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, 2019

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)

2600 Via Fortuna, Suite 360
Austin, Texas 78746
(Address of principal executive offices)

(737) 802-1973
(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 $.001	TFFP	Nasdaq Capital Market

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers in response to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information

statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company (as defined in Rule 12b-2 of the 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The registrant did not have a public float on the last business day of its most recently completed second fiscal quarter because there was no public market for the registrant's common equity as of such date.

The number of shares of the registrant's common stock outstanding as of March 24, 2020 was 18,671,658.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2020 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A within 120 days of the registrant's year ended December 31, 2019 are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

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CAUTIONARY NOTICE

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

our future financial and operating results;

our intentions, expectations and beliefs regarding anticipated growth, market penetration and trends in our business;

the timing and success of our plan of commercialization;

our ability to successfully develop and clinically test our product candidates;

our ability to file for FDA approval of our product candidates through the 505(b)(2) regulatory pathway;

our ability to obtain FDA approval for any of our product candidates;

our ability to comply with all U.S. and foreign regulations concerning the development, manufacture and sale of our product candidates;

the adequacy of the current working capital;

the effects of market conditions on our stock price and operating results;

our ability to maintain, protect and enhance our intellectual property;

the effects of increased competition in our market and our ability to compete effectively;

costs associated with initiating and defending intellectual property infringement and other claims;

the attraction and retention of qualified employees and key personnel;

future acquisitions of or investments in complementary companies or technologies; and

our ability to comply with evolving legal standards and regulations, particularly concerning requirements for being a public company.

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.

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. As of the date of this report, LTI owns 4,000,000 shares of our common stock, or approximately 21% 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 an early-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. In November 2019, we initiated Phase I human clinical trials of our lead product, TFF Vori, however, as of the date of this report, 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 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.

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 at various stages of three

different feasibility studies of new chemical entities owned by three international pharmaceutical companies. In addition, we recently commenced preliminary analysis and testing of dry powder formulations of certain drugs and vaccines through topical, ocular and nasal applications in connection with our participation in submissions made to certain government agencies for government contracts.

Our business model is to develop 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 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.

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 Visiongain, the market for biologics is expected to top $270 billion by 2019. 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. 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.

We have entered into short-term contract manufacturing agreements with IriSys, Inc. and CoreRx, Inc. for their provision of certain product testing, development and clinical manufacturing services for our TFF Vori and TFF Tac-Lac product candidates, respectively. Our agreements with IriSys and CoreRx 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 both IriSys and CoreRx, 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 Patheon's, CoreRx's and IriSys' facilities and services are conducted in accordance with the FDA's current good manufacturing practices, or cGMPs, regulations, and IriSys and CoreRx are in the process of onboarding the TFF technology to support preclinical and clinical supply of our TFF Vori and TFF Tac-Lac drug product candidates, respectively.

Pursuant to the agreements with CoreRx and IriSys, 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.

Our Initial Drug Targets

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 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 early in vitro and animal testing confirms, 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 have already completed performance characterization of a TFF formulation of Voriconazole, early animal model testing and, in 2018, a seven-day toxicology study in rats. Through our drug characterization activities, we have worked with researchers at UT to define the appropriate dosage, particle size, porosity, density and other dosage characteristics of a TFF prepared dry powder formulation of Voriconazole and related excipients. Previous third-party studies suggest that inhaled Voriconazole may be effective in animal models and as a therapy in humans when delivered to the lung by nebulization. Our TFF formulation of Voriconazole has been used to produce a 95% Voriconazole powder for inhalation that has been tested in rats and at inhaled doses up to 4 mg/kg, with no local or systemic toxicity while showing good exposure in lung tissue and plasma.

On February 4, 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. However, the FDA requested that we perform an additional 28-day toxicity study in rats and a 14-day study in dogs, both of which have been completed, as well as a Phase I study in healthy human subjects. 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. In addition, we believe we will need to complete a Phase II study prior to filing for 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 transplants in the U.S. each year as well as approximately 50,000 patients suffering with chronic IPA.

TFF 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, high 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 have already completed development work and performance characterization of our dry powder formulation of Tacrolimus through early animal modeling testing. Through our drug characterization activities, we have worked with researchers at UT to define the particle size, distribution and aerodynamic properties suitable for delivery to humans using a dry powder inhaler. Past third-party studies report that inhaled Tacrolimus delivered to the lungs by nebulization has proven to produce robust drug levels in lung tissue, while the drug level is reduced in peripheral tissues, where toxicity limits dosing. Our TFF formulation of Tacrolimus has been used to produce a 50% Tacrolimus powder for inhalation that has been tested in rats. The inhaled doses in our animal tests exhibited higher pulmonary bioavailability with a prolonged retention time in the lung. In addition, our TFF formulation generated a lower systemic concentration of Tacrolimus, thereby suggesting the possibility of reduced side effects compared to oral or intravenous delivery.

On September 26, 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. However, since we are pursuing a new indication in the

treatment of prophylaxis of organ rejection in patients receiving lung transplants, the FDA confirmed our expectation that we will probably need to complete a Phase I and a Phase IIb/IIIa study prior to filing for marketing approval for TFF Tac-Lac. The proposed Phase IIb/IIIa study would essentially be a Phase II clinical study but would include more rigorous and expansive controlled and uncontrolled clinical trials for purposes of generating greater data on efficacy, dosing and labeling. 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 transplants in the U.S. each year.We intend to conduct Phase 1 clinical trials for our TFF formulation of Tacrolimus in Australia, which we consider to be a highly desirable site to conduct human clinical trials. On March 13, 2020, we had received the approval of the Australian Human Research Ethics Committee to commence Phase 1 trials in Australia. However, later in March 2020, our contract research organization partner in Australia informed us that because of the spread of the COVID-19 virus in Australia, there would be a delay in initiating the trials. One contributing factor is that Tacrolimus is an immunosuppressant drug and, given the threat of the COVID-19 virus, concern exists that even though we would be dosing healthy volunteers the inhalation of an immunosuppressant could increase the risk of severe complications if a volunteer was to contract COVID-19. As of the date of this report, we are unable to predict the length of the delay in the commencement of Phase 1 clinical trials for our TFF Tac-Lac. As of the date of this report, we intend to submit to the FDA an IND for TFF Tac-Lac upon completion of the Phase 1 clinical trials.

Triple Combination For COPD/Asthma

We are developing a dry powder drug combination intended to treat chronic obstructive pulmonary disease, or COPD, and asthma. There is a trend towards a three-drug combination in the treatment of uncontrolled COPD and asthma. Data suggests that therapy with a long-acting antimuscarinic agent, or LAMA, a long-acting β2-agonist, or LABA, and an inhaled corticosteroid, or ICS, is effective in patients with severe COPD. GSK has received FDA approval for a triple combination drug, Trelegy Ellipta, for the treatment of pulmonary disease. In addition, a variety of triple combinations are currently under development by large pharmaceutical companies, including AstraZeneca and Chiesi Farmaceutici.

We are currently pursuing the development of a combination dry powder drug intended for use with a dry powder inhaler for the maintenance treatment of bronchospasm associated with moderate to severe COPD. Unlike most other triple combinations, which are chosen in part from the pharmaceutical company's list of existing products, our triple combination drug contains what we consider will be the best-in-class drug in each category of LAMA, LABA and ICS.

