased manufacturing costs of approximately $5.3 million, which includes approximately $1.6 million related to the Augmenta monoclonal antibody, clinical and preclinical expenses of approximately $1.7 million and $1.7 million,

respectively, related to Niclosamide, TFF Vori and TFF Tac-Lac, increased payroll and related expense of approximately $671,000 and increased stock-based compensation of approximately $319,000. The increase in research and development expenses also includes our preliminary analysis and testing of dry powder formulations of several drugs and vaccines owned or licensed by third parties we believe may lead to the out-licensing of our TFF technology for the development of dry powder product candidates. We expect our spending on research and development activities to continue to increase in upcoming quarters due primarily to clinical trial activity.

The increase in general and administrative expenses in 2021 from the prior year was mainly a result of increases in insurance and investor relation expenses of approximately $576,000, increased consulting and business development expenses of approximately $399,000, payroll and related expenses of approximately $280,000 and increased stock-based compensation of approximately $1.0 million, along other general increases due to the increase in our operations. While we expect our general and administrative expenses to continue to increase over the next few years, we anticipate the rate of increase has begun to decrease.

The following table summarizes our other income and interest income for the years ended December 31, 2021 and December 31, 2020 together with the percentage change for those items.

	Year ended December 31,			
	2021	2020	Favorable (Unfavorable)	Change
Other income	$ 696,714	$ —	$ 696,714	—
Interest income	$ 51,232	$ 126,416	$ (75,184)	(40)%

Other income in 2021 consists of $652,877 of refundable Australian research and development incentive program payments for expenditures incurred during 2020 and $43,836 received from the U.S. Internal Revenue Service related to research and development tax credits for expenditures incurred during 2020. Interest income decreased during fiscal 2021 due to lower interest rates on interest-bearing accounts.

We incurred a net loss of $31.0 million and $18.6 million for the fiscal years ended December 31, 2021 and 2020, respectively.

Financial Condition

As of December 31, 2021, we had total assets of approximately $40.7 million and working capital of approximately $36.9 million. As of December 31, 2021, our liquidity included approximately $33.8 million of cash and cash equivalents. We believe that our cash on-hand as of the date of this report is sufficient to fund our proposed operating plan for, at least, the 12 months following the date of this report. However, as of the date of this report, we believe that we will need additional capital to fund our operations through to the marketing approval for TFF Vori and TFF Tac-Lac, assuming such approval can be obtained at all, and to engage in the substantial development of any other of our drug candidates, such as formulation, early-stage animal testing and formal toxicology studies. If we encounter unforeseen delays or expenses, we may require additional capital in order to fund our current level of ongoing costs over the next twelve months. 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 towards 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.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended December 31, 2021 and 2020:

	2021	2020
Net cash used in operating activities	$(29,556,971)	$(16,615,589)
Cash used in investing activities	(868,505)	(1,102,808)
Cash flows provided by financing activities	28,884,984	24,994,665
Effect of exchange rate changes	34,359	(70,399)
Net change cash and cash equivalents	$ (1,506,133)	$ 7,205,869

The increase in cash used in operating activities is primarily a result of higher operating losses in 2021 due to our business expansion, including additional personnel and increased product candidate development activity. The investing activity is related to purchases of property and equipment. The financing activity primarily consists of the August 2020 private placement and the March 2021 public 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.

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.

Research and Development Expenses

In accordance with authoritative guidance, we charge research and development costs to operations as incurred. Research and development expenses consist of personnel costs for the design, development, testing and enhancement of our technology, and certain other allocated costs, such as depreciation and other facilities related

expenditures.

Collaborative Arrangements

We consider the nature and contractual terms of arrangements and assesses whether an arrangement involves a joint operating activity pursuant to which we are an active participant and exposed to significant risks and rewards dependent on the commercial success of the activity. If we are an active participant and exposed to significant risks and rewards dependent on the commercial success of the activity, we account for such arrangement as a collaborative arrangement.

For collaborative arrangements where a collaborative partner is not a customer for certain research and development activities, we account 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. We classify payments owed or receivables recorded as other current liabilities or prepaid expenses and other current assets.

If payments from the collaborative partner to us represent consideration from a customer in exchange for distinct goods and services provided, then we account for those payments within the scope of ASC 606, Revenue from Contracts with Customers.

Research and Development Tax Incentive

We are 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 we have determined that it has reasonable assurance that we will receive the cash refund for eligible research and development expenditures, we record the Australian Tax Incentive as a reduction to research and development expenses as the Australian Tax Incentive is not dependent on us generating future taxable income, our ongoing tax status, or tax position. At each period end, management estimates the refundable tax offset available to us based on available information at the time.

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 Shareholders 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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

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 24, 2022

TFF PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

AS OF DECEMBER 31, 2021 AND 2020

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,794,672	$ 35,300,805
Receivable due from collaboration agreement	1,628,703	—
Research and development tax incentive receivable	966,646	—
Prepaid assets and other current assets	2,447,930	2,258,229
Total current assets	38,837,951	37,559,034
Property and equipment, net	1,859,860	1,102,808
Total assets	$ 40,697,811	$ 38,661,842
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,493,842	$ 1,297,725
Accrued compensation	416,910	—
Deferred research grant revenue	50,000	24,315
Total liabilities	1,960,752	1,322,040
Commitments and contingencies (see Note 4)		
Stockholders' equity:		
Common stock; $0.001 par value, 45,000,000 shares authorized; 25,371,781 and 22,534,874 shares issued and outstanding as of December 31, 2021 and 2020, respectively	25,372	22,535
Additional paid-in capital	104,078,968	71,648,453
Accumulated other comprehensive loss	(48,921)	(51,538)
Accumulated deficit	(65,318,360)	(34,279,648)
Total stockholders' equity	38,737,059	37,339,802
Total liabilities and stockholders' equity	$ 40,697,811	$ 38,661,842

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

TFF PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020

CONSOLIDATED STATEMENTS OF OPERATIONS	Year Ended December 31, 2021	Year Ended December 31, 2020
Grant revenue	$ 88,161	$ —
Operating expenses:		
Research and development	21,300,865	10,681,565
General and administrative	10,573,954	8,012,085

Total operating expenses	31,874,819	18,693,650
Loss from operations	(31,786,658)	(18,693,650)
Other income:		
Other income	696,714	—
Interest income	51,232	126,416
Total other income	747,946	126,416
Net loss	$ (31,038,712)	$ (18,567,234)
Net loss per share, basic and diluted	$ (1.25)	$ (0.91)
Weighted average common shares outstanding, basic and diluted	24,820,971	20,425,162

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Net loss	$ (31,038,712)	$ (18,567,234)
Other comprehensive loss:		
Foreign currency translation adjustments	2,617	(51,538)
Comprehensive loss	$ (31,036,095)	$ (18,618,772)

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, 2021 AND 2020

	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2020	18,450,992	$ 18,451	$ 43,338,710	$ -	$ (15,712,414)	$ 27,644,747
Sale of common stock, net of offering costs	3,048,654	3,048	24,277,235	-	-	24,280,283
Issuance of common stock for accrued research and development expense	220,666	221	1,131,792	-	-	1,132,013
Issuance of common stock for stock option exercises	285,003	285	714,097	-	-	714,382
Issuance of common stock						

in connection with cashless warrant exercises	529,559	530	(530)	-	-	-
Stock-based compensation	-	-	2,187,149	-	-	2,187,149
Foreign currency translation adjustment	-	-	-	(51,538)	-	(51,538)
Net loss	-	-	-	-	(18,567,234)	(18,567,234)
Balance, December 31, 2020	22,534,874	22,535	71,648,453	(51,538)	(34,279,648)	37,339,802
Sale of common stock, net of offering costs	2,140,000	2,140	28,012,879	-		28,015,019
Issuance of common stock for stock option exercises	252,156	252	689,500	-	-	689,752
Issuance of common stock for warrant exercises	444,751	445	179,768	-	-	180,213
Stock-based compensation	-	-	3,548,368	-	-	3,548,368
Foreign currency translation adjustment	-	-	-	2,617	-	2,617
Net loss	-	-	-	-	(31,038,712)	(31,038,712)
Balance, December 31, 2021	25,371,781	$ 25,372	$ 104,078,968	$ (48,921)	$ (65,318,360)	$ 38,737,059

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

TFF PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020

	Year Ended December 31, 2021	Year Ended December 31, 2020
Cash flows from operating activities:		
Net loss	$ (31,038,712)	$ (18,567,234)
Adjustment to reconcile net loss to net cash used in operating activities:		
Stock based compensation	3,548,368	2,187,149
Depreciation and amortization	111,453	-
Changes in operating assets and liabilities:		
Receivable due from collaboration agreement	(1,628,703)	-

