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As confidentially submitted to the Securities and Exchange Commission on July 17, 2019

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

TFF PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	2834	82-4344737
(State or other jurisdiction of Incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(IRS Employer Identification Number)

2600 Via Fortuna, Suite 360
Austin, Texas 78746
(737) 802-1973

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Glenn Mattes
President and Chief Executive Officer
TFF Pharmaceuticals, Inc.
2600 Via Fortuna, Suite 360
Austin, Texas 78746
(737) 802-1973

(Address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Daniel K. Donahue, Esq. **Christopher M. Piazza, Esq.** **Greenberg Traurig, LLP** **3161 Michelson Drive, Suite 1000** **Irvine, California 92612** **Telephone: (949) 732-6557**	**Kevin K. Leung, Esq.** **Dominador D. Tolentino, Jr., Esq.** **LKP Global Law, LLP** **1901 Avenue of the Stars, Suite 480** **Los Angeles, California 90067** **Telephone: (424) 239-1890**

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. £

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. £

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier

effective registration statement for the same offering. £

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. £

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" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer £	Accelerated filer £
Non-accelerated filer S	Smaller reporting company S
	Emerging Growth Company S

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 to Section 7(a)(2)(B) of the Securities Act. £

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price[(1)]	Amount of Registration Fee
Common Stock, $0.001 par value per share	$ —	$ —
Underwriter Warrant[(2)(3)(4)]	$ —	—
Shares of Common Stock underlying Underwriter Warrant	$ —	$ —

_____

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the aggregate offering price of additional shares that the underwriter has the option to purchase to cover over-allotments, if any.

(2) No registration fee required pursuant to Rule 457(g) under the Securities Act of 1933.

(3) Registers a warrant to be granted to the underwriter for an amount equal to 10% of the number of the shares sold to the public.

(4) Pursuant to Rule 416 under the Securities Act of 1933, this registration statement shall be deemed to cover the additional securities (i) to be offered or issued in connection with any provision of any securities purported to be registered hereby to be offered pursuant to terms which provide for a change in the amount of securities being offered or issued to prevent dilution resulting from stock splits, stock dividends, or similar transactions and (ii) of the same class as the securities covered by this registration statement issued or issuable prior to completion of the distribution of the securities covered by this registration statement as a result of a split of, or a stock dividend on, the registered securities.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment, which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. THESE SECURITIES MAY NOT BE SOLD UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND WE ARE NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

SUBJECT TO COMPLETION, DATED JULY ___, 2019

_____ Shares of Common Stock

TFF PHARMACEUTICALS, INC.

TFF Pharmaceuticals, Inc. is offering shares of common stock on a firm commitment basis. This is an initial public offering of our common stock and there is presently no public market for our common stock. The initial public offering price is $____ per share. We intend to apply for listing of our common stock on the NASDAQ Capital Market under the symbol "TFFP."

We are an "emerging growth company" under the federal securities laws and will have the option to use reduced public company reporting requirements. Please see "Risk Factors" beginning on page 7 to read about certain factors you should consider before buying our securities.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Price to Public	Underwriting Discounts and Commissions[1]	Proceeds to TFF Pharmaceuticals, Inc.
Per Share	$ —	$ —	$ —
Total Offering	$ —	$ —	$ —

_____

(1) Does not include our obligation to reimburse the underwriter for its expenses in an amount not to exceed $_____. See "Underwriting" for a description of the compensation payable to the underwriter.

The underwriter may also purchase an additional _____ shares of our common stock, amounting to 15% of the number of shares offered to the public, within 45 days of the date of this prospectus, to cover over-allotments, if any, on the same terms set forth above.

The underwriter expects to deliver the shares on or about _____, 2019.

National Securities Corporation

The date of this prospectus is _____, 2019

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Neither we nor the underwriter has authorized anyone to provide any information or make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. Neither we nor the underwriter takes responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock.

Through and including _____, 2019 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

For investors outside of the United States: Neither we nor the underwriter has done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States are required to inform themselves about, and to observe any restrictions relating to, this offering and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this prospectus, including our financial statements and related notes, before investing in our common stock. If any of the following risks materialize, our business, financial condition, operating results and prospects could be materially and adversely affected. In that event, the price of our common stock could decline, and you could lose part or all of your investment.

Our Company

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 improve the pharmacokinetic effect of the drug to a level allowing for its development and commercialization. As of the date of this prospectus, we have not progressed the development of any of our drug candidates to human clinical trials, but rather 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 our TFF platform was designed to improve solubility of poorly water-soluble drugs generally, we have found that the technology is particularly useful in generating dry powder particles with properties that 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 intend to initially focus on the development of the following product candidates:

- **TFF Vori** is 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. We believe, and early testing confirms, that our TFF platform can be used to formulate a dry powder version of Voriconazole, generally considered to be the best antifungal drug used in the treatment of IPA and which is no longer subject to patent protection. Voriconazole is currently marketed in Australia, Europe and the U.S. as Vfend. As of the date of this prospectus, 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. We believe a TFF prepared dry powder formulation of Voriconazole administered directly to the lungs can maximize both the prophylactic value for immunocompromised patients susceptible to IPA and the treatment value of patients suffering from chronic IPA. We also believe our dry powder drug formulation 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.

- **TFF Tac-Lac** is an inhaled dry powder version of tacrolimus, an immunosuppressive drug used in transplant medicine. Prograf tacrolimus is currently the second most commonly administered immunosuppressive drug used in solid organ transplants, despite what we believe to be the many challenges for patients and physicians when used for extended periods. Prograf tacrolimus can cause toxicity in the kidneys, particularly when used in high doses. Tacrolimus is no longer under patent protection, 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.

- **TFF Triple Combination For COPD/Asthma** is an inhaled dry powder drug combination intended to treat chronic obstructive pulmonary disease, or COPD, and asthma. There is a trend towards the use of a three-drug combination in the treatment of uncontrolled COPD and asthma. A variety of triple combinations are currently approved for marketing or are under development by large pharmaceutical companies, including GSK, AstraZeneca, and Chiesi Farmaceutici. We are currently pursuing the development of combination dry powder drugs intended for use with a dry powder inhaler containing budesonide, formoterol fumarate and tiotropium bromide 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 to be the best-in-class drug in each category. Since competition exists, and typically large clinical trials are needed to approve this type of triple combination drug, we expect to develop the triple combination dry powder drug in partnership with a large pharmaceutical company looking to compete in the COPD and asthma markets. However, as of the date of this prospectus, 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. As of the date of this prospectus, 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.

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. In each case, these are off-patent drugs for which we would directly pursue the development of a dry powder formulation. Because our initial dry powder drug candidates will be established drugs that are off-patent, we believe that our initial drug products 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-IND meeting with the FDA concerning TFF Vori, we believe we will need to conduct Phase I, II and III studies prior to filing for marketing approval for TFF Vori. We also believe that our TFF Tac-Lac will require Phase I, II and III studies prior to market approval due to its target of a new indication.

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 products 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.

Private Placements of Series A Preferred Stock

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 ($12.5 million after deducting offering expenses), 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 ($7.3 million after deducting offering expenses). The shares of our Series A preferred stock accumulate 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, will automatically convert into shares of our common stock concurrent with the completion of this offering at the conversion price equal to the lesser of (i) 50% of the initial public offering price or (ii) $2.50 (subject to proportional adjustment in the events of combinations, subdivisions or the like). Assuming that this offering was completed on March 31, 2019 at a price of $____ per share, and based on dividends accrued through such date in the amount of $_____, the Series A preferred stock would have converted into _____ shares of our common stock.

Risks Related to Our Business

Our business is subject to numerous risks, which are highlighted in the section "Risk Factors" immediately following this prospectus summary. Some of those risks include:

- 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;
- our reliance on third parties to manufacture our product candidates;
- the adequacy of the net proceeds of this offering;
- 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;
- our plans to use the proceeds from this offering;
- 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.

Corporate Information

We were incorporated under the laws of the state of Delaware on January 24, 2018 by Lung Therapeutics, Inc., or LTI. 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 Thin Film Freezing technology, for 4,000,000 shares of our common stock. LTI is an early stage biotechnology company focused on the development of certain technologies in the pulmonary field. As of the date of this prospectus, LTI owns 4,000,000 shares of our common stock, or approximately ___% of our capital stock on a fully-diluted basis. We are no longer a subsidiary of LTI; however, LTI currently provides us with office space and certain administrative services and equipment for no charge, from time to time on an as-needed basis, and three of our directors, Aaron Fletcher, Robert Mills and Brian Windsor, are members of the board of directors of LTI. Our principal executive offices are located at 2600 Via Fortuna, Suite 360, Austin, Texas 78746, and our telephone number is (737) 802-1973. Our website address is www.tffpharma.com. The information contained in, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

We own unregistered trademarks, including our company name. All other trademarks or

trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the symbols ® and ™, but such references should not be construed as any indication that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

Emerging Growth Company

The Jumpstart Our Business Startups Act, or the JOBS Act, was enacted in April 2012 with the intention of encouraging capital formation in the United States and reducing the regulatory burden on newly public companies that qualify as "emerging growth companies." We are an emerging growth company within the meaning of the JOBS Act. As an emerging growth company, we may take advantage of certain exemptions from various public reporting requirements, including:

- the requirement that our internal control over financial reporting be attested to by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002;
- certain requirements related to the disclosure of executive compensation in this prospectus and in our periodic reports and proxy statements;
- the requirement that we hold a nonbinding advisory vote on executive compensation and any golden parachute payments; and
- the ability to delay compliance with new or revised financial accounting standards until private companies are required to comply with the new or revised financial accounting standard.

We may take advantage of the exemptions under the JOBS Act discussed above until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest to occur of (1) the last day of the fiscal year in which we have $1.07 billion or more in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (3) the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

We may choose to take advantage of some, but not all, of the available benefits under the JOBS Act. We are choosing to take advantage of all of the other exemptions discussed above. Accordingly, the information contained herein and in our subsequent filing with the Securities and Exchange Commission may be different than the information you receive from other public companies in which you hold stock.

For certain risks related to our status as an emerging growth company, see the disclosure elsewhere in this prospectus under "Risk Factors—Risks Related to this Offering and Owning Our Common Stock - 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."

The Offering

Common stock offered by us	_____ shares
Common stock to be outstanding after this offering	_____ shares
Over-allotment option offered by us	_____ shares
Proposed NASDAQ symbol	"TFFP"
Use of proceeds	We estimate that the net proceeds from the sale of the shares of common stock in this offering will be approximately $_____ million, or approximately $_____ million if the underwriters exercise their option to purchase additional shares in full, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering for clinical trials and product development, FDA filing fees, laboratory expansion, as well as for other general corporate purposes, including general and administrative expenses and working capital. See "Estimated Use of Proceeds".

The number of shares of our common stock to be outstanding after this offering is based on _____ shares of common stock outstanding as of the date of this prospectus (including preferred stock on an as-converted basis as of March 31, 2019 assuming a conversion price of $_____ per share of the Series A preferred stock), and excludes:

- 1,073,082 shares of our common stock issuable upon exercise of outstanding options as of March 31, 2019, with a weighted average exercise price of $2.50 per share, granted pursuant to our 2018 Equity Incentive Plan, or the 2018 Plan;
- approximately 1,385,012 shares of our common stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of $_____ per share, which includes an estimated 893,000 shares of our common stock issuable upon exercise of warrants issued to the underwriter as placement agent compensation in connection with the offerings of our Series A preferred stock;
- up to _____ shares issuable pursuant to the underwriter's over-allotment option;
- _____ shares issuable upon exercise of a warrant to be issued to the underwriter as part of its compensation in connection with this offering (up to _____ shares if the overallotment option is exercised) at an exercise price of $_____ per share; and
- 556,918 shares of our common stock reserved for future grants under our 2018 Plan as of March 31, 2019; however, upon completion of this offering the number of shares reserved for issuance under the 2018 Plan shall increase to 15% of our then outstanding shares of common stock calculated on a fully diluted basis.

Except as otherwise indicated, all information in this prospectus assumes:

- the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of _____ shares of common stock in connection

with the closing of this offering (assuming a conversion as of March 31, 2019 at a conversion price of $_____ per share of the Series A preferred stock);

- no exercise of outstanding warrants or options described above; and
- no exercise of the underwriter's over-allotment option.

Summary Financial Data

The following tables summarize our financial data. You should read this summary financial data together with the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes that are included elsewhere in this prospectus. The financial information as of and for the fiscal years ended December 31, 2018 and 2017 is derived from the audited financial statements that are included elsewhere in this prospectus. The financial information as of and for the three months ended March 31, 2019 and 2018 is derived from our unaudited condensed financial statements that are included elsewhere in this prospectus. The unaudited condensed financial statements were prepared on a basis consistent with our audited financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future, and our interim results are not necessarily indicative of the results to be expected for the full year or any other period. In connection with our organization on January 24, 2018, we entered into a Contribution and Subscription Agreement with LTI, our former parent, pursuant to which we agreed to acquire from LTI certain intellectual property rights and other assets, or the Acquired Assets. 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 periods January 1, 2017 through January 23, 2018 reflect the results of operations of the Acquired Assets, which were immaterial, while owned by LTI.

	Years Ended December 31,		Three Months Ended March 31, 2019	January 24, 2018 to March 31, 2018[1]
	2018	2017 (Predecessor)	(unaudited)	(unaudited)
(in thousands)				
Revenues	$ —	—	$ —	—
Net loss	$ (3,898)	(179)	$ (2,182,815)	(1,842,536)

	March 31, 2019		
(in thousands)	Actual	Pro Forma[2]	Pro Forma as Adjusted[3]
	(unaudited)	(unaudited)	(unaudited)
Balance Sheet Data:			
Cash and cash equivalents	$ 8,146	$	$
Working capital	$ 6,817	$	$
Total assets	$ 8,322	$	$
Series A preferred stock	$ 12,486	$	$
Total common stock	$ 4	$	$
Additional paid-in capital	$ 497	$	$
Total stockholders' (deficit) equity	$ (5,524)	$	$

(1) The operations surrounding the Acquired Assets during the period January 1, 2018 to January 23, 2018 are deemed to be immaterial.