Each of the drugs in our proposed dry powder triple combination is currently off-patent and each is available for delivery individually by way of breath-actuated inhalers. However, the three drugs in combination are not available for delivery through any breath-actuated inhalers due to the inability to deliver the drugs through the airway in the exact ratio designed for treatment. We believe, however, that our TFF platform allows for all three drugs to end up in each particle delivered to the airway in the exact ratio designed for treatment.

Since competition exists, and typically large clinical trials are needed to approve this type of triple combination drug, our strategy would be to develop the triple combination dry powder drug in partnership with a large pharmaceutical company looking to compete in the COPD and asthma markets. We intend to engage large pharmaceutical companies in discussions concerning a potential joint development of our triple combination dry powder drug. However, as of the date of this report we have no agreements, understandings or arrangements concerning a joint development program and there can be no assurance we will be able to enter into a joint development agreement on terms acceptable to us. We do not intend to pursue the development of our triple combination dry powder drug beyond performance characterization and efficacy data through early animal testing until such time, if ever, as we obtain a development partner.

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.

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.

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 39 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 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 Consultants

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

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 November 2019, we initiated Phase I human clinical trials for our TFF Vori product candidate, 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;
- 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, 2019 and 2018, we incurred a net

loss applicable to common stockholders of $36.7 million and $4.6 million, respectively. As of December 31, 2019, we had an accumulated deficit of $15.7 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. However, there can be no assurance we will be able to obtain regulatory approval for any of our product candidates. Even if we are able to obtain regulatory approval and subsequently commercialize our product candidates, 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, 2019, we had total assets of approximately $29.2 million and working capital of approximately $28.8 million. As of December 31, 2019, our liquidity included approximately $28.1 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 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 intensified. At this time, the United States and certain other countries are the subject of lock-downs and self-isolation procedures, which have significantly limited business operations and restricted internal and external meetings. We had expected to commence Phase 1 clinical trials our TFF formulation of Tacrolimus, or TFF Tac-Lac, in Australia in the first quarter of 2020, and on March 13, 2020 we had received the approval of the Australian Human Research Ethics Committee to commence Phase 1 trials, however later in March 2020 our contract research organization in Australia informed us that because of the spread of the COVID-19 virus in Australia, there would be a delay in initiating the trial. One contributing factor is that Tacrolimus is an immunosuppressant drug and, given the threat of the COVID-19 virus, concern exists that even though we would be dosing healthy

volunteers the inhalation of an immunosuppressant could increase the risk of severe complications if a volunteer was to contract COVID-19. As of the date of this report, we are unable to predict the length of the delay in the commencement of Phase 1 clinical trials for our TFF Tac-Lac. Further, the outbreak and any preventative or protective actions that we or 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. and CoreRx, Inc. 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 approval of our product candidates.

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

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Our business model depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. In November 2019, we initiated Phase I human clinical trials for our TFF Vori product candidate and we had a pre-IND meeting for TFF Tac-Lac in September 2019. We had intended to commence Phase 1 clinical trials for TFF Tac-Lac in the first quarter of 2020, however the commencement of clinical trials has been delayed due to the COVID-19 pandemic. As of the date of this report, we are unable to predict the length of the delay in the commencement of Phase 1 clinical trials for our TFF Tac-Lac. Further, 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

An active, liquid and orderly trading market for our shares may not develop, which may inhibit the ability of our stockholders to sell their shares. We recently commenced trading on the Nasdaq Capital Market, under the symbol "TFFP," on October 25, 2019, and since that date our common shares have been thinly traded. There can be no assurance that an active, liquid or orderly trading market in our shares will develop or, if it does develop, that it will be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other companies by using our shares as consideration.

Our failure to meet the continued listing requirements of NASDAQ could result in a delisting of our common stock. If we fail to satisfy the continued listing requirements of NASDAQ, such as the corporate governance requirements or the minimum closing bid price requirement, NASDAQ may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with NASDAQ's listing requirements.

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.

The market price of our shares may be subject to fluctuation and volatility. You

could lose all or part of your investment. The public offering price for the shares in our initial public offering was determined by negotiations between us and the underwriter and may not be indicative of prices that will prevail in the trading market. The stock market in general, and early stage public companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of such companies. The stock market in general has been, and the market price of our shares in particular will likely be, subject to fluctuation, whether due to, or irrespective of, our operating results and financial condition. The market price of our shares on the NASDAQ Capital Market may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated variations in our and our competitors' results of operations and financial condition;

market acceptance of our product candidates;

changes in earnings estimates or recommendations by securities analysts, if our shares are covered by analysts;

development of technological innovations or new competitive products by others;

announcements of technological innovations or new products by us;

publication of the results of preclinical or clinical trials for our product candidates;

failure by us to achieve a publicly announced milestone;

delays between our expenditures to develop and market new or enhanced products and the generation of sales from those products;

developments concerning intellectual property rights, including our involvement in litigation brought by or against us;

regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products;

changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses;

changes in our expenditures to promote our product candidates;

our sale or proposed sale, or the sale by our significant stockholders, of our shares or other securities in the future;

changes in key personnel;

success or failure of our research and development projects or those of our competitors;

the trading volume of our shares; and

general economic and market conditions and other factors, including factors unrelated to our operating performance.

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.

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 will be 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.

Our status as an "emerging growth company" under the JOBS Act may make it more difficult to raise capital as and when we need it. Because of the exemptions from various reporting requirements provided to us as an "emerging growth company," we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial

condition and results of operations may be materially and adversely affected.

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.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our shares, the price of our shares could decline. The trading market for our shares will rely in part on the research and reports that equity research analysts publish about us and our business, if at all. We do not have control over these analysts and we do not have commitments from them to write research reports about us. The price of our shares could decline if no research reports are published about us or our business, or if one or more equity research analysts downgrades our shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

We will incur significant increased costs as a result of becoming a public company that reports to the Securities and Exchange Commission and our management will be required to devote substantial time to meet compliance obligations. As a public company reporting to the Securities and Exchange Commission, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, and the reporting and governance provisions of the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Wall Street Reform and Protection Act, as well as rules subsequently implemented by the Securities and Exchange Commission, that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. There are significant corporate governance and reporting provisions in these laws that will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel will need to devote a substantial amount of time to these regulations. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, or Board, our Board committees or as executive officers.