Research and development tax incentive receivable	(997,802)	-
Prepaid assets and other current assets	(203,363)	(1,122,495)
Accounts payable	209,193	862,676
Accrued compensation	416,910	-
Deferred revenue	25,685	24,315
Net cash used in operating activities	(29,556,971)	(16,615,589)
Cash flows from investing activities:		
Purchases of property and equipment	(868,505)	(1,102,808)
Net cash used in investing activities	(868,505)	(1,102,808)
Cash flows from financing activities:		
Net proceeds from issuance of common stock	28,015,019	24,280,283
Proceeds from issuance of common stock for stock option exercises	689,752	714,382
Proceeds from issuance of common stock for warrant exercises	180,213	-
Net cash provided by financing activities	28,884,984	24,994,665
Effect of exchange rate changes on cash and cash equivalents	34,359	(70,399)
Net change in cash and cash equivalents	(1,506,133)	7,205,869
Cash and cash equivalents at beginning of year	35,300,805	28,094,936
Cash and cash equivalents at end of year	$ 33,794,672	$ 35,300,805
Supplemental disclosure of non-cash investing and financing activities:		
Cashless exercise of warrants	$ 416	$ 530
Issuance of common stock for accrued research and development expense	$ -	$ 1,132,013

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

TFF PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For The Years Ended December 31, 2021 and 2020

NOTE 1 – ORGANIZATION AND DESCRIPTION OF BUSINESS

TFF Pharmaceuticals, Inc. (the "Company") was incorporated in the State of Delaware on January 24, 2018 by Lung Therapeutics, Inc. ("LTI"), at which time the Company and LTI entered into a Contribution and Subscription Agreement ("Contribution Agreement") pursuant to which LTI agreed to transfer to the Company certain of LTI's non-core intellectual property rights and other assets, including LTI's rights under a patent license agreement with the University of Texas at Austin (see Note 5), in exchange for 4,000,000 shares of the Company's common stock. The transactions under the Contribution Agreement closed in March 2018. LTI's basis in such assets were minimal. LTI is an early-stage biotechnology company focused on the development of certain technologies in the pulmonary field. 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.

August 2020 Private Placement

On August 13, 2020, the Company conducted a private placement of 3,048,654 shares of its common stock, at a purchase price per share of $8.50, for aggregate gross proceeds to the Company of approximately $25,914,000, before deducting selling commissions and other offering expenses payable by the Company. After deducting the placement agent commissions and offering expenses, the Company received net proceeds of approximately $24,280,000. See Note 6 for additional details of the private placement.

March 2021 Public Offering

On March 30, 2021, the Company completed a public offering ("March 2021 Offering"), selling 2,140,000 shares of common stock at an offering price of $14.00 per share. The Company received gross proceeds of approximately $30,000,000. The Company received net proceeds of approximately $28,015,000, after deducting underwriting discounts and offering-related expenses.

COVID-19

As of the date of this report, the COVID-19 pandemic has had a limited impact on our operations. During 2020, we experienced a temporary suspension of dosing in the Phase I clinical trial for our TFF Tac-Lac due to the COVID-19 pandemic, and the pandemic has otherwise caused minor slowing in the timing of certain non-clinical and clinical activities by us and our collaborators and service providers during 2020 and the first nine months of 2021. However, the COVID-19 pandemic has not caused us to forego, abandon or substantially delay any proposed activities. While we believe we have been able to effectively manage the disruption caused by the COVID-19 pandemic to date, there can be no assurance that our operations, including the development of our drug candidates, will not be disrupted or materially adversely affected in the future by the COVID-19 pandemic or an epidemic or outbreak of an infectious disease like the outbreak of COVID-19.

NOTE 2 – LIQUIDITY AND MANAGEMENT'S PLANS

As of December 31, 2021, the Company had cash and cash equivalents of approximately $33,795,000 and a working capital surplus of approximately $36,877,000. The Company has not generated commercial revenues since inception and has incurred recurring operating losses. The Company expects to continue incurring losses for the foreseeable future and may need to raise additional capital to pursue its product development.

The Company expects to further increase its research and development activities, which will increase the amount of cash utilized subsequent to December 31, 2021. Specifically, the Company expects increased spending on research and development activities and higher payroll expenses as it increases its professional and scientific staff and continues to prepare for anticipated manufacturing activities. If the Company encounters unforeseen delays or expenses, it has the ability to curtail its presently planned level of operations. The Company currently believes its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of these consolidated financial statements.

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, 2021 and 2020, 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, and which in the opinion of management are subject to insignificant risk of loss in value. As of December 31, 2021 and 2020, the Company had cash in Australia of AUD$831,984 (US$604,944) and AUD$214,240 (US$165,092), 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, 2021 and 2020, approximately $431,000 and $1,103,000, 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.

Fair Value of Financial Instruments

Authoritative guidance requires disclosure of the fair value of financial instruments. The Company's financial

instruments consist of cash and cash equivalents and accounts payable, the carrying amounts of which approximate their estimated fair values primarily due to the short-term nature of the instruments or based on information obtained from market sources and management estimates. 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, 2021 or 2020.

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 2018 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

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 condensed 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 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. During the years ended December 31, 2021 and 2020, the Company rendered the related services and recognized revenue and research and development expenses of $88,161 and $0, respectively. As of December 31, 2021 and 2020, the Company had receivables due related to Feasibility Agreements of $11,996 and $0, respectively, which is included in prepaid assets and other current assets in the accompanying consolidated balance sheets, and deferred grant revenue of $50,000 and $24,315, respectively.

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").

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

In accordance with authoritative guidance, the Company charges research and development costs to operations as incurred. Research and development expenses consist of personnel costs for the design, development, testing and enhancement of the Company's technology, and certain other allocated costs, such as depreciation and other facilities related expenditures.

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. During the year ended December 31, 2021, the Company received its first cash refund under the Australian Tax Incentive, which was for expenditures incurred during 2020. Therefore, the Company recorded amounts received, or that it expects to receive, for expenditures incurred during 2020 as other income in the consolidated statements of operations.

As the Company has determined that it has reasonable assurance that it will receive the cash refund for eligible research and development expenditures, beginning with expenditures incurred during the year ended December 31, 2021, 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, 2021 and 2020.

The research and development incentive receivable represents an amount due in connection with the Australian Tax Incentive. The Company has recorded a research and development tax incentive receivable of $966,646 and $0 as of December 31, 2021 and 2020, respectively, in the consolidated balance sheets. The Company has recorded other income of $652,877 and $0, in the consolidated statements of operations for the years ended December 31, 2021 and 2020, respectively, related to refundable Australian research and development incentive program payments for expenditures incurred during 2020. The Company recorded a reduction to research and development expenses of $997,801 and $0 during the years ended December 31, 2021 and 2020, respectively, for expenditures incurred during 2021. In addition, the Company also received $43,837 and $0 during the years ended December 31, 2021 and 2020, respectively, from the United States Internal Revenue Service related to research and development tax credits for expenditures incurred during 2020, which has been included in other income in the consolidated statements of operations.

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. Basic weighted average shares outstanding for the years ended December 31, 2021 and 2020 include 400,000 shares underlying a warrant to purchase common shares that was exercisable for little consideration (an aggregate exercise price of $0.01 per share) and was deemed issued for the purposes of basic earnings per share. The warrant was exercised during the year ended December 31, 2021.

For the years ended December 31, 2021 and 2020, 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:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Stock Options	2,893,839	2,610,495
Warrants	389,233	417,355
	3,283,072	3,027,850

Use of Estimates

The preparation of 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 stock-based compensation, valuation allowance against deferred tax assets and related disclosures. Actual results could differ from those estimates.

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's freestanding derivatives consist of warrants to purchase common stock that were issued in connection with services provided to the Company. 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. Such warrants 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 December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, *Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes,* which clarifies and simplifies certain aspects of the accounting for income taxes. The standard is effective for years beginning after December 15, 2020, and interim periods within annual periods beginning after December 15, 2020. The adoption of this standard on January 1, 2021 did not have a material impact on the Company's consolidated financial statements.

In January 2020, the FASB issued ASU 2020-01, *Investments – Equity Securities, Investments – Equity Method and Joint Ventures, and Derivatives and Hedging – Clarifying the Interactions Between Topic 321, Topic 323, and Topic 815*, intended to clarify the interactions between ASC 321, ASC 323 and ASC 815. The new standard addresses accounting for the transition into and out of the equity method and measurement of certain purchased options and forward contracts to acquire investments. The standard is effective for annual and interim periods beginning after December 15, 2020, with early adoption permitted. Adoption of the standard requires changes to be made prospectively. The adoption of this standard on January 1, 2021 did not have a material impact on the Company's

consolidated financial statements.