(2) The pro forma column reflects (i) the issuance of an aggregate of 3,268,000 shares of our Series A preferred stock in May 2019 and our receipt of approximately $7.3 million in aggregate net proceeds therefrom and (ii) the automatic conversion of 8,930,000 shares of our Series A preferred stock at the close of this offering into _____ shares of our common stock and reclassified into common stock and additional paid-in capital and the reclassification of the warrant liability into additional paid-in capital.

(3) The pro forma as adjusted column reflects all adjustments included in the pro forma column and gives effect to the sale by us of _____ shares of common stock offered by this prospectus at the public offering price of $____, less estimated offering expenses of $_____.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this prospectus, including our consolidated financial statements and related notes, before investing in our common stock. If any of the following risks materialize, our business, financial condition, operating results and prospects could be materially and adversely affected. In that event, the price of our common stock could decline, and you could lose part or all of your investment.

Risks Relating to Our Business

We are an early-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. To date, our operations have 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 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, 2018 and 2017, and for the three months ended March 31, 2019, we incurred a net loss of $4.6 million, $178,605 and $2.2 million, respectively. As of March 31, 2019, we had an accumulated deficit of $5.5 million. Following completion of this offering, 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. We also believe that, at a minimum, it will take us ___ months from the initial close of the offering for us to obtain regulatory approval of our first drug candidates, assuming we are able to get regulatory approval at all. Even if we are able to 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 March 31, 2019, we had total assets of $8.3 million and working capital of $6.8 million. As of March 31, 2019, our liquidity included $8.1 million of cash and cash equivalents. The foregoing does not give effect to our receipt of approximately $7.3 million of net proceeds from the May 2019 private placement of Series A preferred stock. We believe that we require a minimum of $24 million of capital, in addition to our cash on hand, in order to fund our current business plan, which contemplates our pursuit of up to two initial drug candidates, through the regulatory approval of at least one drug candidate. We have undertaken this initial public offering of our common shares to acquire the necessary capital to fund our business plan. However, we may require additional capital, the receipt of which there can be no assurance. In the event we require additional capital, we will seek additional funds through various financing sources, including the sale of our equity and debt securities, licensing fees for our technology and joint ventures with industry or capital 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 prospectus, 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.

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. In June 2018, we entered into a one-year agreement with Patheon Development Services, Inc., pursuant to which Patheon provided to us certain product testing, development and clinical manufacturing services. The agreement expired in June 2019; however, we are currently in discussions with Patheon for a longer-term contract manufacturing agreement that would appoint Patheon as our exclusive contract manufacturer for products incorporating our TFF technology. In the meantime, 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. 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 prospectus, we do not carry product liability insurance. However, immediately following this offering, we intend to obtain product liability insurance that we consider adequate for our current level of clinical testing and development. However, we will need additional product liability coverage 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 prospectus, 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 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 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 a February 2019 pre-IND meeting with the FDA concerning TFF Vori, we believe we will need to conduct Phase I, Phase II and Phase III studies prior to filing for marketing approval for TFF Vori. We also believe our TFF Tac-Lac will require Phase I, Phase II and Phase III studies prior to market approval due to its target of a new indication.

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 Investigational New Drug Application, or 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. Our product candidates are in the early stages of development and as of the date of this prospectus we have not progressed any of our product candidates beyond performance characterization and animal testing. We have not submitted an IND to the FDA, nor an application to any comparable foreign regulatory authority, for any of our product candidates, which is the means by which drug companies obtain approval to initiate clinical trials in humans in the United States or other countries. As of the date of this prospectus, we had a pre-IND meeting for our TFF Vori product candidate in February 2019 and plan on submitting our initial IND for TFF Vori in late 2019. In addition, we have scheduled a pre-IND meeting with the FDA on September 26, 2019 for our TFF Tac-Lac product candidate and plan on submitting an IND for that product candidate in the first quarter of 2020. We may not be successful in obtaining approval from the FDA or comparable foreign regulatory authorities to start clinical trials for any 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.

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 – General 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 this Offering and 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 shares following this offering. The offering under this prospectus is an initial public offering of our common shares. Prior to this offering there has been no public market for our shares. Upon completion of this offering, our common stock will commence trading on the NASDAQ Capital Market under the symbol "TFFP." However, an active, liquid or orderly trading market in our shares may not develop upon completion of this offering, or if it does develop, it may not 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, after listing, 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 initial public offering price for the

shares will be determined by negotiations between us and the underwriter and may not be indicative of prices that will prevail in the trading market. The price of our shares may decline following this offering. 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. 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 consolidated 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 the common stock we are offering.

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 after this offering, 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 this 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 close of this 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 this offering. 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, commencing on the 90th day following the close of this offering, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, or the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, non-affiliate stockholders may sell freely after six months subject only to the current public information requirement (which disappears after one year). Following the 180th day following the close of this offering, certain stockholders will be eligible to begin publicly selling their shares under Rule 144.

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.

You will experience immediate dilution in the book value per share of the common stock you purchase. Because the price per share of our common stock being offered is substantially higher than the book value per share of our common stock, you will experience substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the offering price of $____ per share, if you purchase shares of common stock in this offering, you will experience immediate and substantial dilution of $____ per share in the net tangible book value of the common stock at March 31, 2019.

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.

We have broad discretion in how we use the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline. We may invest or spend these proceeds in ways with which you do not agree and in ways that may not yield a return on your investment. Our management will have considerable discretion in the application of the net proceeds of this offering, including for any purpose described in the section of this prospectus entitled "Estimated Use of Proceeds". However, our needs may change as our business and industry evolve and, as a result, the proceeds we receive from this offering may be used in a manner substantially different from our current expectations. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value. The failure by our management to apply these funds effectively could result in financial losses that could harm our business, cause the price of our common stock to decline and delay the

development of our product candidates. You will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately and, as a result, you will be relying on our management's judgment.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable. Upon the closing of this offering, provisions of our 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, once we become a publicly traded corporation, 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 in effect upon the closing of this offering 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.

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.

Ownership portions held by our executives and directors, as well as by our former parent company, LTI, may limit your ability to influence corporate matters. Following this offering, and after giving effect to the conversion of our Series A preferred stock, our directors and executive officers will beneficially own approximately ____% of our common stock. Additionally, LTI, our former parent company, will beneficially own approximately ____% of our outstanding common stock. Accordingly, these parties, together, will be able to significantly influence, though not independently determine, the outcome of matters required to be submitted to our stockholders for approval, including decisions relating to the election of our Board and the outcome of any proposed merger or consolidation of our company. These interests may not be consistent with those of our other stockholders. In addition, the significant interest held by these

parties, and particularly by LTI, may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of our shares.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled "Prospectus Summary," "Risk Factors," "Estimated Use of Proceeds," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Our Business," contains forward-looking statements. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements concerning the following:

- 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 net proceeds of this offering;
- 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;
- our plans to use the proceeds from this offering;
- 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 forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" and elsewhere in this prospectus. 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 prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in our forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. 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 undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

INDUSTRY AND MARKET DATA

This prospectus, particularly the sections "Our Business – The Problem We Address", "– Our Thin Film Freezing Platform" and "– Our Initial Drug Targets", contain observations, statistical data, estimates, and forecasts that are based on independent industry, government and non-government organization publications or other publicly available information, as well as other information based on our internal sources. Although we believe that the third-party sources referred to in this prospectus are reliable, estimates as they relate to projections involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section titled "Risk Factors" and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Certain information in the text of this prospectus is contained in independent industry government and non-governmental organizational publications. The sources of these publications are provided below:

- Lipinski, C. (2002). Poor aqueous solubility: An industry wide problem in drug discovery. Am Pharm Rev 5, 82-5;
- Denning, DW; Pleuvry, A; Cole, DC (May 2013). "Global burden of allergic bronchopulmonary aspergillosis with asthma and its complication chronic pulmonary aspergillosis in adults". Medical mycology. 51 (4): 361–70. doi:10.3109/13693786.2012.738312. PMID 23210682;
- Kasim, N.A., Whitehouse, M., Ramachandran, C., Bermejo, M., Lennernäs, H., Hussain, A.S., Junginger, H.E., Stavchansky, S.A., Midha, K.K., Shah, V.P., Amidon, G.L. (2004). Molecular Properties of WHO Essential Drugs and Provisional Biopharmaceutical Classification. Mol. Pharm., 1(1):85-96;
- Global Biologics Market, Industry and R&D: Forecasts 2015-2025 – Challenges and Opportunities from Rising Drug Demand and Biosimilar Competition; and
- Liversidge, E. (2002). Particles. Orlando, FL: Marcel Dekker.

OUR BUSINESS

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. As of the date of this prospectus, we have not progressed the development of any of our drug candidates to human clinical trials, but rather 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 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.

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 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-IND meeting with the FDA concerning TFF Vori, we believe we will need to conduct Phase I, Phase II and Phase III studies prior to filing for marketing approval for TFF Vori. We also believe our TFF Tac-Lac will require Phase I, Phase II and Phase III studies prior to market approval due to its target of a new indication.

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. According to Lipinski, 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. According to Kasim, only two-thirds of the drugs on the 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.

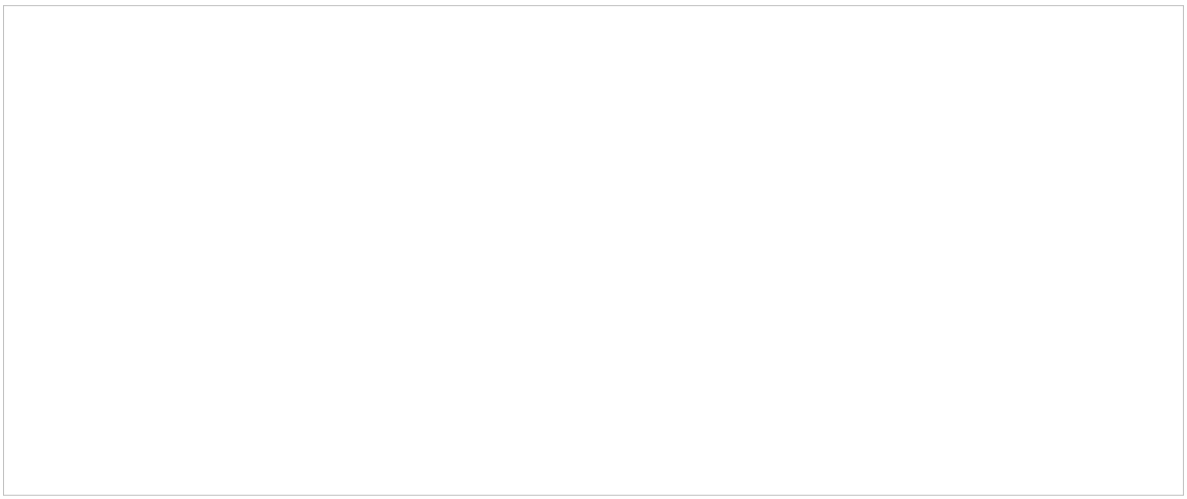
We believe the primary benefit of a breath-actuated inhaler is its ability to administer a greater portion of the drug dosage directly to the target site. Dosing directly to the lungs has been shown to allow for better effect with fewer adverse events. In addition, it has been shown that dosing directly 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.

- **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.

In addition to our continuing collaboration with UT, in June 2018 we entered into a one-year agreement with Patheon Development Services, Inc., an international company engaged in the business of providing, among other things, contract testing, development and manufacturing services to the pharmaceutical industry. Our agreement with Patheon was an industry standard fee-for-service contract manufacturing agreement pursuant to which Patheon provided to us certain product testing, development and manufacturing services. The Patheon agreement expired in June 2019; however, we are currently in discussions with Patheon for a longer-term contract manufacturing agreement

that would appoint Patheon as our exclusive contract manufacturer for products incorporating our TFF technology. In the meantime, 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 Patheon, 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, and may not be able to engage other contract manufacturers for the commercial supply, of any of our product candidates on favorable terms to us, or at all, should the need arise.

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 $500 million. As of the date of this prospectus, we have identified 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 prospectus, 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 report that inhaled Voriconazole has been 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 addition, we will need to complete a Phase II and a Phase III study prior to filing for marketing approval. We believe that the subsequent Phase I, II and III programs for TFF Vori will cost about $5.8 million in total. 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 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 Liversidge, 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.

We have scheduled a pre-IND meeting with the FDA for September 26, 2019 and we expect to submit an IND for our TFF formulation of Tacrolimus in the first quarter of 2020. Since there is extensive data on the marketed Prograf product, we believe that our dry powder formulation will qualify for the FDA's 505(b)(2) approval pathway. However, the 505(b)(2) NDA for Tacrolimus inhalation powder will require Phase I, Phase II and Phase III clinical studies since we are pursuing a new indication in the treatment of prophylaxis of organ rejection in patients receiving lung transplants. 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.

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 prospectus 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

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
Itraconazole	Prophylaxis	Asthma - exacerbation prevention
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 are also 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 cannabidiol, or CBD, administration. CBD is recognized for the treatment of various epilepsy syndromes as well as anxiety, insomnia, and different types of pain. The broader class of cannabinoids are believed to be additionally beneficial 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. We intend to execute a relative bioavailability study in rodents in the near future to assess the effect of the TFF platform on the bioavailability and pharmacokinetics of CBD delivered by dry powder inhalation. There can be no assurance, however, that our early testing and development will lead to a commercial dry powder formulation of CBD.

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 32 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 investigational new drug, or IND, the application for 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, (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 prospectus, we have seven employees and consultants, including our executive officers, providing management and financial services, and general administrative responsibilities.

Legal Proceedings

From time to time, we may become party to legal proceedings and claims in the ordinary course of business. As of the date of this prospectus, we are not a party to any legal proceedings.