Assuming a market for our common stock develops, shares eligible for future sale may adversely affect the market for our common stock. We, all of our directors and officers, and all of our common shares outstanding prior to our initial public offering, are subject to lock-up agreements whereby the holder has agreed not to sell, transfer, pledge or lend, or offer to do any of the same, directly or indirectly, any of our securities for a period of one year following the October 29, 2019 close of our initial public offering. The holders of common shares issuable upon conversion of our Series A preferred stock have agreed not to sell, transfer, pledge or lend, or offer to do any of the same, directly or indirectly, any of our securities for 180 days following the close of our initial public offering, other than certain holders who purchased our Series A preferred stock as part of our May 2019 private placement and are deemed "related persons" under the rules of FINRA, who have agreed to a one-year lock-up period. Notwithstanding the lock-up agreements, we have agreed to register for resale shares of common stock expected to be issued upon conversion of our Series A preferred stock and shares of common stock underlying certain warrants. Furthermore, after the 180^{th} day following the close of our initial public offering, certain stockholders will be eligible to begin publicly selling their shares under Rule 144, promulgated under the Securities Act of 1933, or the Securities Act. Rule 144 becomes available to the holders of our restricted stock on the 90^{th} day following the close of our initial public offering. However, as noted above, the holders of our restricted stock have agreed not to publicly sell any restricted stock pursuant to Rule 144 or otherwise for at least 180 days following the close of our initial public offering. See "Shares Eligible for Future Sale". Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus (including sales by investors of securities acquired in connection with this offering) may have a material adverse effect on the market price of our common stock.

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

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

limit who may call stockholder meetings;

do not provide for cumulative voting rights; and

provide that all board vacancies may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum.

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

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

any derivative action or proceeding brought on our behalf;

any action asserting a claim of breach of a fiduciary duty owed to us or our stockholders by any of our directors, officers or other employees;

any action asserting a claim against us or any of our directors, officers or other employees arising pursuant to any provision of Delaware law or our charter documents; or

any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine, but excluding actions to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

These exclusive forum provisions do not apply to claims under the Securities Act or the Exchange Act. These exclusive forums provisions, however, do provide that if no state court located in the State of Delaware has jurisdiction, the federal district court for the District of Delaware shall be the exclusive forum. By becoming a stockholder in our company, you will be deemed to have notice of and have consented to the provisions of our Certificate and amended and restated bylaws related to choice of forum, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. The choice of forum provisions in our Certificate and amended and restated bylaws may limit our stockholders' ability to obtain a

favorable judicial forum for disputes with us or any of our directors, officers or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in our Certificate and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our former parent, LTI, currently provides us with office space and certain administrative services and equipment for no charge. Those offices are located at 2600 Via Fortuna, Suite 360 Austin, Texas, 78746; telephone number (737) 802-1975. We also lease 1,500 square feet of office space in Doylestown, Pennsylvania. The lease agreement is for one year and expires October 31, 2020, 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 Capital Market under the symbol "TFFP," since our initial public offering on October 25, 2019. Since then, our common stock common stock has been relatively thinly traded and has experienced, and is expected to experience in the future, significant price and volume volatility. The following table shows the reported high and low closing prices per share for our common stock based on information provided by the NASDAQ Capital Market for the periods indicated.

Fiscal Year Ended December 31, 2019	High	Low
Fourth Quarter (commencing on October 25, 2019)	$ 5.40	$ 4.71

Holders of Record

As of March 24, 2020, there were 377 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 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 initially reserved 1,630,000 shares of our common stock under the 2018 Plan; however, upon completion of our initial public offering the number of shares reserved for issuance under the Plan increased to 3,284,480, representing 15% of our outstanding shares of common stock calculated on a fully diluted basis upon the close of our initial public offering. All officers, directors, employees and consultants to our company are eligible to participate under the plan. The purpose of the plan is to provide eligible participants with an opportunity to acquire an ownership interest in our company.

The following table sets forth certain information as of December 31, 2019 about our stock plans under which our equity securities are authorized for issuance.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options	(b) Weighted-Average Exercise Price of Outstanding Options	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected In Column (a))
Equity compensation plans approved by security holders	2,139,078	$ 3.46	1,145,402
Equity compensation plans not approved by security holders	—	—	—
Total	2,139,078	$ 3.46	1,225,402

Unregistered Sales of Equity Securities and Use of Proceeds

During the fiscal year ended December 31, 2019, we issued, in May 2019, 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 ($7.3 million after deducting offering expenses). In connection with the close of our initial public offering, we issued 9,571,692 shares of our common stock upon the conversion of all outstanding shares of our Series A preferred stock, which included of 5,662,000 shares of our Series A preferred stock issued in March 2018 and the conversion of all accrued and unpaid dividends. All of the aforementioned issuances were exempt under Section 4(a)(2) of the Securities Act of 1933 and Rule 506 there under. All of the investors were accredited investors, as such term is defined in Rule 501 under the Securities Act.

Item 6. Selected Financial Data

Not applicable.

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 totalled $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.

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 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. The operations surrounding the Acquired Assets are deemed to be our accounting predecessor and the results of operations in the financial summary below for the period January 1, 2018 through January 23, 2018 reflect the results of operations of the Acquired Assets, which were immaterial, as our predecessor.

During the fiscal years ended December 31, 2019 and 2018, we incurred $8.8 million and $848,809 of research and development expenses and $3.2 million and $3.0 million of general and administrative expenses, respectively. The increase in research and development expenses during 2019 was due to the ramp-up of research and development activities following the completion of our funding in May 2019. We incurred a net loss applicable to common stockholders of $36.7 million and $4.6 million for the fiscal years ended December 31, 2019 and 2018, respectively. The increase in net loss applicable to common stockholders in 2019 was due to a deemed dividend of $24.0 million upon the conversion of our Series A preferred stock in October 2019.

Financial Condition

As of December 31, 2019, we had total assets of approximately $29.2 million and working capital of approximately $28.8 million. As of December 31, 2019, our liquidity included approximately $28.1 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 ultimately 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.

Cash Flows

The following table sets forth a summary of our cash flows for the periods ended December 31, 2019 and 2018:

	Year ended December 31, 2019	Period from January 24, 2018 (Inception) to December 31, 2018[(1)]
Net cash used in operating activities	$(11,216,122)	$ (2,126,988)
Cash from investing activities	-	-
Cash flows provided by financing activities	29,049,387	12,388,659
Net increase in cash and cash equivalents	$ 17,833,265	$ 10,261,671

(1) The period from January 1, 2018 through January 23, 2018 was not material

The increase in cash used in operating activities is primarily a result of higher operating losses in 2019 due to our business expansion, including additional personnel and increased product candidate development activity. The financing activity primarily consists of the Series A preferred stock private placements in 2018, 2019 and the October 2019 initial public offering, or IPO.

Critical Accounting Policies

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.

We account for the fair value of equity instruments issued to non-employees using either the fair value of the services received or the fair value of the equity instrument, whichever is considered more reliable. We utilize the Black-Scholes-Merton option-pricing model to measure the fair value of options issued to non-employees.

For grants prior to the IPO, the fair value of the common stock was determined by the board of directors based on a variety of factors, including valuations prepared by third parties, our financial position, the status of our development efforts, the current climate in the marketplace and the prospects of a liquidity event, among others. For grants after the IPO, 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.

Common Stock Warrants

We classify as equity any warrants that (i) require physical settlement or net-share settlement or (ii) provides us with a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). We classify 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 our 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. We assess 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. Our freestanding derivatives consist of warrants to purchase common stock that were issued in connection with services provided to us. We 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 we determine using the Black-Scholes-Merton option-pricing model.