TFF PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For The Years Ended December 31, 2021 and 2020

NOTE 4 – 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 expires on October 31, 2022, as amended. The lease has an additional one-year option for renewal, and the base rent is $36,000 per year. The Company has determined that the lease agreement is considered a short-term lease under ASC 842 and has not recorded a right-of-use asset or liability. The Company rents another office space on a month-to-month basis with no long-term commitment, which is considered a short-term lease as well. Short-term lease expense for the years ended December 31, 2021 and 2020 was approximately $78,000 and $59,000, respectively.

Approximate future minimum lease payments required under the operating leases are as follows:

	Amount
Year Ending December 31, 2022	$ 30,000

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.

TFF PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For The Years Ended December 31, 2021 and 2020

NOTE 5 – LICENSE AND AGREEMENTS

In July 2015, the University of Texas at Austin ("UT") granted to the Company's former parent, LTI, an exclusive worldwide, royalty bearing license to the patent rights for the TFF platform in all fields of use, other than vaccines for which LTI received a non-exclusive worldwide, royalty bearing license to the patent rights for the TFF platform. In March 2018, LTI completed an assignment to the Company all of its interest to the TFF platform, including the patent

license agreement with UT, at which time the Company paid UT an assignment fee of $100,000 in accordance with the patent license agreement. In November 2018, the Company and UT entered into an amendment to the patent license agreement pursuant to which, among other things, the Company's exclusive patent rights to the TFF platform were expanded to all fields of use. The patent license agreement requires the Company to pay royalties and milestone payments and conform to a variety of covenants and agreements, and in the event of the Company's breach of agreement, UT may elect to terminate the agreement. For the period ended December 31, 2018, the Company did not achieve any of the milestones and, as such, was not required to make any milestone payments. During the ended December 31, 2019, the Company achieved one milestone by gaining IND approval on first indication of a licensed product on November 24, 2019. The milestone fee associated with this achievement was $50,000 and the Company's issuance of common shares to UT equal to 1% of the Company's outstanding shares of common stock, on a fully diluted basis, as of 30 days after IND approval, which was December 24, 2019. The Company paid the $50,000 and issued the shares in January 2020. As of the date of these consolidated financial statements, the Company is in compliance with the patent license agreement as all required amounts have been paid in accordance with the agreement.

In May 2018, the Company entered into a master services agreement and associated individual study contracts with ITR Canada, Inc. ("ITR") to provide initial contract pre-clinical research and development services for the Company's drug product candidates. In January 2019, the Company cancelled all of the individual study contracts with ITR and entered into contracts with 11036114 Canada Inc. (initially dba VJO Non-Clinical Development and now dba Strategy Point Innovations ("SPI")) and 11035835 Canada Inc., (dba Periscope Research) to complete additional pre-clinical research and development services in order to take advantage of eligible Canadian Tax Credits. The services related to the contract with SPI were sub-contracted to ITR and others under substantially the same terms as the initial contract with ITR. Desire Ventures, LLC facilitates the invoicing for the various affiliates. The accounts payable due in connection with this agreement as of December 31, 2021 and 2020 was $0 and $56,000, respectively. During the years ended December 31, 2021 and 2020, the Company recorded research and development costs of approximately $4,789,000 and $3,001,000, respectively.

In April 2019, the Company entered into a master services agreement with Irisys, LLC to provide contract manufacturing services for one of the Company's drug product candidates, Voriconazole. The accounts payable due in connection with this agreement was approximately $21,000 and $59,000 as of December 31, 2021 and 2020, respectively. During the years ended December 31, 2021 and 2020, the Company recorded research and development costs of approximately $1,940,000 and $1,837,000, respectively.

In January 2020, TFF Australia entered into a master consultancy agreement with Novotech (Australia) Pty Ltd. (formally known as Clinical Network Services Pty Ltd.) to provide initial contract clinical research and development services for the Company's drug product candidates. The accounts payable due in connection with this agreement was approximately AUD$138,000 (US$100,000) and AUD$170,000 (US$131,000) as of December 31, 2021 and 2020, respectively. During the years ended December 31, 2021 and 2020, the Company recorded research and development costs of approximately AUD$2,080,000 (US$1,561,000) and AUD$590,000 (US$407,000), respectively, pertaining to this agreement.

In May 2020, TFF Australia entered into an amended clinical trial research agreement with Nucleus Network Pty Ltd. to provide a Phase I study of one of the Company's drug candidates, Tacrolimus. The accounts payable due in connection with this agreement was approximately AUD$161,000 (US$117,000) and AUD$51,000 (US$40,000) as of December 31, 2021 and 2020, respectively. During the years ended December 31, 2021 and 2020, the Company recorded research and development costs of approximately AUD$714,000 (US$536,000) and AUD$489,000 (US$337,000), respectively, pertaining to this agreement.

On August 12, 2020, the Company entered into a licensing and collaboration agreement with UNION therapeutics A/S in which UNION acquired an option to obtain a worldwide exclusive license for the TFF technology in combination with niclosamide. Pursuant to the terms of the license agreement, UNION can exercise its option to obtain the license within 45 days after the complete data has been received by UNION from investigator-initiated trials. Upon exercise of the option, UNION shall be responsible to pay all expenses incurred in the development of any licensed product. The Company will be eligible to receive milestone payments upon the achievement of certain milestones in the development the licensed products, based on completion of clinical trials, pre-marketing approvals and/or the receipt of at least $25,000,000 of grant funding. The Company will receive a single-digit tiered royalty on net sales. The Company will also be entitled to receive sales-related milestone payments based on the commercial success of the licensed products.

In January 2021, the Company entered into a master services agreement with Experic to provide contract manufacturing services for one of the Company's drug product candidates, Voriconazole. The accounts payable due in connection with this agreement was approximately $313,000 as of December 31, 2021. During the year ended December 31, 2021, the Company recorded research and development costs of approximately $1,823,000 pertaining to this agreement.

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 experiences a default on its required payment, Augmenta will have 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 will 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 has determined that the likelihood of the Put Right being exercised to be remote.

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 year ended December 31, 2021, the Company recorded research and development expenses of $1,626,153 and has recorded a receivable of $1,628,703 for reimbursement due from Augmenta as of December 31, 2021.

NOTE 6 – STOCKHOLDERS' EQUITY

Common Stock

UT Agreement

In November 2019, the Company achieved a milestone in connection with the UT agreement (see Note 5). As a result of the milestone, the Company owed UT 220,666 shares of common stock, which had a fair value of approximately $1,132,000, which was accrued in accrued research and development expense as of December 31, 2019. In January 2020, the Company issued the 220,666 shares of common stock to UT.

August 2020 Private Placement

On August 10, 2020, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement") with certain institutional and other accredited investors pursuant to which the Company issued and sold to the investors 3,048,654 shares of the Company's common stock at a price of $8.50 per share for gross proceeds of approximately $25.91 million, before deducting placement agent commissions and other offering expenses. After deducting the placement agent commissions and other offering expenses, the Company received net proceeds of approximately $24.28 million. The Purchase Agreement included customary representations, warranties, and covenants by the investors and the Company, and an indemnity from the Company in favor of the investors. Jefferies LLC acted as placement agent for the private placement and the private placement closed on August 13, 2020. Pursuant to the terms of the Registration Rights Agreement, the Company filed a resale registration statement on Form S-1 with the SEC that was declared effective on September 15, 2020.

March 2021 Offering

On March 30, 2021, the Company completed the March 2021 Offering, selling 2,140,000 shares of common stock at an offering price of $14.00 per share. The Company received gross proceeds of approximately $30,000,000. The Company received net proceeds of approximately $28,015,000, after deducting underwriting discounts and offering-related expenses.

Stock Option Exercises

During November and December 2020, 285,003 shares of common stock were issued in connection with the exercise of stock options for total proceeds of $714,382.

During the year ended December 31, 2021, 252,156 shares of common stock were issued in connection with the exercise of stock options for total proceeds of $689,752.

Warrant Exercises

During August through December 2020, 529,559 shares of common stock were issued in connection with the cashless exercise of 659,108 common stock warrants.

During the year ended December 31, 2021, 415,917 shares of common stock were issued in connection with the cashless exercise of 424,288 common stock warrants.

During the year ended December 31, 2021, 28,834 shares of common stock were issued in connection with the exercise of common stock warrants for total proceeds of $180,213.

NOTE 7 – WARRANTS

On February 1, 2021, the Company issued a five-year warrant to purchase 25,000 shares of common stock at $15.90 per share to a consultant. The fair value of the warrant on the grant date was estimated using the Black-Scholes-Merton option pricing model with a common stock value of $16.13 per share, a contractual life of 5.0 years, a dividend yield of 0%, volatility of 97.09% and an assumed risk-free interest rate of 0.42%. The warrant is immediately exercisable. The fair value of the warrant was determined to be approximately $293,000 and was recorded in general and administrative expenses in the consolidated statement of operations during the year ended December 31, 2021.