Executive Offices

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 have entered into a lease agreement for 1,500 square feet of office space in Doylestown, Pennsylvania. The lease agreement is for one year and expires October 31, 2019, subject to our option to renew for an additional year. The monthly lease rate is $3,500. We intend to relocate our executive offices to this facility in late 2019.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

General

We were formed in January 2018 as a specialty pharmaceutical company focused on developing and commercializing innovative pharmaceutical products based on our patented Thin Film Freezing platform.

To date, we have capitalized our operations primarily from the March 2018 private placement of approximately $14.2 million ($12.5 million net of offering expenses) of Series A preferred stock, par value $0.001, or the Series A preferred stock, and the May 2019 private placement of approximately $8.2 million ($7.3 million after deducting offering expenses) of Series A preferred stock. The Series A preferred stock accumulates dividends at the rate of 6% per annum. The shares of Series A preferred stock plus all accrued but unpaid dividends on the Series A preferred stock will automatically convert into shares of our common stock concurrent with the completion of this offering, at the conversion price of 50% of the initial public offering price. Assuming that this offering was completed on March 31, 2019 at a price of $_____ per share, and based on dividends accrued through such date in the amount of $_____, the Series A preferred stock would have converted into _____ shares of our common stock.

Results of Operations

We were formed on January 24, 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 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. 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 periods January 1, 2017 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, 2018 and 2017, we incurred $848,809 and $0 of research and development expenses and $3,049,337 and $178,605 of general and administrative expenses, respectively. The increase in research and development expenses during 2018 was due to the ramp-up of research and development activities following the completion of our initial funding in March 2018. The increase in general and administrative expenses in 2018 was due to the expense associated with our formation and increased corporate activities following our March 2018 funding and includes $1,329,074 of stock-based compensation issued to our officers, directors and consultants in 2018. We incurred a net loss of $4,570,536 and $178,605 for the 2018 and 2017 fiscal years, respectively.

For the three months ended March 31, 2019 and 2018, we incurred $1,670,862 and $0 of research and development expenses, respectively. The increase in research and development expenses in 2019 was due to the ramp-up of research and development activities following the close of the Series A preferred stock financing in March 2018. For the three months ended March 31, 2019 and 2018, we incurred $531,598 and $269, 371 of general and administrative expenses, respectively. The increase in general and administrative expenses in 2019 was due to a higher level of activity in the first quarter of 2019 compared to the prior year period. We incurred a net loss of $2,182,815 and $267,501 for the three months ended March 31, 2019 and 2018, respectively. The increase in net loss in 2019 was due to the increase in research and development and general corporate activities following the close of the Series A preferred stock financing in March 2018. We expect our research and development expenses as well as our general and administrative expenses to continue to increase in accordance with our business plan.

Financial Condition

As of March 31, 2019, we had total assets of $8.3 million and working capital of $6.8 million. As of March 31, 2019, our liquidity included $8.1 million of cash and cash equivalents. The foregoing does not give effect to our receipt of approximately $7.3 million of net proceeds from the May 2019 private placement of Series A preferred stock. As of the date of this prospectus, we have no debt or plans for material capital expenditures. As of the date of this prospectus, our projected working capital needs consist of funds with which to pursue clinical trials, product licensing opportunities and product development, FDA filing fees, and other general corporate purposes, including general and administrative expenses. See "Estimated Use of Proceeds."

We believe certain of our expenses are controllable and that we have enough cash on-hand as of the date of this prospectus to manage our business for 12 months from the date of this prospectus. However, to fully implement our current business plan, consisting of the pursuit of up to two initial drug candidates through the marketing approval of at least one drug candidates, we believe that we require a minimum of $24 million of additional capital in order to fund our current business plan over, at least, the 12 months following the date of this prospectus. We have undertaken this initial public offering of our common shares to acquire the necessary capital. However, we may require additional capital prior to the end of such 24 month period, the receipt of which there can be no assurance. In the event we require additional capital, we will endeavor to seek additional funds through various financing sources, including the sale of our equity and debt securities, licensing fees for our technology 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.

Off Balance Sheet Transactions

We do not have any off-balance sheet transactions.

MANAGEMENT

Set forth below are our directors and executive officers:

Name	Age	Position
Glenn Mattes	62	President, Chief Executive Officer and Director
Kirk Coleman	47	Chief Financial Officer
Aaron Fletcher, Ph.D.	39	Chairman of the Board
Robert S. Mills	66	Director
Brian Windsor, Ph.D.	52	Director
Stephen Rocamboli	48	Director
Harlan Weisman, M.D.	66	Director
Randy Thurman	69	Director

Mr. Mattes has served as our President and Chief Executive Officer and a member of our Board since May 1, 2018. From December 2015 to April 2018, Mr. Mattes was Chief Executive Officer of Cornovus, Inc., a late stage-clinical stage company focused on the development of therapies for end stage congestive heart failure. Mr. Mattes has also served as chairman of the board of directors of Cornovus from December 2015 to date. From April 2011 to July 2014, Mr. Mattes was Chief Executive Officer of Arno Therapeutics, Inc., a clinical stage company focused on oncology therapeutics. From March 2003 to April 2011, Mr. Mattes served as President of Tibotec Therapeutics, Inc., a wholly-owned subsidiary of Johnson & Johnson engaged in the development of oncological therapeutics. Since May 2018, Mr. Mattes has also served as an Operating Partner of Revival Healthcare Capital, a private equity firm focused on investment and buy-out opportunities in the healthcare industry. Mr. Mattes has over 30 years of experience in the pharmaceutical industry, including several senior executive positions and manager level positions in the fields of product development and marketing. Mr. Mattes serves on the board of directors of several pharmaceutical companies, including Advantagene, Inc. and Deck Therapeutics, Inc. Mr. Mattes has also served as a senior healthcare advisor to The Gores Group, a private equity investment firm since May 2015.

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

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

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

We believe that Dr. Fletcher's significant experience and knowledge of the pharmaceutical industry as a research analyst, venture investor and academic bring valuable knowledge and insights to our Board.

Mr. Mills has served as a member of our Board since January 2018. Mr. Mills also served as our President and Chief Executive Officer from January 2018 to May 1, 2018, and also served as the Executive Chairman of our Board from January 2018 to December 2018. Mr. Mills has served as the founder and President of RSM Consulting, LLC since January 1, 2015 and as the chairman of the board of directors of LTI since May 7, 2015. From

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

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

Dr. Windsor has served as a member of our Board since January 2018. Since January 2018, Dr. Windsor has also provided consulting services to us in the area of science and technology. Dr Windsor is currently the President, Chief Executive Officer and a member of the board of directors of LTI, which positions he has held since July 2013. From November 2009 to March 2013, Dr. Windsor served as President of Enavail, LLC, a specialty pharmaceutical manufacturing company, where he oversaw all aspects of the company's pharmaceutical drug development. Before joining Enavail, Dr. Windsor directed portfolio company management for Emergent Technologies, Inc., an early stage technology venture creation and management company, where he served as Managing Director or President for ten portfolio companies. He holds a Ph.D. in Molecular Biology from The University of Texas at Austin, is an invited speaker for both scientific and technology transfer events, and is an inventor on multiple patents and patent applications.

We believe that Dr. Windsor's significant experience as chief executive officer in pharmaceutical companies, including LTI, and significant experience with pharmaceutical drug development bring valuable knowledge and insights to our Board.

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

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

Dr. Weisman has served as a member of our Board since December 2018. Dr. Weismann has

been Managing Director of And-One Consulting, LLC, since 2012, advising medical product companies, investment firms, and government and non-government healthcare organizations in formulating and implementing strategies for driving innovation in healthcare products and services. Since 2014, Dr. Weisman has also served as Executive Chairman of the Board of 3DBio Therapeutics, a company using 3D bioprinting technology to develop whole tissue implants that fully integrate into body. Since February 2016, Dr. Weisman has also served as co-founder and Chief Scientific Officer

for Mycrobiomics, a company developing counseling and educational material to help consumers to understand the microbiome and improve their health and well-being. Between December 2012 and December 2013, Dr. Weisman was Chairman and Chief Executive Officer of Coronado Biosciences, a biopharmaceutical company developing novel immunotherapies for autoimmune diseases and cancer. Since 2012, Dr. Weisman has been on the Board of Directors of ControlRad, Inc, a medical device company developing technology to reduce radiation exposure during fluoroscopic procedures. Dr. Weisman also serves on the Board of Directors of Caelum Biosciences, Inc. Since 2012, Dr. Weisman has also been a senior advisor to CRG, an investment management firm making structured debt and equity investments in healthcare companies. Since 2016, Dr. Weisman has been a venture advisor to the Israel Biotech Fund, which invests and develops clinical-stage biotechnology companies based in Israel. From 2010 to 2016, Dr. Weisman served on the Board of Governors of the Patient Centered Outcomes Research Institute, established by the U.S. Congress as part of the Patient Protection and Affordable Care Act of 2010. Dr. Weisman was the Chief Science and Technology Officer of the Johnson & Johnson Medical Devices and Diagnostics Group from 2006 to 2012, and served as Chairman of the J&J Worldwide R&D Council. Dr. Weisman was Company Group Chairman, J&J Pharmaceutical Research & Development, from 2004 to 2006.

We believe that Dr. Weismann's significant education and experience in the field of healthcare bring valuable knowledge and insights to our Board.

Mr. Thurman has served as a member of our Board since April 2019. Mr. Thurman has been a senior advisor and operating partner for private equity funds since 2008, having co-led nearly $2 billion in acquisitions, debt transactions and equity investments in life sciences, industrial, IT and service companies in the United States and Europe. He currently serves as Senior Advisor for BC Partners and is an Adjunct Professor — Finance at Merrimack College Graduate School. Between 2000 and 2007, Mr. Thurman was the founder, Chair and Chief Executive Officer of Viasys Healthcare, Inc., which was a diversified, research-based medical technology company with global revenue over $700 million. Mr. Thurman led Viasys Healthcare, Inc. through a successful initial public offering until its acquisition by Cardinal Health in 2007. Prior to that, he served as Chairman of the Board and Chief Executive Officer of Corning Life Sciences Inc. and President, Chief Executive Officer and Director of Rhone-Poulenc Rorer Pharmaceuticals Inc. (now Aventis). In 2007, Mr. Thurman was named an Entrepreneur of the Year by Ernst & Young. Mr. Thurman served as a fighter pilot in the United States Air Force and Air National Guard from 1971 to 1992. Mr. Thurman received his B.A. degree in Economics from Virginia Polytechnic Institute, earned an M.A. in management from Webster University and is a graduate of the USAF Air Command and Staff Leadership College.

We believe that Mr. Thurman's significant experience as chief executive officer and director of pharmaceutical companies bring valuable knowledge and insights to our Board.

Board Composition

Our Board may establish the authorized number of directors from time to time by resolution. Our Board currently consists of seven members, six of whom qualify as independent under the NASDAQ Stock Market rules.

Generally, under the listing requirements and rules of the NASDAQ Stock Market, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of this offering. Our Board has determined that none of our directors other than Glenn Mattes has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each is "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and rules of the NASDAQ Stock Market. In making this determination, our Board considered the current and prior relationships our Board members have with our company and all other facts and circumstances our Board deemed relevant in determining their independence, including their beneficial ownership of our capital stock. With regard to Robert Mills, our Board determined that Mr. Mills is independent notwithstanding his service as an officer of our company from January 2018 to December 2018 based on NASDAQ guidelines that allow for an independent director's past service as an executive officer provided such service was an interim arrangement lasting less than one year.

Role of the Board in Risk Oversight

One of the key functions of our Board is informed oversight of our risk management process. Our Board does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our Board that address risks inherent in their respective areas of oversight. In particular, our Board is responsible for monitoring and assessing strategic risk

exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements.

Board Committees

Our Board has established an audit committee, compensation committee and nominating and corporate governance committee, each of which operate pursuant to a committee charter. Our Board may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below.

Audit Committee

Our audit committee consists of Aaron Fletcher, Stephen Rocamboli and Randy Thurman. Our Board has determined that each of these individuals meets the independence requirements of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, Rule 10A-3 under the Exchange Act and the applicable listing standards of NASDAQ. Each member of our audit committee can read and understand fundamental financial statements in accordance with NASDAQ audit committee requirements. In arriving at this determination, the Board has examined each audit committee member's scope of experience and the nature of their prior and/or current employment.

Our Board has determined that Mr. Thurman qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the NASDAQ Listing Rules.

The functions of this committee include, among other things:

- select a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discuss the scope and results of the audit with the independent registered public accounting firm, and review, with management and the independent registered public accounting firm, our interim and year-end operating results;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- develop procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- review our policies on risk assessment and risk management;
- review related-party transactions; and
- reviewing and evaluating on an annual basis the performance of the audit committee and the audit committee charter.

We believe that the composition and functioning of our audit committee will comply with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and NASDAQ rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee

Our compensation committee consists of Brian Windsor, Stephen Rocamboli and Harlan Weisman. These individuals are non-employee directors, as defined in Rule 16b-3 promulgated under the Exchange Act, and are "outside directors," as defined pursuant to Section 162(m) of the Internal Revenue Code. Our Board has determined that all of these individuals are "independent" as defined under the applicable listing standards of NASDAQ, including the standards specific to members of a compensation committee. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full Board regarding) our overall compensation strategy and policies;

- making recommendations to the full Board regarding the compensation and other terms of employment of our executive officers;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full Board regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements; and
- reviewing and evaluating on an annual basis the performance of the compensation committee and the compensation committee charter.

We believe that the composition and functioning of our compensation committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and NASDAQ rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Aaron Fletcher, Robert Mills and Harlan Weisman. The composition of our nominating and corporate governance committee meets the requirements for independence under the applicable listing standards of NASDAQ and SEC rules and regulations. Our nominating and corporate governance committee will, among other things:

- identify, evaluate and make recommendations to our board of directors regarding nominees for election to our board of directors and its committees;
- evaluate the performance of our board of directors and of individual directors;
- consider and make recommendations to our board of directors regarding the composition of our board of directors and its committees;
- review developments in corporate governance practices;
- evaluate the adequacy of our corporate governance practices and reporting; and
- develop and make recommendations to our board of directors regarding corporate governance guidelines and matters.