Beneficial Conversion Feature

On the date of the IPO, the outstanding Series A preferred stock, and related accrued and unpaid dividends, automatically converted into shares of our common stock. The conversion share calculation was based on the $2.50 initial issuance price for the Series A preferred stock plus any accrued but unpaid dividends and converted to common stock using a stated divisor conversion price equal to 50% of the IPO price to the public, which was $5.00 per share. In accordance with relevant accounting literature, since the stated terms of the conversion option did not permit us to compute the additional number of shares that it would need to issue upon conversion of the Series A preferred stock when the contingent event occurred, we recorded the beneficial conversion amount as a deemed dividend at the date of the IPO.

Off Balance Sheet Transactions

We do not have any off-balance sheet transactions.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of TFF Pharmaceuticals, Inc. (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations**,** stockholders' equity (deficit) and cash flows for the year ended December 31, 2019, period from January 24, 2018 to December 31, 2018 and period from January 1, 2018 to January 23, 2018 (Predecessor), and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the year ended December 31, 2019, period from January 24, 2018 to December 31, 2018 and period from January 1, 2018 to January 23, 2018 (Predecessor), in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2018

New York, NY
March 26, 2020

TFF PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,094,936	$ 10,261,671
Prepaid assets and other current assets	1,092,462	12,065
Total current assets	29,187,398	10,273,736
Deferred offering costs	—	127,768
Total assets	$ 29,187,398	$ 10,401,504
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 410,638	$ 428,645
Accrued dividends payable	—	728,350
Total current liabilities	410,638	1,156,995
Accrued research and development expense (see Note 5)	1,132,013	—
Total liabilities	1,542,651	1,156,995
Commitments and contingencies (see Note 4)		
Series A Preferred Stock:		
Series A Preferred Stock, $0.001 par value, 10,000,000 shares authorized; 0 and 5,662,000 shares issued and outstanding as of December 31, 2019 and 2018, respectively	—	12,485,971
Stockholders' equity (deficit):		
Common stock; $0.001 par value, 45,000,000 shares authorized; 18,450,992 and 4,000,000 shares issued and outstanding as of December 31, 2019 and 2018, respectively	18,451	4,000
Additional paid-in capital	43,338,710	596,724
Accumulated deficit	(15,712,414)	(3,842,186)
Total stockholders' equity (deficit)	27,644,747	(3,241,462)
Total liabilities, Series A Preferred Stock and stockholders' equity (deficit)	$ 29,187,398	$ 10,401,504

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

TFF PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31, 2019	January 24, 2018 to December 31, 2018	January 1, 2018 to January 23, 2018 (Predecessor)
Operating expenses:			
Research and development	$ 8,822,226	$ 848,809	$ *
General and administrative	3,165,331	3,049,337	*
Total operating expenses	11,987,557	3,898,146	*
Loss from operations	(11,987,557)	(3,898,146)	*
Other income:			
Interest income	117,329	55,960	*
Total other income	117,329	55,960	*
Net loss	(11,870,228)	(3,842,186)	*
Preferred stock dividend	(875,359)	(728,350)	*
Deemed dividend for beneficial conversion feature of Series A Preferred Stock	(23,929,751)	—	*
Net loss applicable to common stock	$ (36,675,338)	$ (4,570,536)	$ *
Net loss applicable to common stock per share, basic and diluted	$ (5.31)	$ (1.31)	
Weighted average common shares outstanding, basic and diluted	6,904,983	3,483,836	

* Operations were not material.

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

TFF PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Additional Paid in	Parent's Net	Accumulated	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit	Deficit	(Deficit)
Balance, January 1, 2018 (Predecessor)	$ -		$ -	$ (1,833)	$ -	$ (1,833)
Net loss (Predecessor)	-	-	-	-	-	-
Transfers from former parent (Predecessor)				1,833	-	1,833
Balance, January 23, 2018	**-**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**
Balance, January 24, 2018	-	$ -	$ -	$ -	$ -	$ -
Common stock issued to former parent	4,000,000	4,000	(4,000)	-	-	-
Issuance of common stock warrants	-	-	1,178,088	-	-	1,178,088
Stock-based compensation	-	-	150,986	-	-	150,986
Dividends on preferred stock	-	-	(728,350)	-	-	(728,350)
Net loss	-	-	-	-	(3,842,186)	(3,842,186)
Balance, December 31, 2018	4,000,000	4,000	596,724	-	(3,842,186)	(3,241,462)
Issuance of common stock in connection with IPO, including underwriter's over-allotment, net of offering costs and underwriter's discount	4,879,300	4,879	21,748,969	-	-	21,753,848
Stock-based compensation	-	-	590,041	-	-	590,041
Dividends on preferred stock	-	-	(875,359)	-	-	(875,359)
Conversion of Series A Preferred Stock						

(including accrued dividends) to common stock	9,571,692	9,572	21,278,335	-	-	21,287,907
Net loss	-	-	-	-	(11,870,228)	(11,870,228)
Balance, December 31, 2019	18,450,992	$ 18,451	$ 43,338,710	$ -	$ (15,712,414)	$ 27,644,747

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

TFF PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2019	January 24, 2018 to December 31, 2018	January 1, 2018 to January 23, 2018 (Predecessor)
Cash flows from operating activities:			
Net loss	$ (11,870,228)	$ (3,842,186)	$ -
Adjustment to reconcile net loss to net cash used in operating activities:			
Stock based compensation	590,041	1,329,074	-
Changes in operating assets and liabilities:			
Prepaid assets	(1,080,397)	(12,065)	-
Accounts payable	12,449	(398,189)	(1,833)
Accrued research and development expense	1,132,013	-	-
Net cash used in operating activities	(11,216,122)	(2,126,988)	(1,833)
Cash flows from investing activities:			
Net cash used in investing activities	-	-	-
Cash flows from financing activities:			
Net transfers from parent	-	-	1,833
Payment of offering costs	-	(97,312)	-
Net proceeds from issuance of common stock in connection with IPO	21,851,160	-	-
Net proceeds from issuance of preferred stock	7,198,227	12,485,971	-
Net cash provided by financing activities	29,049,387	12,388,659	1,833
Net increase in cash and cash equivalents	17,833,265	10,261,671	-
Cash and cash equivalents at beginning of period	10,261,671	-	-
Cash and cash equivalents at end of period	$ 28,094,936	$ 10,261,671	$ -
Supplemental disclosure of non-cash investing and financing activities:			
Common stock issued to former parent for acquired assets	$ -	$ 4,000	$ -
Accrued offering costs	$ -	$ 30,456	$ -
Accrued dividend	$ 875,359	$ 728,350	$ -
Conversion of Series A Preferred Stock (including accrued dividends) to common stock	$ 21,287,907	$ -	$ -
Offering costs netted with proceeds from IPO	$ 97,312	$ -	$ -
Deemed dividend for beneficial conversion feature of Series A Preferred Stock	$ 23,929,751	$ -	$ -

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

TFF PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For The Year Ended December 31, 2019, Period From January 24, 2018 to December 31, 2018 and Period from January 1, 2018 to January 23, 2018 (Predecessor)

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, having not yet started planned principal operations, and is devoting substantially all of its efforts toward technology research and development.