In determining the fair value for warrants, the expected life of the Company's warrants was determined using the contractual life. The methodology in determining all other inputs to calculate the fair value utilizing the Black-Scholes-Merton option pricing model is the same as the stock option methodology described in Note 8 for stock options.

A summary of warrant activity for the years ended December 31, 2021 and 2020 is as follows:

	Number of Shares	Range of Exercise Prices	Weighted-Average Exercise Prices	Weighted-Average Remaining Life
Outstanding at January 1, 2020	1,476,463	$0.01 – $6.25	$ 2.71	4.1
Exercised	(659,108)	2.50 – 6.25	2.75	—
Outstanding at December 31, 2020	817,355	0.01 – 6.25	2.68	3.7
Issued	25,000	15.90	15.90	—
Exercised	(453,122)	0.01 – 6.25	0.74	—
Outstanding at December 31, 2021	389,233	$2.50 – $15.90	$ 5.79	4.4

The warrants outstanding at December 31, 2021 had an aggregate intrinsic value of approximately $1,432,000.

NOTE 8 – 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. The Company initially reserved 1,630,000 shares of its common stock under the 2018 Plan; however, upon completion of the Company's IPO the number of shares reserved for issuance under the 2018 Plan increased to 3,284,480, representing 15% of the Company's outstanding shares of common stock calculated on a fully diluted basis upon the close of the IPO. 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.

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 4,200,000 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, 2021 and 2020 for stock options and warrants:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Research and development	$ 459,492	$ 140,278
General and administrative	3,088,876	2,046,871
	$ 3,548,368	$ 2,187,149

As of December 31, 2021, there was approximately $9,474,000 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 2.5 years.

The Company records compensation expense for employee and nonemployee 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 employee and nonemployee stock options using the Black-Scholes option pricing model. The fair value of stock options issued was estimated using the following assumptions:

	Ended December 31, 2021	Year Ended December 31, 2020
Weighted average exercise price	$ 8.86	$ 10.42
Weighted average grant date fair value	$ 6.83	$ 9.25
Assumptions		
Expected volatility	89-97%	87-91%
Expected term (in years)	6.0-10.0	6.3-10
Risk-free interest rate	0.81-1.55%	0.36-1.47%
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.

The following table summarizes stock option activity during the years ended December 31, 2021 and 2020:

	Number of Shares	Weighted-Average Exercise Prices	Weighted-Average Remaining Contractual Term (In Years)	Intrinsic Value
Outstanding at January 1, 2020	2,139,078	$ 3.46	9.17	$ 4,052,512
Granted	782,045	10.42	—	—
Exercised	(285,003)	2.74	—	—
Cancelled	(25,625)	4.86	—	—
Outstanding at December 31, 2020	2,610,495	$ 5.63	8.60	$22,789,233
Granted	535,500	8.86	—	—
Exercised	(252,156)	2.74	—	—
Outstanding at December 31, 2021	2,893,839	$ 6.48	8.05	$ 9,932,413
Exercisable at December 31, 2021	1,219,841	$ 4.91	7.46	$ 5,730,660

NOTE 9 – INCOME TAXES

The Company had no income tax expense due to operating losses incurred for the years ended December 31, 2021 and 2020. 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.

The Company's income tax expense for the years ended December 31, 2021 and 2020 are summarized below:

	December 31, 2021	December 31, 2020
Current:		
Federal	$ -	$ -
State	-	-

Foreign	-	-
Total current	$ -	$ -
Deferred:		
Federal	$ (6,076,003)	$ (4,502,016)
State	-	-
Foreign	(240,902)	(480,666)
Change in valuation allowance	6,316,905	4,982,682
Total deferred	-	-
Income tax provision (benefit)	$ -	$ -

The Company's deferred tax assets are as follows:

	December 31, 2021	December 31, 2020
Deferred tax assets:		
Net operating loss carryforwards	$ 13,087,758	$ 6,807,300
Research and development tax credit	785,761	1,092,345
Intangibles	143,854	136,226
Stock compensation	1,054,242	761,741
Total deferred tax assets	15,071,615	8,797,612
Valuation allowances	(15,071,615)	(8,797,612)
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, 2021	December 31, 2020
Statutory rate	21.00%	21.00%
State rate	0.00%	0.00%
Foreign	(0.54)%	(1.81)%
Permanent book/tax differences	(1.95)%	(0.26)%
Research and development credit	1.07%	5.09%
Changes in valuation allowance	(19.58)%	(24.02)%
Total	-	-

As of December 31, 2021 and 2020, the Company had gross federal income tax net operating loss ("NOL") carryforwards of $59,111,972 and $30,126,830, respectively, and federal research tax credits of $1,047,681 and $1,486,704, respectively. Additionally, the Company had gross foreign income tax net operating loss carryforwards of $2,247,481 and $1,602,220 as of December 31, 2021 and 2020, respectively. The federal and foreign NOL have an indefinite life while the federal research tax credits will expire by 2041.

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 has not

conducted 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 CARES Act was signed into law on March 27, 2020 as a response to the economic challenges facing U.S. businesses caused by the COVID-19 global pandemic. The CARES Act allowed net operating loss incurred in 2018-2020 to be carried back five years or carried forward indefinitely, and to be fully utilized without being subjected to the 80% taxable income limitation. Net operating losses incurred after December 31, 2020 will be subjected to the 80% taxable income limitation. In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion, or all, of the deferred tax asset will be realized. The ultimate realization of deferred tax assets is dependent upon the Company attaining future taxable income during periods in which those temporary differences become deductible.

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, 2021.

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, 2021, the Company had a reserve for uncertain tax positions of $261,920, and no interest or penalties have been charged to the Company for the years ended December 31, 2021 and 2020. If incurred, the Company will classify any interest and penalties as a component of interest expense and operating expense, respectively. If recognized, $261,920 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, 2021 is as follows:

	Federal and State
Balance at December 31, 2020	$ 394,358
Additions for tax positions related to current year	110,827
Decreases for tax positions related to prior years	(243,265)
Balance at December 31, 2021	$ 261,920

NOTE 10 – SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to December 31, 2021 through the filing date of this Annual Report. Based on its evaluation, nothing other than the events described below need to be disclosed.

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, 2021 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, 2021 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, 2021 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, 2021, and based on that evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2021.

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

On March 21, 2022, Dr, Brian Windsor, our Chief Science Officer and a member of our Board, resigned as an officer and director of the Company effective as of March 21, 2022.

On March 22, 2022, our Board approved the appointment of Brandi Roberts to our Board effective as of March 25, 2022. Ms. Roberts has more than 25 years of public accounting and finance experience, including 22 years at publicly traded pharmaceutical, medical technology, and life science companies. Ms. Roberts has served as the Chief Financial Officer of Longboard Pharmaceuticals, Inc., a publicly traded clinical stage biopharmaceutical company, since January 2021. Previously, Ms. Roberts served as Chief Financial Officer of Lineage Cell Therapeutics, Inc., a publicly traded clinical-stage biotechnology company, from January 2019 to January 2021. Ms. Roberts served as Chief Financial Officer of REVA Medical, Inc., a medical device company, from August 2017 to January 2019. Subsequently, Reva filed a prepackaged voluntary Chapter 11 bankruptcy petition on January 14, 2020 and emerged

from bankruptcy protection in United States effective February 26, 2020. Ms. Roberts previously served as Chief Financial Officer of Mast Therapeutics, Inc., a publicly traded biopharmaceutical company, from January 2013 to April 2017, and as its Senior Vice President, Finance, from March 2011 to January 2013. Previously, she held senior positions at Alphatec Spine, Inc., Artes Medical, Inc., Stratagene Corporation, and Pfizer, Inc. Ms. Roberts currently serves as Chair of the Southern California Chapter of the Association of Bioscience Financial Officers and has served on the Board of Temple Therapeutics BV since November 2019. Ms. Roberts is a certified public accountant with the State of California and received her B.S. degree in business administration from the University of Arizona and her M.B.A. from the University of San Diego.

We believe that Ms. Roberts' significant accounting and finance background, including her significant experience as a chief financial officer of biopharmaceutical companies, qualifies her to serve on our Board.

In connection with her appointment, the Compensation Committee of our Board approved a grant to Ms. Roberts of options under our 2021 Stock Incentive Plan to purchase 95,000 shares of our common stock at an exercise price of $6.90 per share. The options vest over a four-year period, with 25% of the options vesting on the one anniversary of date of grant and the balance vesting thereafter in 12 equal quarterly installments.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The following sets forth information regarding the current executive officers and directors of the Company as of March 24, 2022.