The nominating and corporate governance committee operates under a written charter that satisfies the applicable listing requirements and rules of the Nasdaq Stock Market.

Compensation Committee Interlocks and Insider Participation

None of our independent directors is currently or has been at any time one of our officers or employees, other than Robert Mills, who served as our Executive Chairman of the Board from January 2018 to December 2018 and also served as our President and Chief Executive Officer from January 2018 to May 1, 2018. None of our executive officers currently serves, or has served during the last year, as a member of the Board or compensation committee of any entity that has one or more executive officers serving as a member of our Board.

Code of Business Conduct and Ethics

We intend to adopt a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. Once adopted, the Code of Conduct will be available on our website at www.tffpharma.com. The audit committee of our Board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. In addition, we intend to post on our

website all disclosures that are required by law or the listing standards of the applicable stock exchange concerning any amendments to, or waivers from, any provision of the Code of Conduct.

Executive Compensation

We have entered into the following agreements and arrangements with our executive officers.

Glenn Mattes

We entered into an agreement with Mr. Mattes dated April 23, 2018. Pursuant to that agreement, Mr. Mattes serves as our President and Chief Executive Officer. The agreement contains customary provisions relating to intellectual property assignment, confidentiality and indemnification. We have agreed to pay Mr. Mattes at the rate of $25,000 per month under the agreement. Mr. Mattes was also eligible to receive a bonus of up to $150,000 for calendar year 2018, based on performance parameters set by our Board. Mr. Mattes received his full $150,000 bonus for 2018.

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

In the first half of 2018, we granted Mr. Mattes options to purchase up to 200,000 shares of our common stock at an exercise price of $2.50 per share. The options vested and became exercisable on May 1, 2019. On September 26, 2018, we granted Mr. Mattes options to purchase up to an additional 413,023 shares of our common stock at an exercise price of $2.50 per share. Those options vest and first become exercisable as to 103,255 shares on the first anniversary of the date of grant, with the remaining 309,768 shares vesting in 12 equal quarterly installments; provided that the vesting of the option shares will accelerate and those options held by Mr. Mattes will become fully vested upon a Change in Control, as defined in our 2018 Plan. In addition, we have agreed to grant Mr. Mattes, upon the close of this offering, stock options that will increase his beneficial ownership of our common stock, on a fully diluted basis after giving effect to the close of this offering and the conversion of our Series A preferred stock, to 5% of our then outstanding common stock. The exercise price of those options shall be equal to the price per share in this offering.

Kirk Coleman

From January 2018 to February 2019, Mr. Coleman was compensated for his services as our chief financial officer at the hourly rate of $150 per hour. Effective as of February15, 2019, we entered into an employment agreement with Mr. Coleman pursuant to which we have agreed to pay Mr. Coleman at the rate of $16,666 per month. Mr. Coleman is eligible to receive a bonus of up to 30% of his base salary, commencing with calendar year 2019, based on performance parameters set by our Board, and is also eligible for participation in our incentive compensation plans. Mr. Coleman's employment agreement entitles him to reasonable and customary health insurance and other benefits, at our expense. Mr. Coleman's employment agreement is an "at will" agreement subject to termination by either party at any time and for any reason. The agreement contains customary provisions relating to intellectual property assignment, confidentiality and indemnification. In connection with his employment agreement, we also granted Mr. Coleman options to purchase up to 150,000 shares of our common stock at an exercise price of $2.50 per share. The options vest and first become exercisable as to 37,500 shares on the first anniversary of the date of grant, with the remaining 112,500 options vesting thereafter in 12 equal quarterly installments. In addition, we have agreed to grant Mr. Coleman, upon the close of this offering, stock options that will increase his

beneficial ownership of our common stock, on a fully diluted basis after giving effect to the close of this offering and the conversion of our Series A preferred stock, to 1.22% of our then outstanding common stock. The exercise price of those options shall be equal to the price per share in this offering.

Non-Employee Director Compensation

We have agreed to compensate each of our non-employee directors as follows:

Aaron Fletcher

An entity affiliated with Dr. Fletcher receives a fee of $8,750 per quarter for his service as a director, along with an additional $1,250 per quarter for his serving as chairman of any committee of the Board. In the event we ask Dr. Fletcher to provide to us consulting services unrelated to his Board service, we have agreed to compensate the affiliated entity at the rate of $500 per hour. We also granted a warrant to purchase up to 10,000 shares of our common stock to the entity affiliated with Dr. Fletcher. The warrant has an exercise price of $2.50 per share. The warrant vested and became exercisable one year after the date of grant. On September 26, 2018, we granted the entity affiliated with Dr. Fletcher a warrant to purchase up to an additional 82,012 shares of our common stock at an exercise price of $2.50 per share. That warrant vests and first becomes exercisable as to 20,503 shares on the first anniversary of the date of grant, with the remaining 61,509 shares vesting in 12 equal quarterly installments; provided that the vesting of the warrant shares will accelerate and the warrant will become fully vested, upon a Change in Control, as defined in our 2018 Plan. We have also agreed to grant to Dr. Fletcher's affiliated entity, upon the close of this offering, additional warrants that will increase its beneficial ownership of our common stock, on a fully diluted basis after giving effect to the close of this offering and the conversion of our Series A preferred stock, to 0.75% of our then outstanding common stock. The exercise price of those warrants shall be equal to the price per share in this offering.

Robert Mills

We have entered into a consulting agreement with Mr. Mills dated February 10, 2018, as amended and restated on December 20, 2018. Pursuant to that agreement, Mr. Mills served as our Executive Chairman of the Board from January 2018 to December 2018 and, from February 2018 to April 2018, served as our interim President and Chief Executive Officer. Pursuant to the agreement, Mr. Mills was compensated at the rate of $25,000 per month from February 10, 2018 through July 8, 2018, and at the rate of $12,500 per month from July 8, 2018 to December 20, 2018. Commencing December 20, 2018, Mr. Mills serves as a consultant to our company on matters relating to the manufacturing and commercialization of our product candidates and such other matters as we may request from time to time, for which Mr. Mills shall receive consulting fees at the rate of $25,000 per calendar quarter. Mr. Mills is also entitled to receive a fee of $8,750 per quarter for his service as a director. Mr. Mills' agreement with us is coterminus with his service on our Board; however, the agreement may be terminated by either party, with or without cause, on 180 day's prior written notice. The agreement contains customary provisions relating to intellectual property assignment, confidentiality and indemnification.

In April 2018, we granted Mr. Mills options to purchase up to 40,000 shares of our common stock at an exercise price of $2.50 per share. The options vested and became exercisable one year after the date of grant. On September 26, 2018, we granted Mr. Mills options to purchase up to an additional 144,023 shares of our common stock at an exercise price of $2.50 per share. Those options vest and first become exercisable as to 36,006 shares on the first anniversary of the date of grant, with the remaining 108,017 shares vesting in 12 equal quarterly installments; provided that the vesting of the option shares will accelerate and those options held by Mr. Mills will become fully vested upon a Change in Control, as defined in our 2018 Plan. In addition, we have agreed to grant Mr. Mills, upon the close of this offering, stock options that will increase his beneficial ownership of our common stock, on a fully diluted basis after giving effect to the close of this offering and the conversion of our Series A preferred stock, to 1.0% of our then outstanding common stock. The exercise price of those options shall be equal to the price per share in this offering.

Brian Windsor

Dr. Windsor receives a fee of $8,750 per quarter for his service as a director, along with an additional $1,250 per quarter for serving as chairman of any committee of the Board. In April 2018, we granted Dr. Windsor options to purchase up to 20,000 shares of our common stock at an exercise

price of $2.50 per share. The options vested and became exercisable one year after the date of grant. On September 26, 2018, we granted Dr. Windsor options to purchase up to an additional 72,012 shares of our common stock at an exercise price of $2.50 per share. Those options vest and first become exercisable as to 18,003 shares on the first anniversary of the date of grant, with the remaining 54,009 shares vesting in 12 equal quarterly installments; provided that the vesting of the option shares will accelerate and those options held by Dr. Windsor will become fully vested, upon a Change in Control, as defined in our 2018

Plan. In addition, we have agreed to grant Dr. Windsor, upon the close of this offering, options, restricted common stock or restricted stock units that will increase his beneficial ownership of our common stock, on a fully diluted basis after giving effect to the close of this offering and the conversion of our Series A preferred stock, to 0.75% of our then outstanding common stock. The exercise price of those options shall be equal to the price per share in this offering.

In addition to his compensation for services as a member of our Board, we have entered into a Consulting Agreement with Dr. Windsor dated February 12, 2018, as amended. Pursuant to that agreement, Dr. Windsor provides to us consulting services in the area of science and technology and is currently compensated at the rate of $115,000 per year; however, commencing upon the close of this offering Dr. Windsor will be compensated at the rate of $65,000 per year. The agreement has a term of five years; however, we may terminate the agreement for any reason on 180 days prior written notice.

Stephen Rocamboli, Dr. Harlan Weisman and Randy Thurman

Dr. Weisman and Mr. Thurman receive a fee of $8,750 per quarter for their service as directors, along with an additional $1,250 per quarter for serving as chairman of any committee of the Board. Mr. Rocamboli does not receive cash compensation for his services as a director. In connection with their appointment to our Board, we granted to Mr. Rocamboli, Mr. Thurman and Dr. Weisman each options to purchase up to 92,012 shares of our common stock at an exercise price of $2.50 per share. Those options vest and first become exercisable as to 23,003 shares on the first anniversary of the date of grant, with the remaining 69,009 shares vesting in 12 equal quarterly installments; provided, that the vesting of the options will accelerate and become fully vested upon a Change in Control, as defined in our 2018 Plan. We have also agreed to grant to Mr. Rocamboli, Mr. Thurman and Dr. Weisman, upon the close of this offering, additional options that will increase each of their beneficial ownership of our common stock, on a fully diluted basis after giving effect to the close of this offering and the conversion of our Series A preferred stock, to 0.75% of our then outstanding common stock. The exercise price of those options shall be equal to the price per share in this offering.

In addition to Dr. Weisman's compensation for services as a member of our Board, we have entered into a consulting agreement with an entity affiliated with Dr. Weisman dated September 2018. Pursuant to that agreement, Dr. Weisman provides to us consulting services in the area of regulatory affairs and is currently compensated at the rate of $750 per hour. We do not expect to compensate Dr. Weisman in excess of $120,000 in any calendar year pursuant to this agreement. The agreement may be terminated by us for any reason upon thirty days advance written notice.

In the event any other non-employee director is appointed to our Board, we expect such director to be compensated on terms similar to our other non-employee directors.

Related Party Transactions

We were incorporated under the laws of the state of Delaware on January 24, 2018 by LTI. 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 related to our TFF platform, in exchange for 4,000,000 shares of our common stock. LTI is an early-stage company focused on the development of certain technologies in the pulmonary field. LTI currently provides us with office space and certain administrative services and equipment for no charge, from time to time on an as-needed basis, and three of our directors, Aaron Fletcher, Robert Mills and Brian Windsor, are members of the board of directors of LTI. Except as described above, since January 24, 2018, we have not been a party to any transaction in which the amount involved in the transaction exceeded $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our voting securities or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than compensation arrangements, which include equity and other compensation, termination, change in control and other arrangements, which are described under "Executive Compensation."

Limitation of Liability of Directors and Indemnification of Directors and Officers

The Delaware General Corporation Law provides that corporations may include a provision in their certificate of incorporation relieving directors of monetary liability for breach of their fiduciary duty as directors, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct

or a knowing violation of law, (iii) for unlawful payment of a dividend or unlawful stock purchase or redemption, or (iv) for any transaction from which the director derived an improper personal benefit. Our amended and restated certificate of incorporation provides that directors are not liable to us or our stockholders for monetary damages for breach of their fiduciary duty as directors to the fullest extent permitted by Delaware law. In addition to the foregoing, our amended and restated certificate of incorporation provides that we may indemnify directors and officers to the fullest extent permitted by law.

The above provisions in our amended and restated certificate of incorporation may have the effect of reducing the likelihood of derivative litigation against directors and may discourage or deter stockholders or management from bringing a lawsuit against directors for breach of their fiduciary duty, even though such an action, if successful, might otherwise have benefited us and our stockholders. However, we believe that the foregoing provisions are necessary to attract and retain qualified persons as directors.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information regarding the beneficial ownership of our common stock as of the date of this prospectus by:

- each person who is known by us to be the beneficial owner of more than five percent (5%) of our issued and outstanding shares of common stock;
- each of our directors and executive officers; and
- all directors and executive officers as a group.

The beneficial ownership of each person was calculated based on _____ shares of common stock issued and outstanding prior to the offering, including 4,000,000 shares issued and outstanding as of the date of this prospectus, and _____ shares issuable upon the conversion of our outstanding Series A Preferred stock outstanding as of March 31, 2019. The SEC has defined "beneficial ownership" to mean more than ownership in the usual sense. For example, a person has beneficial ownership of a share not only if he owns it, but also if he has the power (solely or shared) to vote, sell or otherwise dispose of the share. Beneficial ownership also includes the number of shares that a person has the right to acquire within 60 days of the date of this prospectus, pursuant to the exercise of options or warrants or the conversion of notes, debentures or other indebtedness. Two or more persons might count as beneficial owners of the same share. Unless otherwise indicated, the address for each reporting person is c/o TFF Pharmaceuticals, Inc., 2600 Via Fortuna, Suite 360, Austin, Texas 78746.

Name of Director, Executive Officer or Director Nominee	Number of Shares	Percentage Owned Prior to Offering	Percentage Owned After Offering
Glenn Mattes[1]	200,000	*	*
Kirk Coleman	—	—	—
Aaron Fletcher[2]	10,000	*	*
Robert S. Mills, Jr.[3]	40,000	*	*
Brian Windsor[4]	20,000	*	*
Steve Rocamboli[5]	—	—	—
Harlan Weisman[5]	—	—	—
Randy Thurman[5]	—	—	—
Directors, executive officers and director nominees, as a group	270,000	*	*

_____

* Less than 1%.