In October 2019, the Company completed an initial public offering ("IPO"), selling 4,400,000 shares of common stock at an offering price of $5.00 per share. The Company received gross proceeds of approximately $22,000,000 (see Note 7). In addition, the Company granted the underwriter a 45-day option to purchase an additional 660,000 shares of common stock at the initial public offering price, less underwriting discounts and commissions. The option was exercised in November 2019 and the underwriter purchased an additional 479,300 shares of common stock and the Company received additional gross proceeds of approximately $2,397,000.

The accompanying financial statements of the Company for the period from January 1, 2018 to January 23, 2018 reflect the historical results of operations, changes in net investment and cash flows of the operations for the assets acquired by the Company from LTI, the Company's former parent. These financial statements have been derived from the accounting records of LTI and should be read in conjunction with the accompanying notes thereto. The operations surrounding the acquired assets is deemed to be the Company's predecessor prior to January 24, 2018, the deemed date of acquisition. These financial statements do not necessarily reflect what the results of operations, financial position, or cash flows would have been had the Company been a separate entity during the periods prior to January 24, 2018 nor are they indicative of future results of the Company.

All of the assets, liabilities and results of operations of the Company as of and for the period ended January 23, 2018 were identified based on the assets acquired by the Company from LTI. Management believes the assumptions underlying the Company's carve-out financial statements are reasonable. Nevertheless, the financial statements may not include all of the actual expenses that would have been incurred had the Company operated as a standalone company during the periods presented, and may not reflect the Company's results of operations, financial position and cash flows had the Company operated as a standalone company during the periods presented. Actual costs that would have been incurred if the Company had operated as a standalone company would depend on multiple factors, including organizational structure and strategic decisions made in various areas, including information technology and infrastructure.

NOTE 2 - LIQUIDITY AND MANAGEMENT'S PLANS

As of December 31, 2019, the Company had cash and cash equivalents of approximately $28,095,000 and a working capital surplus of approximately $28,777,000. The Company has not generated 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.

NOTE 2 - LIQUIDITY AND MANAGEMENT'S PLANS, continued

The Company expects to further increase its research and development activities, which will increase the amount of cash utilized subsequent to December 31, 2019. 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. 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.

Financial Statements

The financial statements for the periods from January 1, 2018 through January 23, 2018 (predecessor) have been prepared using the accounting records of LTI. All material inter-company balances and transactions have been eliminated.

Deferred Offering Costs

The Company complies with the requirements of Accounting Standards Codification ("ASC") 340, *Other Assets and Deferred Costs*. Deferred offering costs of $127,768 as of December 31, 2018 consisted primarily of legal, accounting and filing fees incurred through the consolidated balance sheet date that are related to the Company's IPO and were charged to capital upon completion of the IPO in October 2019. There are no deferred offering costs as of December 31, 2019.

Cash and Cash Equivalents

The Company maintains its operating accounts in a single financial institution. The balances are insured by the U.S. Federal Deposit Insurance Corporation ("FDIC") 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.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, continued

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, 2019 or 2018.

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 was incorporated during 2018 which is the only open year at this time.

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.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, continued

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 year ended December 31, 2019 and the period from January 24, 2018 to December 31, 2018 include 400,000 shares underlying a warrant to purchase common shares. As the shares underlying this warrant can be issued for little consideration (an aggregate exercise price of $0.01 per share), these shares are deemed to be issued for purposes of basic earnings per share.

For the year ended December 31, 2019 and the period from January 24, 2018 to December 31, 2018, 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, 2019	Period from January 24, 2018 (inception) to December 31, 2018
Stock Options	2,139,078	1,073,082
Series A Convertible Preferred Stock*	—	5,953,340
Warrants	1,076,463	658,212
	3,215,541	7,684,634

* *On an as-converted basis*

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.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, continued

Beneficial Conversion Feature

On the date of the IPO, the outstanding Series A Convertible Preferred Stock ("Series A Preferred Stock"), and related accrued and unpaid dividends, automatically converted into shares of the Company's common stock. The conversion share calculation was based on the $2.50 initial issuance price for the Series A Preferred Stock plus any accrued but unpaid dividends and converted to common stock using a stated divisor conversion price equal to 50% of the IPO price to the public, which was $5.00 per share. In accordance with relevant accounting literature, since the stated terms of the conversion option did not permit the Company to compute the additional number of shares that it would need to issue upon conversion of the Series A Preferred Stock when the contingent event occurred, the Company recorded the beneficial conversion amount of approximately $23,930,000 as a deemed dividend at the date of the IPO.

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.

The Company accounts for the fair value of equity instruments issued to non-employees using either the fair value of the services received or the fair value of the equity instrument, whichever is considered more reliable. The Company utilizes the Black-Scholes-Merton option-pricing model to measure the fair value of options issued to non-employees.

Parent Net Deficit

LTI's net investment in the Company's business is presented as "Parent Net Deficit" in lieu of stockholders' equity in the Statement of Stockholders' Equity (Deficit). The changes in Parent's Net Deficit on the Statement of Stockholders' Equity (Deficit) include net cash transfers between LTI and the Company. LTI performed cash management and other treasury-related functions on a centralized basis for all of its divisions, which included the Company. Liabilities recorded by LTI, whose related expenses were pushed down to the Company, are included in Parent Net Deficit.

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 and warrants, valuation allowance against deferred tax assets and related disclosures. Actual results could differ from those estimates.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, continued

Recent Accounting Standards

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, *Leases (Topic 842)*. This ASU will require lessees to recognize a ROU asset and lease liability on the consolidated balance sheet for leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. In July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Topic 842, Leases* and ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements.* /ASU No. 2018-10 provides certain amendments that affect narrow aspects of the guidance issued in ASU No. 2016-02. ASU No. 2018-11 allows entities the option to prospectively apply the new lease standard at the adoption date instead of recording the cumulative impact of all comparative reporting periods presented within retained earnings. This guidance is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and effective for all other entities for fiscal years beginning after December 15, 2019 and interim periods within fiscal years beginning after December 15, 2020. The Company is currently evaluating this standard.

In July 2017, the FASB issued Accounting Standards Update ("ASU") 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*, (ASU 2017-11). Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This guidance is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and effective for all other entities for fiscal years beginning after December 15, 2019 and interim periods within fiscal years beginning after December 15, 2020. The Company is currently evaluating this standard.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. The guidance in this ASU expands the scope of ASC Topic 718 to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. This guidance is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and effective for all other entities for fiscal years beginning after December 15, 2019 and interim periods within fiscal years beginning after December 15, 2020. The Company is currently evaluating this standard.

In August 2018, the FASB issued ASU 2018-13, "*Fair Value Measurement* (Topic 820), - Disclosure Framework -

Changes to the Disclosure Requirements for Fair Value Measurement," which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. The Company is currently evaluating this standard.

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 the Company exercised a one-year lease renewal in October 2019 that will expire on October 31, 2020. The lease has an additional one-year option for renewal, and the base rent is $36,000 per year.

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

Year ending December 31,	Amount
2020	$ 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.

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. For the year 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 to be paid is $50,000 and the Company must issue UT common shares 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 total amount of common shares due and payable on December 31, 2019 to UT are 220,666 common shares, which have a fair value of approximately $1,132,000 based on the closing stock price of $5.13 on December 24, 2019. As of December 31, 2019, the Company has not paid the $50,000 or issued the shares and has included the $50,000 in accounts payable and the share amount due as a research and development expense payable. 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.