Name	Age	Position
Glenn Mattes	66	President, Chief Executive Officer and Director
Kirk Coleman	49	Chief Financial Officer
Christopher Cano	51	Chief Operating Officer and Vice President of Business Development
Aaron Fletcher, Ph.D. (b), (c)	41	Chairman of the Board, Independent Director
Robert S. Mills (c)	69	Independent Director
Stephen C. Rocamboli (a), (b)	50	Independent Director
Harlan Weisman, M.D. (b), (c)	69	Independent Director
Randy Thurman (a)	72	Independent Director
Malcolm Fairbairn (a)	59	Independent Director

(a) Member of the Audit Committee of our Board.
(b) Member of the Compensation Committee of our Board.
(c) Member of the Nominating and Corporate Governance Committee of our Board.

Glenn Mattes has served as our President and Chief Executive Officer and a member of our Board since May 1, 2018. From December 2015 to April 2018, Mr. Mattes was Chief Executive Officer of Cornovus, Inc., a late stage-clinical stage company focused on the development of therapies for end stage congestive heart failure. From April 2011 to July 2014, Mr. Mattes was Chief Executive Officer of Arno Therapeutics, Inc., a clinical stage company focused on oncology therapeutics. From March 2003 to April 2011, Mr. Mattes served as President of Tibotec Therapeutics, Inc., a wholly-owned subsidiary of Johnson & Johnson engaged in the development of oncological therapeutics. Since May 2018, Mr. Mattes has also served as an Operating Partner of Revival Healthcare Capital, a private equity firm focused on investment and buy-out opportunities in the healthcare industry. Mr. Mattes has over 30 years of

experience in the pharmaceutical industry, including several senior executive positions and manager level positions in the fields of product development and marketing.

We believe that Mr. Mattes' valuable perspective and experience as our President and Chief Executive Officer, considerable experience in the pharmaceuticals industry and extensive leadership skills qualify him to serve on our Board.

Kirk Coleman has served as our Chief Financial Officer since January 2018. Since 2012, Mr. Coleman also served as an executive officer of Steelhead Capital Management, LLC and Bios Partners, LP, a venture capital firm focused on investment in early-stage and growth-stage biotech and medical device companies. From 1998 to 2008, Mr. Coleman was Treasurer for EFO Holdings, LP, a family office. Mr. Coleman has over 20 years of experience in venture capital investments. Mr. Coleman received a BBA in Accounting from Texas Christian University in 1995.

Christopher Cano has served our Chief Operating Officer and Vice President of Business Development since September 24, 2020, and previously served as our Director of Business Development since December 1, 2018. Prior to joining the Company, Mr. Cano served as the Vice President of Business Development at Aqua Pharmaceuticals, LLC, an Almirall company. Prior to Aqua Pharmaceuticals, Mr. Cano was the Head of Business Development at Duchesnay USA, Inc. and held a number of other business development roles at Noven Pharmaceuticals, Inc., a Hitsamitsu company, Agile Therapeutics, Liberty Medical, Nucryst Pharmaceuticals, and Barrier Therapeutics. Mr. Cano has served as the founder and Managing Partner of C2 Strategic Solutions, LLC, a consulting firm providing business development and licensing services to life science companies since January 2011. Mr. Cano holds a bachelor's degree in finance from Villanova University and a master's degree in business management from Rider University.

Aaron Fletcher, Ph.D. has served as a member of our Board since January 2018 and has served as the Chairman of the Board since December 2018. Since 2012, Dr. Fletcher has served as founder and President of Bios Research, a financial services firm that provides public equity research in the healthcare industry tailored to institutional firms and large family offices. Since 2014, Dr. Fletcher has also served as Managing Partner of Bios Partners, LP, a venture capital firm focused on investment in early-stage and growth-stage biotech and medical device companies. Dr. Fletcher also serves as a director of LTI, Cue Biopharma, Inc (Nasdaq: CUE), Actuate Therapeutics, AbiliTech Medical, and CogRx Therapeutics. Dr. Fletcher holds a Ph.D. in Biochemistry from Colorado State University and serves as a visiting professor at Dallas Baptist University. Dr. Fletcher has worked as an independent consultant for the biotech/healthcare equity industry for over ten years.

We believe that Dr. Fletcher's significant experience and knowledge of the pharmaceutical industry as a research analyst, venture investor and academic qualifies him to serve on our Board.

Robert S. Mills has served as a member of our Board since January 2018. Mr. Mills also served as our President and Chief Executive Officer from January 2018 to May 1, 2018, and also served as the Executive Chairman of our Board from January 2018 to December 2018. Mr. Mills has served as the founder and President of RSM Consulting, LLC since January 1, 2015 and as the chairman of the board of directors of LTI since May 7, 2015. From August 2011 to December 2014, Mr. Mills was President and Chief Executive Officer of SPL Pharmaceuticals, the leading manufacturer of heparin and pancreatin, until its sale to a Chinese pharmaceutical company. Mr. Mills also served as a member of the board of directors of SPL Pharmaceuticals from 2011 to 2014. From May 2010 to February 2011, Mr. Mills served as President and as a member of the board of directors of Qualitest Pharmaceuticals, which was acquired by Endo Pharmaceuticals for $1.2 billion. From 2006 to 2010, Mr. Mills served as President and Chief Operating/Executive Officer and as a member of the board of directors of Columbia Laboratories, Inc., which has since been renamed Juniper Pharmaceuticals, Inc. (Nasdaq: CBRX). Mr. Mills was recognized as a finalist for Entrepreneur of the Year for New Jersey in 2009 by Ernst and Young. Mr. Mills holds a B.S. Degree from Grove City College and numerous graduate business credits from Temple University.

We believe that Mr. Mills' significant experience as chief executive officer in various pharmaceutical companies and his service on several other boards, including the board of LTI, qualifies him to serve on our Board.

Stephen C. Rocamboli has served as a member of our Board since December 2018. Mr. Rocamboli has served as Chief Business Officer, General Counsel and Corporate Secretary of Advantagene, Inc., d/b/a Candel Therapeutics, a privately held immune-oncology company based in Needham, Massachusetts, between April 2015 and May 2020. Between 2010 and April 2015, Mr. Rocamboli served as general partner of Integrin Partners, LLC, a consulting firm providing corporate development and strategic transaction advisory and general counsel services to life science companies, investors and entrepreneurs. Between 2010 and 2012, Mr. Rocamboli also served as partner of Beijing International Group, an international affiliate of Integrin Partners. Between 2014 and 2015, Mr. Rocamboli also served as Special Counsel to Wyrick Robbins Yates & Ponton, LLP, focusing on life sciences transactions. Between 2008 and 2018, Mr. Rocamboli was a co-founder and served as President of Pear Tree Pharmaceuticals, a development stage pharmaceutical company focused on the development and commercialization of innovative pharmaceuticals that address the unique unmet needs of aging women and women with breast cancer until its sale to Daré Bioscience, Inc. Prior to joining Pear Tree, Mr. Rocamboli was Senior Managing Director and General Counsel of Paramount BioCapital and its affiliated companies between 2004 and 2007, and was Deputy General Counsel of Paramount from 1999 to 2004. During his tenure at Paramount he was also Partner at Orion Biomedical Fund. Mr. Rocamboli has served as a member of the board of directors of several public and private life sciences companies, including Foresight Biotherapeutics (sold to Shire Pharmaceuticals in 2015) and currently serves as a member of the board of directors of two privately held life sciences companies in New York. Mr. Rocamboli received his B.A. degree from The State University of New York at Albany and his J.D. from Fordham University School of Law.

We believe that Mr. Rocamboli's significant experience and knowledge of the pharmaceutical industry as a counsel and entrepreneur, and his service on other corporate boards, qualifies him to serve on our Board.

Harlan Weisman, M.D. has served as a member of our Board since December 2018. Since 2012, Dr. Weisman has also been Managing Director of And-One Consulting, LLC, which is engaged in the business of advising medical product companies, investment firms, and government and non-government healthcare organizations in formulating and implementing strategies for driving innovation in healthcare products and services. Since 2014, Dr. Weisman has also served as Executive Chairman of the Board of 3Dbio Therapeutics, a company using 3D bioprinting technology to develop whole tissue implants that fully integrate into the body. Dr. Weisman was co-founder, Chairman and Chief Executive Officer of Flame Biosciences, Inc. a clinical stage company focused on the research, development and commercialization of transformative therapies for cancer, from January 2020 to January 2022. From February 2016 through 2019, Dr. Weisman served as co-founder and Chief Scientific Officer for Mycrobiomics, a company developing counseling and educational material to help consumers to understand the microbiome and improve their health and well-being. Between December 2012 and December 2013, Dr. Weisman was Chairman and Chief Executive Officer of Coronado Biosciences, a biopharmaceutical company developing novel immunotherapies for autoimmune diseases and cancer. Between 2012 and 2019, Dr. Weisman served on the Board of Directors of ControlRad, Inc, a medical device company developing technology to reduce radiation exposure during fluoroscopic procedures. Dr. Weisman also served on the Board of Directors of Caelum Biosciences, Inc. from 2019 until its acquisition by AstraZeneca in 2021. Since 2012, Dr. Weisman has also been a senior advisor to CRG, an investment management firm making structured debt and equity investments in healthcare companies. Since 2016, Dr. Weisman has been a venture advisor to the Israel Biotech Fund, which invests and develops clinical-stage biotechnology companies based in Israel. From 2010 to 2016, Dr. Weisman served on the Board of Governors of the Patient Centered Outcomes Research Institute, established by the U.S. Congress as part of the Patient Protection and Affordable Care Act of 2010. Dr. Weisman was the Chief Science and Technology Officer of the Johnson & Johnson Medical Devices and Diagnostics Group from 2006 to 2012 and served as Chairman of the J&J Worldwide R&D Council. Dr. Weisman was Company Group Chairman of J&J Pharmaceutical Research & Development from 2004 to 2006.