Name and Address of 5% + Holders	Number of Shares	Percentage Owned Prior to Offering	Percentage Owned After Offering
Lung Therapeutics, Inc. 2600 Via Fortuna, Suite 360 Austin, TX 78746	4,000,000	%	%
Maestro Venture Partners, LLC[6] 10 Orinda View Road Orinda, CA 94563	—	%	%

_____

(1) Includes 200,000 shares of common stock issuable upon exercise of vested stock options. Excludes (i) 413,023 shares of common stock issuable upon exercise of unvested stock options and (ii) _____

shares of common stock issuable upon exercise of options awarded upon the closing of this offering.

(2) Includes (i) _____ shares of common stock issuable upon conversion of 40,000 shares of our Series A preferred stock and (ii) 10,000 common shares issuable upon exercise of a vested warrant held by an entity affiliated with Dr. Fletcher. Excludes (i) 82,012 shares of common stock issuable upon exercise of unvested warrants held by Dr. Fletcher's affiliated entity and (ii) _____ shares of common stock issuable upon exercise of a warrant issued upon the closing of this offering.

(3) Includes (i) _____ shares of common stock issuable upon conversion of 10,000 shares of Series A preferred stock and (ii) 40,000 shares issuable upon exercise of vested stock options. Excludes (i) 144,203 shares of common stock issuable upon exercise of unvested stock options and (ii) _____ shares of common stock issuable upon exercise of options awarded upon the closing of this offering.

(4) Includes 20,000 shares of common stock issuable upon exercise of vested stock options. Excludes (i) 72,012 shares of common stock issuable upon exercise of unvested stock options and (ii) _____ shares of common stock issuable upon exercise of options awarded upon the closing of this offering.

(5) Excludes (i) 92,012 shares of common stock issuable upon exercise of unvested stock options and (ii) _____ shares of common stock issuable upon exercise of options awarded upon the closing of this offering.

(6) Represents _____ shares of common stock issuable upon conversion of 1,200,000 shares of Series A preferred stock. Emily Fairbairn is the managing partner of Maestro Venture Partners, LLC.

ESTIMATED USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of _____ shares of our common stock in this offering will be approximately $____ million (or $____ million if the underwriters exercise in full their option to purchase additional shares), assuming an initial public offering price of $___ per share, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

As of March 31, 2019, we had cash and cash equivalents of $8.1 million. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $____ million to fund clinical trials, product licensing opportunities and product development;
- approximately $____ million to fund FDA filing fees; and
- the balance for other general corporate purposes, including general and administrative expenses and working capital.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with complete certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above. We believe opportunities may exist from time to time to expand our current business through the acquisition or in-license of complementary product candidates. While we have no current agreements for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes.

The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our clinical trials and other development and commercialization efforts for our initial product candidates, as well as the amount of cash used in our operations. Based on our current operational plans and assumptions, we expect our cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our planned operations over, at least, the 24 months following the close of this offering.

However, we cannot estimate with certainty the amount of net proceeds to be used for the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we plan to invest the net proceeds from this offering in short-and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the government.

CAPITALIZATION

The following table sets forth our capitalization as of March 31, 2019:

- on an actual basis;
- on a pro forma basis to give effect to the (i) issuance of an aggregate of 3,268,000 shares of our Series A preferred stock in May 2019 and our receipt of approximately $7.3 million in aggregate net proceeds therefrom and (ii) the automatic conversion of all outstanding shares of our Series A preferred stock into an aggregate of _____ shares of common stock, which will occur upon the closing of this offering; and
- on a pro forma as adjusted basis to reflect, in addition, our sale of _____ shares of common stock in this offering at the initial public offering price of $____ per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information in this table together with our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus.

	As of March 31, 2019 (in thousands)		
	Actual	Pro Forma	Pro Forma As Adjusted
Cash and cash equivalents	$ 8,146	$ —	$ —
Series A preferred stock; $0.001 par value, 6,000,000 shares authorized, 5,662,000 shares issued and outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	12,486	—	—
Stockholders' (deficit) equity:			
Common stock, $0.001 par value, 45,000,000 shares authorized, 4,000,000 shares issued and outstanding, actual; _____ shares issued and outstanding, pro forma; _____ shares issued and outstanding, pro forma as adjusted	4	—	—
Additional paid-in capital	497	—	—
Accumulated deficit	(6,025)	—	—
Total stockholders' (deficit) equity	(5,524)	—	—
Total capitalization	$ 6,962	$ —	$ —

The number of shares of our common stock to be outstanding after this offering is based on 4,000,000 shares of our common stock outstanding as of the date of this prospectus, plus _____ shares common stock issuable upon conversion of our Series A preferred stock as of March 31, 2019, and excludes:

- 1,073,082 shares of our common stock issuable upon exercise of outstanding options as of March 31, 2019, with an average weighted exercise price of $2.50 per share, granted pursuant to our 2018 Plan;
- approximately 1,385,012 shares of our common stock issuable upon exercise of outstanding warrants, with an average weighted exercise price of $____ per share as of March 31, 2019, which includes an estimated 893,000 shares of our common stock issuable upon exercise of a warrant issued to the underwriter as placement agent compensation in connection with the offering of our Series A preferred stock;
- up to _____ shares issuable pursuant to the underwriter's over-allotment option;

- _____ shares issuable upon exercise of a warrant to be issued to the underwriter as part of its compensation in connection with this offering (up to _____ shares if the overallotment option is exercised) at an exercise price of $_____ per share; and
- 556,918 shares of our common stock reserved for future grants under our 2018 Plan as of March 31, 2019; however, upon completion of this offering the number of shares reserved for issuance under the 2018 Plan shall increase to 15% of our then outstanding shares of common stock calculated on a fully diluted basis.

DILUTION

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after the completion of this offering.

As of March 31, 2019, our pro forma net tangible book value was approximately $____ million, or $____ per share of common stock. Our pro forma net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities and divided by the total number of shares of our common stock outstanding as of March 31, 2019, after giving effect to (i) the issuance of an aggregate of 3,268,000 shares of our Series A preferred stock in May 2019 and our receipt of approximately $7.3 million in aggregate net proceeds therefrom and (ii) the automatic conversion of all outstanding shares of our preferred stock into common stock immediately prior to the closing of this offering.

After giving effect to our sale in this offering of _____ shares of our common stock, at the initial public offering price of $____ per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2019 would have been approximately $____ million, or $____ per share of our common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of $____ per share to our existing stockholders and an immediate dilution of $____ per share to investors purchasing shares in this offering.

The following table illustrates this dilution:

Initial public offering price per share		$ —
Pro forma net tangible book value per share as of March 31, 2019, before giving effect to this offering	$ —	
Increase in pro forma net tangible book value per share attributable to new investors purchasing shares in this offering	—	
Pro forma as adjusted net tangible book value per share, after giving effect to this offering		$ —
Dilution per share to new investors purchasing shares in this offering		$ —

If the underwriters exercise their option to purchase additional shares of our common stock in full, the pro forma as adjusted net tangible book value after this offering would be $____ per share, the increase in pro forma net tangible book value per share would be $____ and the dilution per share to new investors would be $____ per share, in each case assuming an initial public offering price of $____ per share.

The following table summarizes, on a pro forma as adjusted basis as described above, the difference between existing stockholders and new investors with respect to the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid, before deducting underwriting discounts and commissions and estimated offering expenses:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	—	%	$ —	%	$ —
New public investors	—	%	—	%	$ —
Total	—	100.0%	$ —	100.0%	

To the extent that our outstanding options and warrants are exercised, investors will experience further dilution.

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriter's over-allotment option. If the underwriter exercises its over-allotment option in full, our existing stockholders would own ____% and our new investors would own ____% of the total number of shares of our common stock outstanding upon the completion of this offering.

The foregoing tables and calculations are based on the number of shares of our common stock outstanding as of March 31, 2019, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into common stock immediately prior to the closing of this offering, and excludes:

- 1,073,082 shares of our common stock issuable upon exercise of outstanding options as of March 31, 2019, with a weighted average exercise price of $2.50 per share, granted pursuant to our 2018 Plan;
- approximately 1,385,012 shares of our common stock issuable upon exercise of outstanding warrants, with an average weighted exercise price of $____ per share, which includes an estimated 893,000 shares of our common stock issuable upon exercise of a warrant issued to the underwriter as placement agent compensation in connection with the offering of our Series A preferred stock;
- up to ____ shares issuable pursuant to the underwriter's over-allotment option;
- ____ shares issuable upon exercise of a warrant to be issued to the underwriter as part of its compensation in connection with this offering (up to ____ shares if the overallotment option is exercised) at an exercise price of $____ per share; and
- 556,918 shares of our common stock reserved for future grants under our 2018 Plan as of March 31, 2019; however, upon completion of this offering the number of shares reserved for issuance under the plan shall increase to 15% of our then outstanding shares of common stock calculated on a fully diluted basis.

DESCRIPTION OF SECURITIES

Common Stock

Our amended and restated certificate of incorporation authorizes us to issue up to 45,000,000 shares of common stock, $0.001 par value per share. As of March 31, 2019, we had 4,000,000 shares of common stock outstanding, held by one stockholder of record. As of March 31, 2019, after giving effect to the conversion of all of the outstanding shares of our Series A preferred stock into ____ shares of common stock, there would have been ____ shares of common stock issued and outstanding, held by 387 stockholders of record.

Holders of shares of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders generally. Stockholders are entitled to receive such dividends as may be declared from time to time by the Board out of funds legally available therefore, and in the event of liquidation, dissolution or winding up of the company to share ratably in all assets remaining after payment of liabilities. The holders of shares of common stock have no preemptive, conversion, subscription rights or cumulative voting rights.

Preferred Stock

As of the date of this prospectus, there are 8,930,000 shares of Series A preferred stock outstanding. All currently outstanding shares of preferred stock will convert automatically into ____ shares of common stock immediately prior to the closing of this offering.

Dividends

We do not anticipate the payment of cash dividends on our common stock in the foreseeable future.

2018 Stock Incentive Plan

We have adopted the TFF Pharmaceuticals, Inc. 2018 Stock Incentive Plan, or 2018 Plan, providing for the grant of non-qualified stock options and incentive stock options to purchase shares of our common stock and for the grant of restricted and unrestricted share grants and restricted stock units. We currently have reserved 1,630,000 shares of our common stock under the 2018 Plan; however, upon completion of this offering the number of shares reserved for issuance under the plan shall increase to 15% of our then outstanding shares of common stock calculated on a fully diluted basis. The purpose of the 2018 Plan is to provide eligible participants with an opportunity to acquire an ownership interest in our company. All officers, directors, employees and consultants to our company are eligible to participate under the 2018 Plan. The 2018 Plan provides that options may not be granted at an exercise price less than the fair market value of our common shares on the date of grant. As of the date of this prospectus, we have outstanding options granted under the 2018 Plan, exclusive of certain gross-up options to be granted to our chief executive officer, chief financial officer and members of the Board upon completion of this offering, to purchase an aggregate of 1,333,594 shares of our common stock with a weighted average exercise price of $2.50 per share.

Warrants

Upon the completion of this offering, we will have outstanding the following warrants to purchase shares of our common stock:

- warrants to purchase up to 92,012 shares of our common stock exercisable at $2.50 per share. The warrants were issued in April and September 2018 to an entity affiliated with Aaron Fletcher as consideration for the services of Dr. Fletcher on our Board.
- warrants to purchase up to 400,000 shares of our common stock exercisable at $0.01 per share. The warrants were issued in January 2018 to Liquid Patent Advisors, LLC as consideration for consulting services; and

- warrants issued to National Securities Corporation in March 2018 and May 2019, as placement agent compensation in connection with our March 2018 and May 2019 placements of Series A preferred stock, to purchase shares of our common stock in an amount equal to 10% of the shares of common stock issuable upon conversion of 5,662,000 and 3,268,000 shares, respectively, of our Series A preferred stock issued in such placements, at an exercise price equal to the lesser of (i) 50% of the initial public offering price or (ii) $2.50 (subject to proportional adjustment in the events of combinations, subdivisions or the like). Assuming the conversion of all of our Series A preferred stock as of March 31, 2019, the placement agent warrants would entitle the holder to purchase up to ____ shares of our common stock.

The warrants contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrants in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations. The holders of the shares issuable upon exercise of the warrants issued to Liquid Patent Advisors, LLC and National Securities Corporation are entitled to registration rights with respect to such shares as described in greater detail under the heading "— Registration Rights" below.

Registration Rights

Following the completion of this offering, certain holders of an aggregate of _____ shares of our common stock, or their permitted transferees, are entitled to rights with respect to the registration under the Securities Act of their shares of common stock, including demand registration rights and piggyback registration rights. These rights are provided under the terms of a registration rights agreement between us and the investors. In any registration made pursuant to this agreement, all fees, costs and expenses of the registrations will be borne by us, and all selling expenses, including estimated underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

In connection with our May 2019 Series A preferred stock financing, we entered into an amended and restated registration rights agreement, pursuant to which we will be required, upon the written request at any time more than 180 days after the completion of this offering by the holders of at least 50% of the shares that are entitled to registration rights under the registration rights agreement, to register, as soon as practicable, all or a portion of these shares for public resale. We are required to effect only one registration pursuant to this provision of the registration rights agreement. These demand registration rights terminate as to each investor when their shares subject to the registration rights agreement may be sold by the investor pursuant to Rule 144 under the Securities Act without regard to both the volume limitations for sales as provided in Rule 144.

In connection with our issuance to Liquid Patent Advisors, LLC and National Securities Corporation of warrants to purchase shares of our common stock, we entered into a registration rights agreement with Liquid Patent Advisors, LLC and National Securities Corporation pursuant to which we will be required, upon the written request at any time more than 180 days after the completion of this offering by the holders of at least 50% of the shares that are entitled to registration rights under that agreement and the registration rights agreement we entered into with the Series A preferred stock investors, as a group, to register, as soon as practicable, all or a portion of these shares for public resale. We are required to effect only one registration pursuant to this provision of the registration rights agreement. These demand registration rights terminate as to each stockholder when their shares subject to the registration rights agreement may be sold by the investor pursuant to Rule 144 under the Securities Act without regard to both the volume limitations for sales as provided in Rule 144.