NOTE 5 – LICENSE AND AGREEMENTS, continued

In June 2018, the Company entered into a one-year agreement with Patheon Development Services, Inc. to provide initial contract manufacturing services for the Company's drug product candidates. The fees payable for contract manufacturing services under this agreement total $273,000, with no minimum fee requirement. During the years ended December 31, 2019 and 2018, the Company recorded costs associated with this agreement of $81,000 and $192,000, respectively, as research and development costs.

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. The fees payable for pre-clinical research and development services under these study contracts totaled $1,790,000, with no minimum fee requirement. In January 2019, the Company cancelled all of the individual study contracts with ITR and entered into a contract with Canada Inc. (dba VJO Non-Clinical Development ("VJO")) 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 VJO were sub-contracted to ITR under substantially the same terms as the initial contract with ITR, with fees payable for the services under this contract totaling $4,412,000, as amended. During the years ended December 31, 2019 and 2018, the Company recorded research and development costs of approximately $2,746,000 and $273,000, 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 fees payable for contract manufacturing services under this agreement total $1,352,000, as amended, with additional pass-through costs. During the year ended December 31, 2019, the Company recorded costs associated with this agreement of approximately $867,000 as research and development costs.

In June 2019, the Company entered into a master services agreement with CoreRx to provide contract manufacturing services for one of the Company's drug product candidates, Tacrolimus. The fees payable for contract manufacturing services under this agreement total $918,794, as amended, with additional pass-through costs. During the year ended December 31, 2019, the Company recorded costs associated with this agreement of approximately $290,000 as research and development costs.

In August 2019, the Company entered into a master services agreement and associated individual study contracts with Conform Clinical Development, Inc. and its affiliate, Les Entreprises Envie Inc. (dba Envie Ventures), which sub-contracted with Inflamax Research Limited (dba Cliantha Research ("Cliantha")) to perform a Phase 1 study of one of the Company's drug candidates, Voriconazole. The fees payable for the services under this contract total approximately $1,258,400, as amended, as amended. During the year ended December 31, 2019, the Company recorded costs associated with this contract of approximately $977,000 as research and development costs.

NOTE 6 - RELATED PARTY TRANSACTIONS

On March 22, 2018, the Company raised financing through a private placement of Series A preferred stock (as further discussed in Note 7). Certain of the Company's officers and directors participated in the private placement in the aggregate amount of $125,000, representing 0.88% of the Series A preferred stock sold by the Company.

NOTE 7 – STOCKHOLDERS' EQUITY (DEFICIT)

Common Stock

In October 2019, the Company completed an IPO, selling 4,400,000 shares of common stock at an offering price of $5.00 per share. The Company received gross proceeds of approximately $22,000,000. In addition, the Company granted the underwriter a 45-day option to purchase an additional 660,000 shares of common stock at the initial public offering price. The option was exercised and the underwriter purchased an additional 479,300 shares of common stock and the Company received additional gross proceeds of approximately $2,397,000. The Company received net proceeds from the IPO and the underwriter's purchase of additional shares of approximately $21,754,000, after deducting underwriting discounts and commissions and offering-related expenses. Warrants for 317,155 shares of the Company's common stock were issued to the IPO underwriter at an exercise price of $6.25 per share as part of the underwriter's compensation for the IPO. The estimated fair value of the warrants of approximately $977,000 was considered an offering cost and netted against additional paid-in capital.

In conjunction with the IPO, the Company's outstanding shares of Series A Preferred Stock automatically converted into 9,571,692 shares of its common stock (see below). Also in conjunction with the issuance of shares in the IPO, the Company granted options to officers and directors to purchase 627,984 shares of common stock at an exercise price of $5.00.

Series A Convertible Preferred Stock

The Company is authorized to issue up to 10,000,000 shares of preferred stock, $0.001 par value, all of which has been designated as Series A Preferred Stock and has a stated value of $2.50 per share. As of December 31, 2019 and 2018, there are 0 and 5,662,000 shares, respectively, issued and outstanding. The Series A Preferred Stock ranks senior to common stock with respect to dividends rights and liquidation preferences and has full voting rights. The Series A Preferred Stock accrues a dividend at a rate of 6% per annum, and such amount aggregated $0 and $728,350 as of December 31, 2019 and 2018, respectively. Dividends accrued during the periods ended December 31, 2019 and 2018 were $875,359 and $728,350, respectively.

Pursuant to the Company's amended and restated certificate of incorporation, holders of the Series A Preferred Stock have the following methods of conversion: (i) automatic conversion into common stock upon the consummation of an IPO at a conversion price of 50% of the IPO price, (ii) automatic conversion into common stock upon the consummation of a subsequent private placement of securities at a conversion price of 50% of the purchase price of the securities being sold by the Company approved by the holders of the Series A preferred stock, and (iii) at any time after the issuance date and until ten calendar days prior to the consummation of an IPO, each holder shall be entitled to convert into common stock at a conversion price of $2.50 per share.

The Series A Preferred Stock automatically converted into 9,571,692 common shares upon completion of the IPO in October 2019, based on the number of shares of Series A Preferred Stock outstanding as of the date of the IPO. The conversion share calculation was based on the $2.50 initial issue price for the Series A Preferred Stock plus $1,603,709 of accrued and unpaid dividends and automatically converted into shares of the Company's common stock using a stated divisor conversion price equal to 50% of the IPO price to the public which was $5.00 per share. In accordance with relevant accounting literature, since the terms of the conversion option did not permit the Company to compute the additional number of shares that it would need to issue upon conversion of the Series A Preferred when the contingent event occurred, the Company recorded the beneficial conversion amount

of approximately $23,930,000 as a deemed dividend at the date of the IPO.

NOTE 7 – STOCKHOLDERS' EQUITY (DEFICIT), continued

2018 Private Placement

In March 13, 2018, the Company entered into a securities purchase agreement with various accredited investors to raise gross proceeds of $14.2 million in a private placement (the "2018 Private Placement"). On March 22, 2018, the Company completed the 2018 Private Placement, issuing 5,662,000 shares of its Series A Preferred Stock. The shares of the Series A Preferred Stock were sold for $2.50 per share. The Company received net proceeds of approximately $12.5 million from the 2018 Private Placement, after paying placement agent fees and offering expenses.

The Series A Preferred Stock was accounted for under Section 480-10-S99 — Distinguishing Liabilities from Equity (FASB Accounting Standards Codification 480) as amended by ASU 2009-04 — *for Redeemable Equity Instruments* ("ASU 2009-04"). Under ASU 2009-04, a redeemable equity security is to be classified as temporary equity if it is conditionally redeemable upon the occurrence of an event that is not solely within the control of the issuer. While the Series A Preferred stock are mandatorily redeemable 21 months from the final closing date, it also contains a substantive conversion option. Therefore, the Company classified the Series A Preferred Stock as temporary equity in the consolidated balance sheet as of December 31, 2018.

In connection with, and upon closing of, the 2018 Private Placement, the Company issued 4,000,000 shares of common stock to LTI in consideration of LTI's assignment of the acquired assets consisting of certain patent license rights and other valuable consideration. LTI's basis in such assets was minimal.