We believe that Dr. Weisman's significant education and experience as a senior executive officer in the field of healthcare qualifies him to serve on our Board.

Randy Thurman has served as a member of our Board since April 2019. Mr. Thurman has been a senior advisor and operating partner for private equity funds since 2008, having co-led nearly $2 billion in acquisitions, debt

transactions and equity investments in life sciences, IT and service companies in the United States, Europe and Asia. He currently serves as a senior advisor to GMS Capital Partners as well as being Executive Chairman of Outlook Therapeutics, Inc., Vice Chairman of Syntone Biotech and an Adjunct Professor - Finance at Merrimack College Graduate School. He is also on the Advisory Board of Villanova University Law School, John F. Scarpa Center for Entrepreneurship and Law. Between 2000 and 2007, Mr. Thurman was the founder, Chair and Chief Executive Officer of VIASYS Healthcare, Inc., which was a diversified, research-based medical technology company. Mr. Thurman led VIASYS Healthcare, Inc. through a successful initial public offering and multiple acquisitions until its acquisition by Cardinal Health in 2007. Previously, he served as Chairman of the Board and Chief Executive Officer of Corning Life Sciences, Inc. and President, Chief Executive Officer and Director of Rhone-Poulenc Rorer Pharmaceuticals Inc. In 2007, Mr. Thurman was named an Entrepreneur of the Year by Ernst & Young. Mr. Thurman served as a fighter pilot in the United States Air Force and Air Force Reserves from 1971 to 1992 and was named in 2020 to America's Distinguished Flying Cross Society. Mr. Thurman received his B.A. degree in Economics from Virginia Polytechnic Institute and served as a trustee of the Pamplin School of Business. He also earned an M.A. in management from Webster University and is graduate of the USAF Air Command and Staff College.

We believe that Mr. Thurman's significant experience as chief executive officer and director of pharmaceutical companies qualifies him to serve on our Board.

Malcolm Fairbairn has served as a member of our Board since January 2020. Mr. Fairbairn is the founder of Ascend Capital, a $3.5 billion long/short equity fund for which he served as Chief Executive Officer and Chief Investment Officer from January 1999 to December 2018. Prior to founding Ascend Capital, Mr. Fairbairn was a Managing Director of Citadel Investment Group. Mr. Fairbairn holds an MBA from Harvard Business School and an MS and BS in Chemical Engineering from MIT.

We believe that Mr. Fairbairn's significant experience in finance and investing experience, in addition to significant leadership and strategic planning skills, qualifies him to serve on our Board.

On March 22, 2022, our Board approved the appointment of Brandi Roberts to our Board effective as of March 25, 2022. Please refer to Item 9B – Other Information above for information concerning Ms. Roberts and her appointment.

Corporate Governance

Audit Committee

Our Audit Committee consists of Randy Thurman, Stephen Rocamboli and Malcolm Fairbairn, with Mr. Thurman serving as Chairperson. The composition of our Audit Committee meets the requirements for independence under current Nasdaq Stock Market listing standards and Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Each member of our Audit Committee meets the financial literacy requirements of the Nasdaq Stock Market listing standards. Mr. Thurman is an audit committee financial expert within the meaning of Item 407(d) of Regulation S-K under the Securities Act of 1933, as amended ("Securities Act").

Compensation Committee Interlocks and Insider Participation

None of our independent directors, Aaron Fletcher, Ph.D., Robert S. Mills, Stephen C. Rocamboli, Harlan Weisman, M.D., Randy Thurman or Malcolm Fairbairn, is currently or has been at any time one of our officers or employees, except for Mr. Mills' service as an interim executive officer from January 2018 to December 2018. None of our executive officers currently serves, or has served during the last year, as a member of the board or compensation committee of any entity that has one or more executive officers serving as a member of our Board.

Code of Conduct

We have adopted a code of conduct for all employees, including the chief executive officer, principal financial officer and principal accounting officer or controller, and/or persons performing similar functions, which is available on our website, under the link http://ir.tffpharma.com/corporate-governance.

Section 16(A) Beneficial Ownership Reporting Compliance

Rules adopted by the SEC under Section 16(a) of the Exchange Act require our officers and directors, and persons who own more than 10% of the issued and outstanding shares of our equity securities, to file reports of their ownership, and changes in ownership, of such securities with the SEC on Forms 3, 4 or 5, as appropriate. Such persons are required by the regulations of the SEC to furnish us with copies of all forms they file pursuant to Section 16(a).

Based solely upon a review of Forms 3, 4 and 5 and amendments thereto furnished to us during our most recent fiscal year, and any written representations provided to us, we believe that all of the officers, directors, and owners of more than 10% of the outstanding shares of our common stock complied with Section 16(a) of the Exchange Act for the year ended December 31, 2021.

Item 11. Executive Compensation

Officer Compensation

The following table sets forth the compensation awarded to or earned by our chief executive officer and our two other highest paid executive officers for the years ended December 31, 2021 and 2020.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)	Total
Glenn Mattes,	2021	$ 450,000	$ 146,250	$ –	$ 596,250
CEO	2020	$ 429,167	$ 225,000	$ 2,706,741	$ 3,360,908
Kirk Coleman,	2021	$ 300,000	$ 78,500	$ –	$ 378,500
CFO	2020	$ 271,667	$ 90,000	$ 402,105	$ 763,772
Christopher Cano,	2021	$ 325,000	$ 62,250	$ 276,920	$ 664,170
COO and Business Director	2020	$ 278,125	$ 65,000	$ 1,054,733	$ 1,397,858

The dollar amounts in the Option Awards columns above reflect the values of options as of the grant date for the years ended December 31, 2021 and 2020, in accordance with ASC 718, *Compensation-Stock Compensation* and, therefore, do not necessarily reflect actual benefits received by the individuals. Assumptions used in the calculation of these amounts are included in Note 8 to our audited consolidated financial statements.

Narrative Disclosure to Summary Compensation Table

Mattes Employment Agreement

We entered into an agreement with Mr. Mattes dated April 23, 2018. Mr. Mattes served as our President and Chief Executive Officer pursuant to that agreement until December 20, 2018, at which time we entered into a superseding agreement with Mr. Mattes described below. We paid Mr. Mattes at the rate of $25,000 per month under the April 2018 agreement. Mr. Mattes was also eligible to receive a bonus of up to $150,000 for calendar year 2018, based on performance parameters set by our Board. Mr. Mattes received his full $150,000 bonus for 2018. The April 2018 agreement contained customary provisions relating to intellectual property assignment, confidentiality and indemnification.

We have also entered into an executive employment agreement dated December 20, 2018 with Mr. Mattes, which became effective, and replaced and superseded the April 2018 agreement, upon the close of our initial public offering in October 2019. Pursuant to Mr. Mattes' executive employment agreement, he continues to serve as our President and Chief Executive Officer. Pursuant to the December 2018 employment agreement, we agreed to pay Mr. Mattes at the rate of $33,333 per month commencing upon the close of the IPO, and on May 14, 2020 we amended Mr. Mattes' employment agreement to increase his salary to $37,500 effective as of June 1, 2020. Mr. Mattes is also eligible to receive a bonus of up to 50% of his base salary, commencing with calendar year 2019, based on performance parameters set by our Board, and is also eligible for participation in our incentive compensation plans. Mr. Mattes received his full $200,000 bonus for 2019 and his full bonus of $225,000 for 2020. Mr. Mattes' executive employment agreement entitles him to reasonable and customary health insurance and other benefits, at our expense, and a severance payment in the amount of 12 months of his base salary in the event of his termination by us without cause or his resignation for good reason, as such terms are defined in the executive employment agreement. Mr. Mattes' executive employment agreement is an "at will" agreement subject to termination by either party at any time and for any reason. The agreement contains customary provisions relating to intellectual property assignment, confidentiality and indemnification.