In addition, the registration rights agreement contains piggyback registration rights with respect our capital stock held by these investors. These piggyback registration rights terminate with respect to each stockholder when their shares subject to the registration rights agreement may be sold by the stockholder pursuant to Rule 144 under the Securities Act without regard to both the volume limitations for sales as provided in Rule 144.

If we register any of our securities for our own account, after the completion of this offering, the

holders of these shares are entitled to include their shares in the registration. Both we and the underwriters of any underwritten offering have the right to limit the number of shares registered by these holders for marketing reasons, subject to limitations set forth in the registration rights agreement with these investors.

Anti-Takeover Effects of Certain Provisions of Delaware Law and Our Charter Documents

The following is a summary of certain provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws in effect upon the closing of this offering. This summary does not purport to be complete and is qualified in its entirety by reference to the corporate law of Delaware and our amended and restated certificate of incorporation and amended and restated bylaws.

Effect of Delaware Anti-Takeover Statute. We are subject to Section 203 of the Delaware General Corporation Law, an anti-takeover law. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination (as defined below) with any interested stockholder (as defined below) for a period of three years following the date that the stockholder became an interested stockholder, unless:

- prior to that date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares of voting stock outstanding (but not the voting stock owned by the interested stockholder) those shares owned by persons who are directors and officers and by excluding employee stock plans in which employee participants do not have the right to determine whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to that date, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to limited exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation, or who beneficially owns 15% or more of the outstanding voting stock of the corporation at any time within a three-year period immediately prior to the date of determining whether such person is an interested stockholder, and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

Our Charter Documents. Our charter documents include provisions that may have the effect of discouraging, delaying or preventing a change in control or an unsolicited acquisition proposal that a stockholder might consider favorable, including a proposal that might result in the payment of a premium over the market price for the shares held by our stockholders. Certain of these provisions are summarized in the following paragraphs.

Exclusive Forum. Unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) 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; (iii) 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 (iv) 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. A court may determine that these choice of forum provisions are unenforceable, and to the extent they are enforceable, they may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder.

Effects of authorized but unissued common stock. One of the effects of the existence of authorized but unissued common stock may be to enable our Board to make more difficult or to discourage an attempt to obtain control of our Company by means of a merger, tender offer, proxy contest or otherwise, and thereby to protect the continuity of management. If, in the due exercise of its fiduciary obligations, the Board were to determine that a takeover proposal was not in our best interest, such shares could be issued by the Board without stockholder approval in one or more transactions that might prevent or render more difficult or costly the completion of the takeover transaction by diluting the voting or other rights of the proposed acquirer or insurgent stockholder group, by putting a substantial voting block in institutional or other hands that might undertake to support the position of the incumbent Board, by effecting an acquisition that might complicate or preclude the takeover, or otherwise.

Cumulative Voting. Our amended and restated certificate of incorporation does not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of the stock to elect some directors.

Vacancies. Our amended and restated bylaws provide that all vacancies may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum.

Special Meeting of Stockholders and Stockholder Action by Written Consent. A special meeting of stockholders may only be called by our president, Board or such officers or other persons as our Board may designate at any time and for any purpose or purposes as shall be stated in the notice of the meeting.

Transfer Agent and Registrar

Upon the closing of this offering, the transfer agent and registrar for our common stock will be eShares, Inc., doing business as Carta.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for shares of our common stock. Future sales of substantial amounts of shares of common stock, including shares issued upon the exercise of outstanding warrants and options, in the public market after this offering, or the possibility of these sales occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital.

Upon the completion of this offering, a total of ____ shares of common stock will be outstanding, assuming the automatic conversion of all outstanding Series A preferred stock into shares of common stock in connection with the completion of this offering. All ____ shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriter's over-allotment option, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by "affiliates," as that term is defined in Rule 144 under the Securities Act.

The remaining shares ____ of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below.

Subject to the lock-up agreements described below and the provisions of Rules 144 and 701 under the Securities Act, these restricted securities will be available for sale in the public market beginning more than 180 days after the date of this prospectus.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements described below, within any three-month period beginning 90 days after the date of this prospectus, a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding; or
- the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been one of our affiliates during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits our affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. However, all holders of Rule

701 shares are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701.

Lock-Up Agreements

We, our executive officers and directors and the holders of our common stock outstanding on the date of this prospectus have entered into lock-up agreements or otherwise agreed that we and they will not, subject to limited exceptions, (i) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, or file with the SEC a registration statement under the Securities Act relating to, any of our securities or publicly disclose the intention to do any of the foregoing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any of our securities (regardless of whether any of these transactions are to be settled by the delivery of our securities, in cash or otherwise), in each case without the prior written consent of the underwriter for a period of 12 months after the date of this prospectus.

All of the shares common stock issuable upon conversion of our Series A preferred stock upon the closing of this offering are subject to lock-up agreements whereby the holder of those shares has agreed not to sell, transfer or pledge, or offering to do any of the same, directly or indirectly, any of our securities for a period of 180 days following the close of this offering. 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 upon request.

In connection with our issuance of warrants to purchase shares of our common stock to Liquid Patent Advisors, LLC and National Securities Corporation, including the underwriter warrant to be issued to National Securities Corporation upon the completion of this offering, Liquid Patent Advisors and National Securities Corporation have agreed not to sell, transfer or pledge, or offer to do any of the same, directly or indirectly, the shares of common stock issuable upon exercise of such warrants for a period of 12 months following the close of this offering.

Registration Statements on Form S-8

We intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of common stock to be issued or reserved for issuance under our 2018 Plan. Shares covered by this registration statement will be eligible for sale in the public market, upon the expiration or release from the terms of the lock-up agreements and subject to vesting of such shares.

UNDERWRITING

We are offering the shares of common stock described in this prospectus through the underwriter, National Securities Corporation, which is acting as lead managing underwriter of the offering.

We have agreed to enter into an underwriting agreement with the underwriter prior to the closing of this offering. Subject to the terms and conditions of the underwriting agreement, we will agree to sell to the underwriter, and the underwriter will agree to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, as it may be supplemented, shares of common stock.

The underwriter is committed to purchase all of the common shares offered by us, other than those covered by the option to purchase additional shares described below, if they purchase any shares. The underwriting agreement provides that the underwriter's obligations to purchase shares of our common stock are subject to conditions contained in the underwriting agreement. A copy of the underwriting agreement has been filed as an exhibit to the registration statement of which this prospectus forms a part.

We have been advised by the underwriter that the underwriter proposes to offer shares of our common stock directly to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers that are members of the Financial Industry Regulatory Authority, or FINRA. Any securities sold by the underwriter to such securities dealers will be sold at the public offering price less a selling concession not in excess of $ per share. After the public offering of the shares, the offering price and other selling terms may be changed by the underwriter.

None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus and any other offering material or advertisements in connection with the offer and sales of any of our common stock, be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of our common stock and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy any of our common stock included in this offering in any jurisdiction where that would not be permitted or legal.

The underwriter has advised us that it does not intend to confirm sales to any accounts over which they exercise discretionary authority.

Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriter by us.

	Without Over-Allotment	With Over-Allotment
Public offering price	$	$
Underwriting discount to be paid to the underwriter	$	$
Net proceeds, before other expenses	$	$

In addition to the discount set forth in the above table, we have agreed to issue to the underwriter and its designees a warrant to purchase up to _____% of the shares of common stock sold in this offering and to pay $_____ for their counsel's fees as well as $_____ for certain of their accountable/non-accountable expenses. The terms of the underwriter's warrant are more fully described in this section under the caption, "Underwriter Warrants."

Over-Allotment Option

In addition to the discount set forth in the above table, we have granted to the underwriter an

option, exercisable not later than 45 days after the date of this prospectus, to purchase up to an additional _____ shares of our common stock (up to _____**%** of the shares firmly committed in this offering) at the public offering price, less the underwriting discount, set forth on the cover page of this prospectus. The underwriter may exercise the option solely to cover over-allotments, if any, made in connection with this offering. If any additional shares of our common stock are purchased pursuant to the over-allotment option, the underwriter will offer these additional shares of our common stock on the same terms as those on which the other shares of common stock are being offered hereby.

Determination of Offering Price Listing

We intend to apply to list our common stock on The NASDAQ Capital Market under the symbol "TFFP". In order to meet the requirements for listing on that exchange, the underwriters have undertaken to sell a minimum number of shares to a minimum number of beneficial owners as required by that exchange.

Before this offering, there has been no public market for our common stock. There is no current market for our common stock. Our underwriter, National Securities Corporation, is not obligated to make a market in our securities, and even if it chooses to make a market, can discontinue at any time without notice. Neither we nor the underwriter can provide any assurance that an active and liquid trading market in our securities will develop or, if developed, that the market will continue.

The public offering price of the shares offered by this prospectus has been determined by negotiation between us and the underwriter. Among the factors considered in determining the public offering price of the shares were:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the shares. Upon the commencement of trading, the price of our shares will be subject to change as a result of market conditions and other factors, and we cannot assure you that the shares can be resold at or above the public offering price.

Underwriter Warrants

In connection with this offering, we have agreed to issue to National Securities Corporation and its designees a warrant to purchase shares of our common stock equal to _____% of the shares of common stock sold in this offering. This warrant is exercisable at $_____ per share (_____% of the price of the common stock sold in this offering), expiring five years from the date of this prospectus. The warrant and the shares of common stock underlying the warrant have been deemed compensation by FINRA and are therefore subject to a six-month lock-up pursuant to Rule 5110(g)(1) of FINRA. Additionally, National Securities Corporation has contractually agreed that it (or its permitted assignees under the Rule) will not sell, transfer, assign, pledge, or hypothecate this warrant or the securities underlying this warrant, nor will it engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of this warrant or the underlying securities for a period of twelve months from the effective date of the offering.

In connection with its role as placement agent in our offerings of Series A preferred stock, we issued to National Securities Corporation and its designees warrants to purchase shares of our common stock in an amount equal to 10% of the shares of common stock issuable upon conversion of 8,930,000 shares of our Series A preferred stock. The warrants are exercisable at $_____ per share (equal to the lesser of (i) 50% of the price of the common stock sold in this offering or (ii) $2.50 (subject to proportional adjustment in the events of combinations, subdivisions or the like)), expiring five years from March 13, 2018, March 21, 2018, May 16, 2019 and May 23, 2019, the dates the warrants were originally issued. In addition to the lock-up provisions summarized below, the warrants and the shares of common stock underlying the warrants have been deemed compensation by FINRA and are therefore subject to a six-month lock-up pursuant to Rule 5110(g)(1) of FINRA. National Securities Corporation (or permitted assignees under the Rule) will not sell, transfer, assign, pledge, or hypothecate the warrants or the underlying common shares, nor will it engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying common shares for a period of six months from the effective date of the offering.

Pursuant to our engagement agreement with Liquid Patent Advisors, LLC, on January 24, 2018, we issued to Liquid Patent Advisors, LLC warrants to purchase up to 400,000 shares of our common stock, exercisable at $0.01 per share, expiring after a term of five years. The warrants were issued in consideration of Liquid Patent Advisors, LLC's

provision of consulting services. The warrants provide its holders with certain registration and piggyback registration rights. The warrants also contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrants in the event of certain stock dividends, stock splits, reorganizations, reclassifications, and consolidations. The principals of Liquid Patent Advisors, LLC hold investment banking positions with National Securities Corporation. The principals of Liquid Patent Advisors, LLC conduct their investment banking activities at National Securities Corporation under the fictitious business name "Liquid Venture Partners". Liquid Venture Partners is not a broker-dealer and will not participate in this offering. While the principals of Liquid Venture Partners will receive from National Securities Corporation a portion of the underwriting compensation, Liquid Venture Partners will not receive any other compensation or reimbursement of expenses in connection with this offering, directly or indirectly, from TFF Pharmaceuticals or National Securities Corporation.

Lock-Up Agreements

In connection with our issuance of warrants to purchase shares of our common stock to Liquid Patent Advisors, LLC and National Securities Corporation, including the underwriter warrant to be issued to National Securities upon the completion of this offering, Liquid Patent Advisors and National Securities Corporation have agreed not to sell, transfer or pledge, or offering to do any of the same, directly or indirectly, the shares of common stock issuable upon exercise of such warrants for a period of 12 months following the close of this offering. We, all of our directors and officers and our former parent, LTI, have agreed in connection with the present offering, that, without the prior written consent of National Securities Corporation, not to sell, transfer, pledge, lend or offer to do any of the same, directly or indirectly, any of our securities for a period of 12 months following the close of this offering. The holders of all of our other securities convertible into our common stock outstanding immediately prior to this offering have agreed in connection with the present offering, that, without the prior written consent of National Securities Corporation, not to sell, transfer or pledge, or offer to do any of the same, directly or indirectly, any of our securities for a period 180 days following the close of this offering.

The number of shares of common stock outstanding upon the completion of this offering subject to the 180-day lock-up totals _____ shares, and the number of shares underlying options, warrants and restricted stock units subject to the 180-day lock-up totals _____ shares.

Other than in respect of the warrants issued or to be issued to Liquid Patent Advisors, LLC and National Securities Corporation, the underwriter may consent to an early release from the lock-up period if, in its opinion, the market for the common stock would not be adversely impacted by sales and in cases of a financial emergency of an officer, director or other stockholder. We are unaware of any security holder who intends to ask for consent to dispose of any of our equity securities during the relevant lock-up periods.

Indemnification

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act relating to losses or claims resulting from material misstatements in or omissions from this prospectus, the registration statement of which this prospectus is a part, certain free writing prospectuses that may be used in the offering and in any marketing materials used in connection with this offering and to contribute to payments the underwriters may be required to make in respect of those liabilities.

Short Positions and Penalty Bids

The underwriter may engage in over-allotment, syndicate covering transactions, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Exchange Act.