2019 Private Placement

In May 2019, the Company entered into a securities purchase agreement with various accredited investors to raise gross proceeds of $8.2 million in a private placement (the "2019 Private Placement"), issuing 3,268,000 shares of its Series A Preferred Stock. The shares of the Series A Preferred Stock were sold for $2.50 per share. The Company received net proceeds of approximately $7.2 million from the 2019 Private Placement, after paying placement agent fees and offering expenses.

NOTE 8 – WARRANTS

On January 26, 2018 the Company issued a five-year warrant to purchase 400,000 shares of common stock at $0.01 per share to Liquid Patent Advisors, LLC ("LPA"). The warrant represented consideration for business and strategic development performed during 2018. 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 $1.67 per share, a contractual life of 2.5 years, a dividend yield of 0%, a volatility of 102.4% and an assumed risk-free interest rate of 2.19%. The fair value of the warrant was determined to be $664,224 and is included in general and administrative expenses in the statement of operations.

On March 13, 2018 and March 22, 2018, the Company issued to National Securities Corporation warrants to purchase shares of the Company's common stock in an amount equal to 10% of the shares of common stock issuable upon conversion of 5,662,000 shares of the Company's Series A Preferred Stock. The warrants represented placement agent compensation in connection with the 2018 Private Placement. The fair value of the warrants on the grant date was estimated using the Black-Scholes-Merton option pricing model with a common stock value of $1.67 per share, a contractual life of 2.5 years, a dividend yield of 0%, a volatility of 102.4% and an assumed risk-free

interest rate of 2.36%. The fair value of the warrants was determined to be $480,485 and is included in general and administrative expenses in the statement of operations. In connection with the conversion of the Series A Preferred Stock as a result of the IPO, the Company issued additional warrants to purchase 53,679 shares of common stock. The additional warrants were considered offering costs and netted with the proceeds from the IPO.

NOTE 8 – WARRANTS, continued

On April 6, 2018, the Company issued a five-year warrant to purchase 10,000 shares of common stock at $2.50 per share to BP Directors, LP ("BP"). The warrant represented consideration for board service from Dr. Aaron Fletcher. 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 $1.67 per share, a contractual life of 5.5 years, a dividend yield of 0%, a volatility of 89% and an assumed risk-free interest rate of 2.58%. The warrant vests and is being amortized over a one-year period. The fair value of the warrant was determined to be $11,075 and has been amortized in general and administrative expenses in the consolidated statements of operations.

On September 26, 2018, the Company issued a ten-year warrant to purchase 82,012 shares of common stock at $2.50 per share to BP. The warrant represented consideration for board service from Dr. Aaron Fletcher. 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 $1.67 per share, a contractual life of 6.3 years, a dividend yield of 0%, a volatility of 93.5% and an assumed risk-free interest rate of 2.96%. The warrant vests and is being amortized over a one-year period. The fair value of the warrant was determined to be $100,293 and has been amortized in general and administrative expenses in the consolidated statements of operations.

On May 16, 2019 and May 23, 2019, the Company issued to National Securities Corporation 326,800 warrants to purchase shares of the Company's common stock. The fair value of the warrants on the grant date was estimated using the Black-Scholes-Merton option pricing model with a common stock value of $1.67 per share, a contractual life of 5 years, a dividend yield of 0%, a volatility of 89.6% and an assumed risk-free interest rate of 2.11%. The fair value of the warrants was determined to be approximately $347,000 and was included in general and administrative expenses in the statement of operations. On September 13, 2019, these warrants were cancelled by the individual warrant holders and the Company determined that the related expense should be reversed. The reversal of the expense was recorded during the three months ended September 30, 2019, when the warrants were cancelled.

On October 29, 2019, the Company issued a ten-year warrant to purchase 43,794 shares of common stock at $5.00 per share to BP. The warrant represented consideration for board service from Dr. Aaron Fletcher. 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 $5.01 per share, a contractual life of 6.0 years, a dividend yield of 0%, a volatility of 88.48% and an assumed risk-free interest rate of 1.70%. The warrant is subject to a 25% cliff vesting at one year from the date of grant and the balance vesting quarterly over the following two years. The fair value of the warrant was determined to be $161,419 and $6,726 has been amortized in general and administrative expenses in the consolidated statements of operations during the year ended December 31, 2019.

On November 26, 2019, the Company issued to National Securities Corporation and its representatives underwriter warrants to purchase 317,155 shares of the Company's common stock in connection with the IPO. The exercise price of the warrants is $6.25 per share, each has a contractual life of 5 years and they are not exercisable for one year from the date of grant.

On November 29, 2019, the Company issued a ten-year warrant to purchase 3,623 shares of common stock at $5.00 per share to BP. The warrant represented consideration for board service from Dr. Aaron Fletcher. 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 $5.26 per share, a contractual life of 6.0 years, a dividend yield of 0%, a volatility of 90.16% and an

assumed risk-free interest rate of 1.68%. The warrant is subject to a 25% cliff vesting at one year from the date of grant and the balance vesting quarterly over the following two years. The fair value of the warrant was determined to be $14,300 and $298 has been amortized in general and administrative expenses in the consolidated statements of operations during the year ended December 31, 2019.

NOTE 8 – WARRANTS, continued

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 9 for stock options.

A summary of warrant activity for the periods ended December 31, 2019 and 2018 is as follows:

	Number of Shares	Range of Exercise Prices	Weighted-Average Exercise Prices	Weighted-Average Remaining Life
Outstanding at January 1, 2018	—	$ —	$ —	—
Issued	1,058,212	0.01 – $2.50	1.56	—
Outstanding at December 31, 2018	1,058,212	0.01 – 2.50	1.56	4.6
Issued	745,051	1.67 – 6.25	4.26	—
Cancelled	(326,800)	2.50	2.50	—
Outstanding at December 31, 2019	1,476,463	$0.01 – $6.25	$ 2.71	4.1

The warrants outstanding at December 31, 2019 had an aggregate intrinsic value of approximately $4,181,000.

NOTE 9 – 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 2018 Plan provides for the issuance of 1,630,000 shares of common stock. 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.

The following table summarizes the stock-based compensation expense recorded in the Company's results of operations during the years ended December 31, 2019 and 2018 for stock options and warrants:

	Year Ended December 31, 2019	Period from January 24, 2018 (inception) to December 31, 2018
Research and development	$ —	$ —
General and administrative	590,041	1,329,074
	$ 590,041	$ 1,329,074

As of December 31, 2019, there was approximately $3,940,461 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 3.1 years.

NOTE 9 – STOCK BASED COMPENSATION, continued

The Company records compensation expense for employee awards with graded vesting using the straight-line method. The Company records compensation expense for nonemployee awards with graded vesting using the accelerated expense attribution 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 non-employee stock options using the Black-Scholes option pricing model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service periods of the respective awards. The fair value of employee stock options issued was estimated using the following weighted-average assumptions:

	Year Ended December 31, 2019	Year Ended December 31, 2018
Weighted average exercise price	$ 4.42	$ 2.50
Weighted average grant date fair value	$ 3.08	$ 1.21
Assumptions		
Expected volatility	88-90%	92.24%
Weighted average expected term (in years)	6.3	6.26
Risk-free interest rate	1.68-2.31%	2.93%
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. The dividend yield considers that the Company has not historically paid dividends, and does not expect to pay dividends in the foreseeable future.