In the first half of 2018, we granted Mr. Mattes options to purchase up to 200,000 shares of our common stock at an exercise price of $2.50 per share. The options vested and became exercisable on May 1, 2019. On September 26, 2018, we granted Mr. Mattes options to purchase up to an additional 413,023 shares of our common stock at an exercise price of $2.50 per share. In addition, we agreed to grant Mr. Mattes, upon the close of our IPO, stock options that increased his beneficial ownership of our common stock, on a fully diluted basis after giving effect to the close of IPO and the conversion of our Series A preferred stock, to 5% of our then outstanding common stock. Following the close of our IPO in the fourth quarter of 2019, we granted Mr. Mattes options to purchase 358,082 shares of our common stock at an exercise price of $5.00 per share. In August 2020, we granted Mr. Mattes options to purchase 152,000 shares of our common stock at an exercise price of $13.65 per share. Except as described above, all options granted to Mr. Mattes vest over a four-year period, with 25% of the options vesting on the one anniversary of grant and the balance vesting thereafter in 12 equal quarterly installments.

Coleman Employment Agreement

From January 2018 to February 2019, Mr. Coleman was compensated for his services as our Chief Financial Officer at the hourly rate of $150 per hour. Effective as of February 15, 2019, we entered into an employment agreement with Mr. Coleman pursuant to which we have agreed to pay Mr. Coleman at the rate of $16,666 per month, which was amended as of December 1, 2019 to increase Mr. Coleman's salary to $21,666 per month, and further amended on September 24, 2020 to increase Mr. Coleman's salary to $25,000 per month. Mr. Coleman is eligible to receive a bonus of up to 30% of his base salary, commencing with calendar year 2019, based on performance parameters set by our Board, and is also eligible for participation in our incentive compensation plans. Mr. Coleman received his full bonus of $60,000 for 2019 and his full bonus of $90,000 for 2020. Mr. Coleman's employment agreement entitles him to reasonable and customary health insurance and other benefits, at our expense. Mr. Coleman's employment agreement is an "at will" agreement subject to termination by either party at any time and for any reason. The agreement contains customary provisions relating to intellectual property assignment, confidentiality and indemnification.

In connection with his employment agreement, we granted Mr. Coleman options to purchase up to 150,000 shares of our common stock at an exercise price of $2.50 per share. In addition, we agreed to grant Mr. Coleman, upon the close of our IPO, stock options that increased his beneficial ownership of our common stock, on a fully diluted basis after giving effect to the close of IPO and the conversion of our Series A preferred stock, to 1.22% of our then outstanding common stock. Following the close of our IPO in the fourth quarter of 2019, we granted Mr. Coleman options to purchase 77,883 shares of our common stock at an exercise price of $5.00 per share.

On December 20, 2019, we granted Mr. Coleman additional options to purchase 50,000 shares of our

common stock at an exercise price of $5.16 per share. In August 2020, we granted Mr. Coleman options to purchase 40,000 shares of our common stock at an exercise price of $13.65 per share. All options granted to Mr. Coleman vest over a four-year period, with 25% of the options vesting on the one anniversary of grant and the balance vesting thereafter in 12 equal quarterly installments.

Cano Employment Agreement

From December 2018 to September 2020, Mr. Cano was compensated for his services as our Director of Business Development at the rate of $250,000 per year. Effective as of September 24, 2020, we entered into an employment agreement with Mr. Cano pursuant to which we have agreed to pay Mr. Cano a base salary of $325,000, subject to an annual review by the Board. Mr. Cano will be eligible for a commission of 1% of net proceeds received by the Company, up to a maximum of $1,000,000 per calendar year, from sublicenses of patent rights, provided that with respect to any net proceeds from sublicenses for which the Company is obligated to pay a third-party a sales commission, Mr. Cano's commission rate will be 0.5% of such net proceeds. Mr. Cano will also be eligible for an annual bonus of 20% of his base salary for meeting key performance requirements, quotas, and assigned objectives determined annually by the Board.

Pursuant to the employment agreement, Mr. Cano is eligible to participate in all benefits, plans, and programs, which are now, or may hereafter be, available to other executive employees of the Company. Mr. Cano's employment agreement contains standard provisions concerning noncompetition, nondisclosure and indemnification.

In the event Mr. Cano's employment with the Company is terminated by the Company without cause, or Mr. Cano resigns for good reason, the Company shall pay Mr. Cano, in addition to all other amounts then due and payable, twelve (12) additional monthly installments of his base salary, less statutory deductions and withholdings.

In April 2019, we granted Mr. Cano options to purchase 8,500 shares of our common stock at an exercise price of $2.50 per share. In December 2019, we granted Mr. Cano additional options to purchase 30,000 shares of our common stock at an exercise price of $5.16 per share. In June 2020, we granted Mr. Cano options to purchase 30,000 shares of our common stock at an exercise price of $5.81 per share. In August 2020, we granted Mr. Cano options to purchase 10,000 shares of our common stock at an exercise price of $13.65 per share. In September 2020, we granted Mr. Cano options to purchase 78,500 shares of our common stock at an exercise price of $14.06 per share. All options granted to Mr. Cano vest over a four-year period, with 25% of the options vesting on the one anniversary of grant and the balance vesting thereafter in 12 equal quarterly installments.

In September 2021, we granted Mr. Cano options to purchase 43,000 shares of our common stock at an exercise price of $7.93 per share. The option granted to Mr. Cano vests over a four-year period, with 25% of the options vesting on the one-year anniversary of grant and the balance vesting thereafter in 12 equal quarterly installments.

The employment agreements with our executive officers were unanimously approved by our full Board. No officer or employee of our Company was involved in the Board's deliberation over the employment agreements of our executive officers, other Glenn Mattes, our chief executive officer.

Potential Payments upon Termination

As noted above, the officer employment agreements entitle each officer to reasonable and customary health insurance and other benefits, at our expense, and a severance payment based on their then annual salary and related benefits in the event of our termination of their employment without cause or their resignation for good reason.

If a qualifying involuntary termination had occurred on December 31, 2021, our executive officers would

have been eligible to receive the following amounts:

Name	Type of Payment	Termination of Employment ($)	Change in Control ($)
Glenn Mattes	Cash Severance	$ 450,000	–
	Equity Acceleration	$ –	$ –
Kirk Coleman	Cash Severance	$ 300,000	–
	Equity Acceleration	–	$ –
Christopher Cano	Cash Severance	$ 325,000	–
	Equity Acceleration	–	$ –

Outstanding Equity Awards at December 31, 2021

Set forth below is information concerning the equity awards held by our named executive officers as of December 31, 2021.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable[1]	Option Exercise Price ($)	Option Expiration Date
Glenn Mattes	21,170	–	$ 2.50	05/01/2028
	245,581	77,442	$ 2.50	09/26/2028
	166,434	166,434	$ 5.00	10/28/2029
	12,607	12,607	$ 5.00	11/28/2029
	47,500	104,500	$ 13.65	08/23/2030
	44,976	44,976	$ 5.00	11/28/2029
Kirk Coleman	53,750	56,250	$ 2.50	04/11/2029
	35,981	35,982	$ 5.00	10/28/2029
	2,960	2,960	$ 5.00	11/28/2029
	25,000	25,000	$ 5.16	12/19/2029
	12,500	27,500	$ 13.65	08/23/2030
Christopher Cano	5,843	2,657	$ 2.50	02/01/2029
	15,000	15,000	$ 5.16	12/19/2029
	11,250	18,750	$ 5.81	06/24/2030
	3,125	6,875	$ 13.65	08/23/2030
	24,531	53,969	$ 14.06	09/10/2030
	–	43,000	$ 7.93	09/21/2031

1 With regard to unexercisable options, 25% of the option award vests and first becomes exercisable on the first anniversary of the date of grant, with the remaining 75% of the option award vesting in 12 equal quarterly installments thereafter.

Director Compensation

We do not compensate any of our executive directors for their service as a director. We have adopted a non-employee director compensation policy pursuant to which our non-employee directors receive a quarterly $8,750 cash retainer, plus an additional $1,250 per quarter for serving as a chairman of any committee of the Board. We also reimburse our independent directors for their reasonable expenses incurred in connection with attending meetings of our Board. From time to time, we engage our executive directors to provide consulting services on our behalf and, as disclosed below, during 2021 we engaged Robert S. Mills to provide to us certain consulting services in the area of manufacturing and operations.

Set forth below is a summary of the compensation we paid to our non-executive directors during the year ended December 31, 2021.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Aaron Fletcher, Ph.D.	$ 35,000	$ –	$ –	$ 35,000
Robert S. Mills	$ 35,000	$ –	$ 99,999.96[1]	$134,999.96
Stephen Rocamboli	$ 40,000	$ –	$ –	$ 40,000
Harlan Weisman, M.D.	$ 40,000	$ –	$ –	$ 40,000
Randy Thurman	$ 40,000	$ –	$ –	$ 40,000
Malcolm Fairbairn	$ 35,000	$ –	$ –	$ 35,000

(1) Represents our payment of consulting fees to Mr. Mills during 2021.