- Over-allotment involves sales by the underwriter of shares in excess of the number of shares the underwriter is obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a

covered short position, the number of shares over-allotted by an underwriter is not greater than the number of shares that it may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriter may close out any short position by either exercising its over-allotment option and/or purchasing shares in the open market.

- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which it may purchase shares through the over-allotment option. If an underwriter sells more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if an underwriter is concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

- Penalty bids permit an underwriter to reclaim a selling concession from a syndicate member when the shares originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the NASDAQ Capital Market, and if commenced, they may be discontinued at any time.

Neither we nor the underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor the underwriter make any representation that the underwriter will engage in these transactions or that any transaction, once commenced, will not be discontinued without notice.

Electronic Distribution

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by the underwriter, or by its affiliates. In those cases, prospective investors may view offering terms online and, depending upon the underwriter, prospective investors may be allowed to place orders online. The underwriter may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriter on the same basis as other allocations.

Other than the prospectus in electronic format, the information on the underwriter's website and any information contained in any other website maintained by the underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriter in its capacity as underwriter and should not be relied upon by investors.

The underwriter's compensation in connection with this offering is limited to the fees and expenses described above under "Underwriting Discount and Expenses."

LEGAL MATTERS

Greenberg Traurig, LLP, Irvine, California, will pass upon the validity of the shares of common stock offered by this prospectus. LKP Global Law, LLP, Los Angeles, California, is legal counsel to National Securities Corporation. Certain employees of LKP Global Law, LLP participated in the private placements of our Series A preferred stock as investors.

EXPERTS

The financial statements as of and for the fiscal years ended December 31, 2018 and 2017 included in this prospectus have been so included in reliance on the report of Marcum, LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act that registers the shares of our common stock to be sold in this offering. Our SEC filings are and will become available to the public over the Internet at the SEC's website at *www.sec.gov.* You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street N.E., Washington, D.C. 20549. You can also obtain copies of the documents upon the payment of a duplicating fee to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. Some items are omitted in accordance with the rules and regulations of the SEC. You should review the information and exhibits included in the registration statement for further information about us and the securities we are offering. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to these filings. You should review the complete document to evaluate these statements.

TFF PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of TFF Pharmaceutical, Inc. (the "Company") as of December 31, 2018 and December 31, 2017 (Predecessor), the related statements of operations, stockholders' deficit and cash flows for the period from January 24, 2018 to December 31, 2018, period from January 1, 2018 to January 23, 2018 (Predecessor) and year ended December 31, 2017 (Predecessor), and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and December 31, 2017 (Predecessor), and the results of its operations and its cash flows for the period from January 24, 2018 to December 31, 2018, period from January 1, 2018 to January 23, 2018 (Predecessor) and year ended December 31, 2017 (Predecessor), in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2018

New York, NY
February 15, 2019

TFF PHARMACEUTICALS, INC.

BALANCE SHEETS

	As of December 31, 2018	As of December 31, 2017 (Predecessor)
Assets		
Current Assets		
Cash and cash equivalents	$ 10,261,671	$ —
Prepaid assets and other current assets	12,065	—
Total Current Assets	10,273,736	—
Deferred offering costs	127,768	—
Total Assets	$ 10,401,504	$ —
Liabilities and Stockholders' deficit		
Current Liabilities		
Accounts payable	$ 428,645	$ 1,833
Accrued dividends payable	728,350	—
Total Liabilities	1,156,995	1,833
Commitments and Contingencies (see Note 4)		
Series A preferred stock		
Series A preferred stock, $0.001 par value, 6,000,000 shares authorized; 5,662,000 and 0 shares issued and outstanding as of December 31, 2018 and 2017, respectively (Liquidation Preference of $15,742,087)	12,485,971	—
Stockholders' deficit:		
Common stock, $0.001 par value, 45,000,000 shares authorized; 4,000,000 and 0 shares issued and outstanding as of December 31, 2018 and 2017, respectively	4,000	—
Additional paid-in capital	596,724	—
Parent's net deficit	—	(1,833)
Accumulated deficit	(3,842,186)	—
Total Stockholders' Deficit	(3,241,462)	(1,833)

Total Liabilities, Series A preferred stock and Stockholders' Deficit	$ 10,401,504	$ —

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

TFF PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS

	January 24, 2018 to December 31, 2018	January 1, 2018 to January 23, 2018 (Predecessor)	Year ended December 31, 2017 (Predecessor)
Operating expenses			
Research and development	$ 848,809	$ *	$ —
General and administrative	3,049,337	*	178,605
Total operating expenses	3,898,146	*	178,605
		*	
Loss from operations	(3,898,146)	*	(178,605)
		*	
Other income		*	
Interest income	55,960	*	—
Total other income	55,960	*	—
		*	
Net loss	(3,842,186)	*	(178,605)
		*	
Preferred stock dividend	(728,350)	*	—
		*	
Net loss applicable to common stock	$ (4,570,536)	$ *	$ (178,605)
Net loss applicable to common stock per share, basic and diluted	$ (1.31)		
Weighted average common shares outstanding, basic and diluted	3,483,836		

* Operations were not material.

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

TFF PHARMACEUTICALS, INC.

STATEMENTS OF STOCKHOLDERS' DEFICIT

	Common Stock		Additional Paid in Capital	Parent's Net Deficit	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balance January 1, 2017 (Predecessor)	—	$ —	$ —	$ (10,977)	$ —	$ (10,977)
Net loss	—	—	—	(178,605)	—	(178,605)
Advanced from Parent	—	—	—	187,749	—	187,749
Balance, December 31, 2017 (Predecessor)	—	—	—	(1,833)	—	(1,833)
Net Loss (Predecessor)	—	—	—	—	—	—
Transfers from former parent (Predecessor)	—	—	—	1,833	—	1,833
Balance, January 23, 2018 (Predecessor)	—	$ —	$ —	$ —	$ —	$ —
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)

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

TFF PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS

	January 24, 2018 to December 31, 2018	January 1, 2018 to January 23, 2018 (Predecessor)	For the Year Ended December 31, 2017 (Predecessor)
Cash Flows from Operating Activities			
Net loss	$ (3,842,186)	$ —	$ (178,605)
Adjustment to reconcile net loss to net cash provided by operating activities:			
Stock based compensation	1,329,074	—	—
Changes in operating assets and liabilities:			
Prepaid assets	(12,065)	—	—
Accounts payable	398,189	(1,833)	(9,144)
Net Cash Used In Operating Activities	(2,126,988)	(1,833)	(187,749)
Cash Flows From Investing Activities			
Net Cash Used in Investing Activities	—	—	—
Cash Flows From Financing Activities			
Net transfers from parent	—	1,833	187,749
Payment of offering costs	(97,312)		
Proceeds from issuance of preferred stock	12,485,971	—	—
Net Cash Provided by Financing Activities	12,388,659	1,833	187,749
Net Increase in Cash and Cash Equivalents	10,261,671	—	—
Cash and Cash Equivalents – beginning of period	—	—	—
Cash and Cash Equivalents – end of period	$ 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	$ 728,350	$ —	$ —

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

TFF PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
FOR THE PERIOD FROM JANUARY 24, 2018 TO DECEMBER 31, 2018,
JANUARY 1, 2018 TO JANUARY 23, 2018 (PREDECESSOR)
AND YEAR ENDED DECEMBER 31, 2017 (PREDECESSOR)

Note 1 — Background and Basis of Presentation

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, while the Company intends to initially focus on the development of inhaled dry powder drugs to enhance the treatment of pulmonary diseases and conditions.

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.

The accompanying financial statements of the Company as of and for the year ended December 31, 2017 reflect the historical financial position, 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 year ended December 31, 2017 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, 2018, the Company had cash and cash equivalents of approximately $10,261,000 and a working capital surplus of approximately $9,117,000. 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. During March 2018, the Company completed a private placement of 5,662,000 shares of its Series A Convertible Preferred Stock, raising net proceeds of approximately $12,486,000.

The Company expects to further increase its research and development activities, which will increase the amount of cash utilized during 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 continued expansion on manufacturing activities. Based on the funds the Company has available as of the date of the filing of this registration statement, including

proceeds of the private placement completed in May 2019, the Company believes that it has sufficient capital to fund the current business plan over, at least, 12 months from the issuance of these financial statements.

Note 3 — Summary of Significant Accounting Policies

Basis of presentation

The financial statements are presented in accordance with accounting principles generally accepted in the United States of America ("GAAP") and reflect the financial position, results of operations and cash flows for all periods presented.

Financial Statements

The financial statements for the periods from January 1, 2018 through January 23, 2018 (predecessor) and the year ended December 31, 2017 (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 consist primarily of legal, accounting and filing fees incurred through the balance sheet date that are related to the Company's proposed initial public offering of its common stock and that will be charged to capital upon the receipt of the capital raised or charged to expense if the proposed offering is not completed.

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.

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.

Note 3 — Summary of Significant Accounting Policies (cont.)

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, 2018 or 2017.

The Company follows authoritative guidance which requires the evaluation of existing tax positions. Management has analyzed all open tax years, as defined by the statute of limitations, for all major jurisdictions, which includes both federal and states where the Company has operations. Open tax years are those that are open for examination by taxing authorities. There are no open tax years at this time as the Company was incorporated during 2018.

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.

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 include the 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. Accordingly, basic and diluted net loss per share are equal.

For the period 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:

	Period from January 23, 2018 to December 31, 2018
Stock Options	1,073,082

Series A Convertible Preferred Stock*	5,953,340
Warrants	658,212
	7,684,634

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* *On an as-converted basis*

Note 3 — Summary of Significant Accounting Policies (cont.)

Common Stock Warrants

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

Stock-Based Compensation

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

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

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

The Company's equity on the Balance Sheet as of December 31, 2017 represents LTI's net investment in the Company's business and is presented as "Parent Net Deficit" in lieu of stockholders' equity. The changes in Parent's Net Deficit on the Statement of Stockholders' 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 been pushed down to the Company, are included in Parent Net Deficit.

Use of Estimates

The preparation of 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 (cont.)

Recent Accounting Standards

In June 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 amendment will be effective for annual and interim periods beginning after December 31, 2018. The company does not believe this new guidance will have a material effect on its financial position, results of operations or financial statement disclosure.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. This ASU will require lessees to recognize a right of use asset and lease liability on the 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. The amendment will be effective for annual and interim periods beginning after December 15, 2018, including interim periods within those fiscal years. 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. The Company does not currently believe this will have a significant impact on its financial position, results of operations or financial statement disclosure as the Company has not entered into any significant leases.

Subsequent Events

The Company evaluates events and/or transactions occurring after the balance sheet date and before the issue date of the financial statements to determine if any of those events and/or transactions requires adjustment to or disclosure in the financial statements.

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 will expire on October 31, 2019. The lease has a one year option for renewal, and the base rent is $42,000 per year.

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

Years ending December 31,	Amount
2019	$ 35,000

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 year ended December 31, 2018, the Company did not achieve any of the milestones and, as such, was not required to make any milestone payments. As of the date of these financials statements, the Company is in compliance with the patent license agreement.

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 $270,000, with no minimum fee requirement. During the year ended December 31, 2018, the Company recorded costs associated with this agreement of $192,000, 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. 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. During the year ended December 31, 2018, the Company recorded costs associated with this agreement of $273,000, as research and development costs. On January 17, 2019 the Company cancelled all of the individual study contracts with ITR Canada, Inc.

In January 2019, the Company entered into a contract with Canada Inc. (dba VJO Non-Clinical Development) to complete additional pre-clinical research and development services sub-contracted with ITR Canada, Inc., to take advantage of eligible Canadian Tax Credits during 2019.

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' Deficit

Series A Convertible Preferred Stock

The Company is authorized to issue to up 10,000,000 shares of preferred stock, $0.001 par value, all of which has been designated as Series A Convertible Preferred Stock ("Series A preferred stock") and has a stated value of $2.50 per share. As of December 31, 2018, 5,662,000 shares are 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, such amount aggregated $728,350 for the period ending December 31, 2018.

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 Initial Public Offering ("IPO") at a conversion price of 50% of the IPO price, (ii) automatic conversion into

Note 7 — Stockholders' Deficit (cont.)

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.

In addition to these methods of conversion, the Company will be required to repurchase all of the outstanding shares of the Series A preferred stock on July 1, 2020 at a redemption price of the product of two multiplied by the aggregate stated value of all of the Series A preferred stock then held by each holder, plus all accrued but unpaid dividends through the date of payment.

2018 Private Placement

On 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 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.

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.

Note 8 — Warrants (cont.)

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. The Company amortized $8,306 during the period, which is included in general and administrative expenses in the statement 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. The Company amortized $25,073 during the period, which is included in general and administrative expenses in the statement of operations.

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 year ended December 31, 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	4.6
Outstanding at December 31, 2018	1,058,212	$ 0.01 – $2.50	$ 1.56	4.6

The warrants outstanding at December 31, 2018 had an aggregate intrinsic value of approximately $117,684.

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. During the year ended December 31, 2018, the Company granted options under its 2018 Stock Incentive Plan to purchase 1,073,082 shares of its common stock to its employees and board of directors. The fair value of these options was approximately $1,294,795.

Note 9 — Stock Based Compensation (cont.)

The following table summarizes the stock-based compensation expense recorded in the Company's results of operations during the year ended December 31, 2018 and December 31, 2017 (Predecessor) for stock options and restricted stock:

	Year Ended December 31,	
	2018	2017
Research and development	$ —	$ —
General and administrative	150,986	—
	$ 150,986	$ —

As of December 31, 2018, there was approximately $1,143,809 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 3.4 years.

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, 2018
Weighted average exercise price	$ 2.50
Weighted average grant date fair value	$ 1.21
Assumptions	
Expected volatility	92.24%
Weighted average expected term (in years)	6.26
Risk-free interest rate	2.93%
Expected dividend yield	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.

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.

Note 9 — Stock Based Compensation (cont.)