For grants prior to the IPO, the fair value of the common stock was determined by the board of directors based on a variety of factors, including valuations prepared by third parties, the Company's financial position, the status of development efforts within the Company, the current climate in the marketplace and the prospects of a liquidity event, among others. For grants after the IPO, 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 periods ended December 31, 2019 and 2018:

	Number of Shares	Weighted-Average Exercise Prices	Weighted-Average Remaining Contractual Term (In Years)	Intrinsic Value
Outstanding at January 1, 2018	—	$ —	—	$ —

Granted	1,073,082	2.50	—	—
Outstanding at December 31, 2018	1,073,082	2.50	9.64	$ —
Granted	1,065,996	4.42	—	—
Outstanding at December 31, 2019	2,139,078	$ 3.46	9.17	$ 4,052,512
Exercisable at December 31, 2019	470,000	$ 2.62	8.71	$ 1,283,560

NOTE 10 – INCOME TAXES

The Company had no income tax expense due to operating losses incurred for the years ended December 31, 2019 and 2018. 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 periods ended December 31, 2019 and 2018 are summarized below:

	December 31, 2019	December 31, 2018
Current:		
Federal	$ -	$ -
State	-	-
Total current	$ -	$ -
Deferred:		
Federal	$ 2,952,519	$ 862,412
State	-	-
Change in valuation allowance	(2,952,519)	(862,412)
Total deferred	-	-
Income tax provision (benefit)	$ -	$ -

The Company's deferred tax assets are as follows:

	December 31, 2019	December 31, 2018
Deferred tax assets:		
Net operating loss carryforwards	$ 2,789,541	$ 459,522
Research and development tax credit	532,711	59,270
Intangibles	105,580	68,003
Stock compensation	387,098	275,617
Total deferred tax assets	3,814,930	862,412
Valuation allowances	(3,814,930)	(862,412)
Net deferred tax assets	$ -	$ -

NOTE 10 – INCOME TAXES, continued

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

	December 31, 2019	December 31, 2018
Statutory rate	21.00%	21.00%
State rate	0.00%	0.00%
Permanent book/tax differences	(0.12%)	(0.10%)
Research and development credit	3.99%	1.54%
Changes in valuation allowance	(24.87%)	(22.44%)
Total	-	-

As of December 31, 2019 and 2018, the Company had gross federal income tax net operating loss ("NOL") carryforwards of $13,283,530 and $2,188,203, respectively, and federal research tax credits of $690,525 and $59,270, respectively.

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.

Under the Code, the NOL can be carried forward indefinitely and can be used to offset up to 80% of taxable income for losses arising in tax years beginning after December 31, 2017. 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, 2019.

NOTE 10 – INCOME TAXES, continued

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, 2019, the Company had a reserve for uncertain tax positions of $157,814, and no interest or penalties have been charged to the Company for the years ended December 31, 2019 and 2018. If incurred, the Company will classify any interest and penalties as a component of interest expense and operating expense, respectively. If recognized, $157,814 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, 2019 is as follows:

	Federal and State
Balance at December 31, 2018	$ -
Additions for tax positions related to current year	157,814
Additions for tax positions related to prior years	-
Balance at December 31, 2019	$ 157,814

NOTE 11 – SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to December 31, 2019 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 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based upon their evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were not effective as of December 31, 2019 because we have a small number of employees, as a result of our limited operations, which prohibits a segregation of duties. As we grow and expand our operations, we intend to engage additional employees and experts as needed. However, there can be no assurance that our operations will expand.

(b) *Changes in internal control over financial reporting.*

There were no changes to our internal control over financial reporting, as defined in Rules 13a-15(f) under the Exchange Act that occurred during the fiscal quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Item 9B. Other Information

Not applicable.

PART III

The information required by Part III is omitted from this report because we will file a definitive proxy statement within 120 days after the end of our 2019 fiscal year pursuant to Regulation 14A for our 2020 Annual Meeting of Stockholders, or the 2020 Proxy Statement, and the information to be included in the 2020 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be contained in the 2020 Proxy Statement and is hereby incorporated by reference.

Item 11. Executive Compensation

The information required by this item will be contained in the 2020 Proxy Statement and is hereby incorporated by reference.

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

The information required by this item will be contained in the 2020 Proxy Statement and is hereby incorporated by reference.

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

The information required by this item will be contained in the 2020 Proxy Statement and is hereby incorporated by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be contained in the 2020 Proxy Statement and is hereby incorporated by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Financial statements

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

(b) Financial statement schedules

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

(c) Exhibits

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

Number	Exhibit Description	Method of Filing
1.1	Form of Underwriting Agreement	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on September 27, 2019.
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 January 24, 2018 issued to Liquid Patent Consulting, LLC	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
4.3	Warrant dated March 13, 2018 issued to National Securities Corporation	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
4.4	Warrant dated March 22, 2018 issued to National Securities Corporation	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
4.5	Warrant dated May 16, 2019 issued to National Securities Corporation	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.

Number	Exhibit Description	Method of Filing
4.6	Warrant dated May 23, 2019 issued to National Securities Corporation	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
4.7	Warrant dated October 29, 2019 issued to National Securities Corporation	Filed electronically herewith.
4.8	Warrant dated November 20, 2019 issued to National Securities Corporation	Filed electronically herewith.
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.
10.4*	Consulting Agreement effective as of January 24, 2018 between Dr. Brian Windsor and the Registrant, as amended on December 20, 2018 and September 26, 2019	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on September 27, 2019
10.5*	Consulting Agreement dated April 23, 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.
10.6	Lease Agreement dated October 19, 2018	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.7*	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.
10.8	Securities Purchase Agreement dated May 16, 2019 by and among the Registrant and the Buyers named therein	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.9	Amended and Restated Registration Rights Agreement dated May 16, 2019 by and among the Registrant and certain of its stockholders	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.10	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.

Number	Exhibit Description	Method of Filing
10.11*	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.
21.1	List of Subsidiaries	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	XBRL Instance Document	Filed electronically herewith
101.SCH	XBRL Taxonomy Extension Schema Document	Filed electronically herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed electronically herewith
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	Filed electronically herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed electronically herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed electronically herewith

* Indicates management compensatory plan, contract or arrangement.

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 26, 2020

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 26, 2020
/s/ *Kirk Coleman* Kirk Coleman	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 26, 2020
/s/ *Aaron Fletcher* Aaron Fletcher, Ph. D	Chairman of the Board	March 26, 2020
/s/ *Brian Windsor* Brian Windsor, Ph. D	Director	March 26, 2020
/s/ *Robert S. Mills, Jr.* Robert S. Mills, Jr.	Director	March 26, 2020
/s/ *Stephen Rocamboli* Stephen Rocamboli	Director	March 26, 2020
/s/ *Harlan Weisman, M.D.* Harlan Weisman, M.D.	Director	March 26, 2020
/s/ *Randy Thurman* Randy Thurman	Director	March 26, 2020
/s/ *Malcolm Fairbairn* Malcolm Fairbairn	Director	March 26, 2020