The dollar amounts in the Option Awards columns above reflect the values of options as of the grant date for the years ended December 31, 2021, in accordance with ASC 718, *Compensation-Stock Compensation* and, therefore, do not necessarily reflect actual benefits received by the individuals. Assumptions used in the calculation of these amounts are included in Note 8 to our audited consolidated financial statements.

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

The following table sets forth certain information regarding the beneficial ownership of our common stock as of February 25, 2022 by:

each person who is known by us to be the beneficial owner of more than five percent (5%) of our issued and outstanding shares of common stock;

each of our directors, director nominees and executive officers; and

all directors, director nominees and executive officers as a group.

The beneficial ownership of each person was calculated based on 25,371,781 common shares issued and outstanding as of February 25, 2022. The SEC has defined "beneficial ownership" to mean more than ownership in the usual sense. For example, a person has beneficial ownership of a share not only if he owns it, but also if he has the power (solely or shared) to vote, sell or otherwise dispose of the share. Beneficial ownership also includes the number of shares that a person has the right to acquire within 60 days, pursuant to the exercise of options or warrants or the conversion of notes, debentures or other indebtedness. Two or more persons might count as beneficial owners of the same share. Unless otherwise indicated, the address for each reporting person is 1751 River Run, Suite 400, Fort Worth, Texas 76107.

Name of Director, Executive Officer or Director Nominees	Number of Shares	Percentage Owned
Glenn Mattes	621,583(1)	2.4%
Kirk Coleman	165,931(2)	*
Christopher Cano	56,065(3)	*
Aaron Fletcher, Ph.D.	216,031(4)	*
Robert S. Mills	118,022(5)	*
Stephen Rocamboli	73,397(6)	*
Harlan Weisman, M.D.	120,432(7)	*
Randy Thurman	69,726(8)	*
Malcom Fairbairn	1,378,645(9)	5.4%
Brandi Roberts	--	*
Directors, nominees and executive officers as a group	2,819,832	10.9%

* Less than 1%.

Name and Address of 5% + Holders	Number of Shares	Percentage Owned
Lung Therapeutics, Inc. 3801 S. Capital of Texas Hwy, Suite 330 Austin, Texas 78704	2,235,000(10)	8.8%
Maestro Ventures, LP 10 Orinda View Road Orinda, CA 94563	1,317,568	5.2%

(1) Includes 601,583 shares issuable upon exercise of currently exercisable options.
(2) Includes 163,931 shares issuable upon exercise of currently exercisable options.
(3) Includes 56,065 shares issuable upon exercise of currently exercisable options.
(4) Includes 116,031 shares issuable upon exercise of currently exercisable warrants held by an entity affiliated with Dr. Fletcher.
(5) Includes 102,042 shares issuable upon exercise of currently exercisable options.
(6) Represents 57,675 shares issuable upon exercise of currently exercisable options.
(7) Includes 120,432 shares issuable upon exercise of currently exercisable options.
(8) Includes 68,676 shares issuable upon exercise of currently exercisable options.
(9) Includes 1,317,568 shares held by Maestro Ventures, LP and 10,000 shares held by Valley High, LP. Mr. Fairbairn is a controlling person of both entities.
(10) Share ownership is based on the stockholder's Schedule 13G/A filed with the SEC on February 14, 2022.

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

Related Party Transactions

Since January 1, 2020, we have not entered into any transactions where the amount exceeded the lesser of $120,000 or one percent (1%) of the average of our total assets as of December 31, 2021 and 2020 with any of our directors, officers, beneficial owners of five percent or more of our common shares, any immediate family members of the foregoing or entities of which any of the foregoing are also officers or directors or in which they have a material financial interest, other than the compensatory arrangements with our executive officers and directors described elsewhere in this report.

We have adopted a policy that any transactions with directors, officers, beneficial owners of five percent or more of our common stock, any immediate family members of the foregoing or entities of which any of the foregoing are also officers or directors or in which they have a financial interest, will only be on terms consistent with industry standards and approved by a majority of the disinterested directors of our Board.

Director Independence

Our Board may establish the authorized number of directors from time to time by resolution. After giving effect to the resignation of Dr. Brian Windsor as a member of our Board and the appointment of Brandi Roberts to our Board, our Board will consist of eight (8) authorized members. Generally, under the listing requirements and rules of the Nasdaq Stock Market, independent directors must comprise a majority of a listed company's board of directors. Our Board has undertaken a review of its composition, the composition of its committees and the independence of each director. Our Board has determined that, other than Mr. Mattes, by virtue of his executive officer position, none of our director nominees has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each is "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and rules of the Nasdaq Stock Market. In making this determination, our Board considered the current and prior relationships that each nonemployee director nominee has with our Company and all other facts and circumstances our Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each nonemployee director nominee. Accordingly, a majority of our directors are independent, as required under applicable Nasdaq Stock Market rules, as of the date of this report. With regard to Robert Mills, our Board determined that Mr. Mills is independent notwithstanding his service as an officer of our company from January 2018 to December 2018 based on NASDAQ guidelines that allow for an independent director's past service as an executive officer provided such service was an interim arrangement lasting less than one year.

Item 14. Principal Accountant Fees and Services

Fees Incurred for Services by Principal Accountant

The following table sets forth the aggregate fees billed to us for services rendered to us for the years ended December 31, 2021 and 2020 by our independent registered public accounting firm, Marcum LLP.

	2021	2020
Audit Fees (A)	$ 143,800	$ 126,162
Audit - Related Fees	–	–
Tax Fees	14,935	12,389
	$ 158,735	$ 138,551

(A) The audit fees consisted of fees for the audit of our financial statements, the review of the interim financial statements included in our quarterly reports on Form 10-Q, and other professional services provided in connection with the statutory and regulatory filings or engagements and capital market financings.

Pre-Approval Policies and Procedures

The Audit Committee has responsibility for selecting, appointing, evaluating, compensating, retaining and overseeing the work of the independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established policies and procedures in its charter regarding pre-approval of any audit and non-audit service provided to the Company by the independent registered public accounting firm and the fees and terms thereof.

The Audit Committee considered the compatibility of the provision of other services by its registered public accountant with the maintenance of their independence. The Audit Committee approved all audit services provided by Marcum LLP in 2021 and 2020. Except for certain corporate tax compliance services, Marcum LLP did not perform any non-audit services in 2021 or 2020.

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	Amended and Restated Bylaws of the Registrant	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
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	Description of Capital Stock	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 10, 2021
10.1	Patent License Agreement dated July 8, 2015 between Lung Therapeutics, Inc. and The University of Texas at Austin	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.2*	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.
10.3*	Amended and Restated Consulting Agreement dated December 20, 2018 between Robert Mills and the Registrant	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.

Number	Exhibit Description	Method of Filing
10.4*	Executive Employment Agreement dated December 20, 2018 between Glenn Mattes and the Registrant	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.5	Amendment No. 1 to Patent License Agreement dated November 30, 2018 between the Registrant and The University of Texas at Austin	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.6*	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.
10.7	Form of Registration Rights Agreement dated August 10, 2020 between the Company and investors named therein	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on August 11, 2020
10.8*	Amendment No. 1 Dated May 14, 2020 to Executive Employment Agreement Between Glenn Mattes and Registrant	Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q filed on August 13, 2020.
10.9*	Amended and Restated Employment Agreement dated September 24, 2020 by and between the Registrant and Christopher Cano	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 10, 2021.
10.10*	TFF Pharmaceuticals, Inc. 2021 Stock Incentive Plan	Incorporated by reference from the Registrant's Definitive Proxy Statement filed on September 23, 2021
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.
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 24, 2022

By: */s/ Glenn Mattes*
Glenn Mattes,
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/ *Glenn Mattes* Glenn Mattes	Chief Executive Officer and Director *(Principal Executive Officer)*	March 24, 2022
/s/ *Kirk Coleman* Kirk Coleman	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 24, 2022
/s/ *Aaron Fletcher* Aaron Fletcher, Ph. D	Chairman of the Board	March 24, 2022
/s/ *Robert S. Mills, Jr.* Robert S. Mills, Jr.	Director	March 24, 2022
/s/ *Stephen Rocamboli* Stephen Rocamboli	Director	March 24, 2022
/s/ *Harlan Weisman, M.D.* Harlan Weisman, M.D.	Director	March 24, 2022
/s/ *Randy Thurman* Randy Thurman	Director	March 24, 2022
/s/ *Malcolm Fairbairn* Malcolm Fairbairn	Director	March 24, 2022