The following table summarizes stock option activity during the year ended December 31, 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	9.64	—
Outstanding at December 31, 2018	1,073,082	$ 2.50	9.64	$ —
Exercisable at December 31, 2018	129,151	$ 2.50	9.64	$ —

Note 10 — Income Taxes

The Company had no income tax expense due to operating losses incurred for the years ended December 31, 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 deferred tax assets are as follows:

	December 31, 2018
Deferred tax assets:	
Net operating loss carryforwards	$ 459,522
Research and development tax credit	59,270
Intangibles	68,003
Stock compensation	275,617
Total deferred tax assets	862,412
Valuation allowance	(862,412)
Net deferred tax assets	$ —

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

	December 31, 2018
Statutory rate	21.00%
State rate	0.00%

Permanent book/tax differences	(0.10)%
Research and development credit	1.54%
Changes in valuation allowance	(22.44)%
Total	—

Note 10 — Income Taxes (cont.)

As of December 31, 2018, the Company had gross federal income tax net operating loss ("NOL") carryforwards of $2,188,203, and federal research tax credits of $59,270. The Internal Revenue Code ("Code") Sections 382 and 383 limits NOL and tax credit carry forwards when an ownership change of more than 50% of the value of the stock in a loss corporation occurs. Accordingly, the ability to utilize remaining NOL and tax credit carryforwards may be significantly restricted.

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, 2018.

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, 2018, the Company had no uncertain tax positions, and no interest or penalties have been charged to the Company for the years ended December 31, 2018. If incurred, the Company will classify any interest and penalties as a component of interest expense and operating expense, respectively.

TFF PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

	As of March 31, 2019 (Unaudited)	As of December 31, 2018
Assets		
Current Assets		
Cash and cash equivalents	$ 8,146,006	$ 10,261,671
Prepaid assets and other current assets	30,640	12,065
Total Current Assets	8,176,646	10,273,736
Deferred offering costs	144,926	127,768
Total Assets	$ 8,321,572	$ 10,401,504
Liabilities and Stockholders' deficit		
Current Liabilities		
Accounts payable	$ 410,302	$ 428,645
Accrued dividends payable	949,629	728,350
Total Liabilities	1,359,931	1,156,995
Commitments and Contingencies (see Note 4)		
Series A Preferred Stock		
Series A Preferred Stock, $0.001 par value, 6,000,000 shares authorized; 5,662,000 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively (Liquidation Preference of $15,742,087)	12,485,971	12,485,971
Stockholders' deficit:		
Common stock, $0.001 par value, 45,000,000 shares authorized; 4,000,000 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	4,000	4,000
Additional paid-in capital	496,671	596,724
Accumulated deficit	(6,025,001)	(3,842,186)
Total Stockholders' Deficit	(5,524,330)	(3,241,462)

Total Liabilities, Series A Preferred Stock and Stockholders' Deficit	$ 8,321,572	$ 10,401,504

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

TFF PHARMACEUTICALS, INC.

UNAUDITED CONDENSED STATEMENTS OF OPERATIONS

	Three Months ended March 31, 2019	January 24, 2018 to March 31, 2018	January 1, 2018 to January 23, 2018 (Predecessor)
Operating expenses			
Research and development	$ 1,670,862	$ —	$ *
General and administrative	531,598	269,371	*
Total operating expenses	2,202,460	269,371	*
			*
Loss from operations	(2,202,460)	(269,371)	*
			*
Other income			*
Interest income	19,645	1,870	*
Total other income	19,645	1,870	*
			*
Net loss	(2,182,815)	(267,501)	*
			*
Preferred stock dividend	(221,278)	—	*
			*
Net loss applicable to common stock	$ (2,404,093)	$ (267,501)	$ *
Net loss applicable to common stock per share, basic and diluted	$ (0.73)	$ (0.07)	
Weighted average common shares outstanding, basic and diluted	3,287,972	4,000,000	

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

TFF PHARMACEUTICALS, INC.

UNAUDITED CONDENSED STATEMENTS OF STOCKHOLDERS' DEFICIT

	Common Stock		Additional Paid in Capital	Parent's Net Deficit	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balance, January 1, 2019	4,000,000	$ 4,000	$ 596,724	$ —	$ (3,842,186)	$ (3,241,462)
Common stock issued to former parent	—	—	—	—	—	—
Stock-based compensation	—	—	121,226	—	—	121,226
Dividends on preferred stock	—	—	(221,279)	—	—	(221,279)
Net loss	—	—	—	—	(2,182,815)	(2,182,815)
Balance, March 31, 2019	4,000,000	$ 4,000	$ 496,671	$ —	$ (6,025,001)	$ (5,524,330)
Balance, January 1, 2018 (Predecessor)	—	—	—	(1,833)	—	(1,833)
Net Loss (Predecessor)	—	—	—	—	—	—
Transfers from former parent (Predecessor)	—	—	—	1,833	—	1,833
Common stock issued to former parent	4,000,000	$ 4,000	$ (4,000)	$ —	$ —	$ —
Net loss	—	$ —	$ —	$ —	$ (267,501)	$ —
Balance, March 31, 2018	4,000,000	$ 4,000	$ (4,000)	$ —	$ (267,501)	$ (267,501)

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

TFF PHARMACEUTICALS, INC.

UNAUDITED CONDENSED STATEMENTS OF CASH FLOWS

	For the Three Months Ended March 31, 2019	For the Three Months Ended March 31, 2018
Cash Flows from Operating Activities		
Net loss	$ (2,182,815)	$ (267,501)
Adjustment to reconcile net loss to net cash used in operating activities:		
Stock based compensation	121,226	—
Changes in operating assets and liabilities:		
Prepaid assets	(28,390)	—
Accounts payable	(25,686)	226,586
Net Cash Used In Operating Activities	(2,115,665)	(40,915)
Cash Flows From Investing Activities		
Net Cash Used in Investing Activities	—	—
Cash Flows From Financing Activities		
Net Transfers from parent	—	—
Proceeds from issuance of preferred stock	—	12,579,965
Net Cash Provided by Financing Activities	—	12,579,965
Net (Decrease) Increase in Cash and Cash Equivalents	(2,115,665)	12,539,050
Cash and Cash Equivalents – beginning of period	10,261,671	—
Cash and Cash Equivalents – end of period	$ 8,146,006	$ 12,539,050
Supplemental disclosure of non-cash investing and financing activities:		
Common stock issued to former parent for acquired assets	$ —	$ 4,000
Accrued offering costs	$ 38,741	$ —
Accrued dividend	$ 221,279	$ —

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

TFF PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
FOR THE PERIOD FROM JANUARY 1, 2019 TO MARCH 31, 2019,
JANUARY 1, 2018 TO JANUARY 23, 2018 (PREDECESSOR)
AND THREE MONTHS ENDED MARCH 31, 2018

Note 1 — Background and Basis of Presentation

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, while the Company intends to initially focus on the development of inhaled dry powder drugs to enhance the treatment of pulmonary diseases and conditions.

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.

The accompanying financial statements of the Company as of and for the period ended January 23, 2018 reflect the historical financial position, 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 March 31, 2019, the Company had cash and cash equivalents of approximately $8,146,000 and a working capital surplus of approximately $6,817,000. 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.

The Company expects to further increase its research and development activities, which will increase the amount of cash utilized subsequent to March 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 continued expansion on manufacturing activities. Based on the funds the Company has available as of the date of the filing of this registration statement, including proceeds of the private placement completed in May 2019 (see, Note 11), the

Company believes that it has sufficient capital to fund the current business plans over, at least, 12 months from the issuance of these financial statements.

Note 3 — Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial statements and with Form 10-Q and Article 10 of Regulation S-X of the United States Securities and Exchange Commission. Accordingly, they do not contain all information and footnotes required by GAAP for annual financial statements. In the opinion of the Company's management, the accompanying unaudited condensed financial statements contain all the adjustments necessary (consisting only of normal recurring accruals) to present the financial position of the Company as of March 31, 2019 and the results of operations, changes in stockholders' equity and cash flows for the periods presented. The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the operating results for the full fiscal year or any future period. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and related disclosures of the Company as of December 31, 2018 and 2017 and for the years then ended, which are included elsewhere in this document.

The financial statements are presented in accordance with accounting principles generally accepted in the United States of America ("GAAP") and reflect the financial position, results of operations and cash flows for all periods presented.

Financial Statements

The financial statements for the period 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 $144,926 and $127,768 as of March 31, 2019 and December 31, 2018, respectively, consist primarily of legal, accounting and filing fees incurred through the balance sheet date that are related to the Company's proposed initial public offering of its common stock and that will be charged to capital upon the receipt of the capital raised or charged to expense if the proposed offering is not completed.

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.

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

Note 3 — Summary of Significant Accounting Policies (cont.)

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.

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 include the 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. Accordingly, basic and diluted net loss per share are equal.

For the three months ended March 31, 2019 and the period January 24, 2018 to March 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:

	Period from January 1, 2019 to March 31, 2019	Period from January 23, 2018 to December 31, 2018
Stock Options	1,073,082	1,073,082
Series A Convertible Preferred Stock*	5,953,340	5,953,340
Warrants	658,212	658,212
	7,684,634	7,684,634

* *On an as-converted basis*

Use of Estimates

The preparation of 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 (cont.)

Recent Accounting Standards

In June 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 amendment will be effective for annual and interim periods beginning after March 31, 2019. The Company does not believe this new guidance will have a material effect on its financial position, results of operations or financial statement disclosure.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. This ASU will require lessees to recognize a right of use asset and lease liability on the 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. The amendment will be effective for annual and interim periods beginning after December 15, 2018, including interim periods within those fiscal years. 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. The adoption of this standard did not have a significant impact on the Company's financial position, results of operations or financial statement disclosure as the Company has not entered into any significant leases.

Subsequent Events

The Company evaluates events and/or transactions occurring after the balance sheet date and before the issue date of the financial statements to determine if any of those events and/or transactions requires adjustment to or disclosure in the financial statements.

Note 4 — Commitments and Contingencies

Operating leases

In October 2018, the Company entered into a lease agreement for office space in Doylestown, PA. The lease commenced on October 15, 2018 and will expire on October 31, 2019. The lease has a one year option for renewal, and the base rent is $42,000 per year.

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

Years ending December 31,	Amount
2019	$ 35,000

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 TFF'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 assigned to TFF 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. The patent license agreement requires TFF 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 three months ended March 31, 2019, the Company did not achieve any of the milestones and, as such, was not required to make any milestone payments. As of the date of these financials statements, the Company is in compliance with the patent license agreement.

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 $270,000, with no minimum fee requirement. During the three months ended March 31, 2019, the Company recorded costs associated with this agreement of $192,000, 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. 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. During the three months ended March 31, 2019, the Company recorded costs associated with this agreement of $273,000, as research and development costs. On January 17, 2019 the Company cancelled all of the individual study contracts with ITR Canada, Inc.

In January 2019, the Company entered into a contract with Canada Inc. (dba VJO Non-Clinical Development) to complete additional pre-clinical research and development services sub-contracted with ITR Canada, Inc., to take advantage of eligible Canadian Tax Credits during 2019.

Note 6 — Stockholders' Deficit

Series A Convertible Preferred Stock

The Company is authorized to issue to up 10,000,000 shares of preferred stock, $0.001 par value, all of which has been designated as Series A Convertible Preferred Stock ("Series A Preferred Stock") and has a stated value of $2.50 per share. As of March 31, 2019, 5,662,000 shares are 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, such amount aggregated $728,350 as of March 31, 2019. The Company recorded $221,278 of preferred dividends for the three months ended March 31, 2019.

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 Initial Public Offering ("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.

In addition to these methods of conversion, the Company will be required to repurchase all of the outstanding shares of the Series A Preferred Stock on July 1, 2020 at a redemption price of the product of two multiplied by the aggregate stated value of all of the Series A Preferred Stock then held by each holder, plus all accrued but unpaid dividends through the date of payment.

Note 7 — 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.

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. The Company amortized $8,306 during the period, which is included in general and administrative expenses in the statement 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. The Company amortized $25,073 during the period, which is included in general and administrative expenses in the statement of operations.

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 three months ended March 31, 2019 is as follows:

	Number of Shares	Range of Exercise Prices	Weighted-Average Exercise Prices	Weighted-Average Remaining Life
Outstanding at December 31, 2018	1,058,212	$ 0.01 – $2.50	$ 1.56	4.6
Issued	—	—	—	—

Outstanding at March 31, 2019	1,058,212	$ 0.01 – $2.50	$ 1.56	4.4

The warrants outstanding at March 31, 2019 had an aggregate intrinsic value of approximately $117,684.

Note 8 — Stock Based Compensation

In January 2018, the Company's board of directors approved its 2018 Stock Incentive Plan ("2018 Plan"). The 2018 Plan provides for the grant of non-qualified stock options and incentive stock options to purchase shares of the Company's common stock, the grant of restricted and unrestricted share awards and grant of restricted stock units. The 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 three months ended March 31, 2019 and March 31, 2018 for stock options and restricted stock:

	Three Months Ended March 31, 2019	Period From January 24, 2018 to March 31, 2018
Research and development	$ —	$ —
General and administrative	121,226	—
	$ 121,226	$ —

As of March 31, 2019, there was approximately $1,050,425 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 3.2 years.

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:

	Three Months Ended March 31, 2019
Weighted average exercise price	$ 2.50
Weighted average grant date fair value	$ 1.21
Assumptions	
Expected volatility	92.24%
Weighted average expected term (in years)	6.26
Risk-free interest rate	2.93%

Expected dividend yield	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.

Note 8 — Stock Based Compensation (cont.)

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.

The following table summarizes stock option activity during the year ended March 31, 2019:

	Number of Shares	Weighted-Average Exercise Prices	Weighted-Average Remaining Contractual Term (In Years)	Intrinsic Value
Outstanding at December 31, 2018	1,073,082	$ 2.50	9.64	—
Granted	—	—	—	—
Outstanding at March 31, 2019	1,073,082	$ 2.50	9.40	$ —
Exercisable at March 31, 2019	207,469	$ 2.50	9.40	$ —

Note 9 — Subsequent Events

On May 19, 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"). On May 23, 2019, the Company completed 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.

In connection the 2019 Private Placement, the Company granted the placement agent, National Securities Corporation, and its designees warrants to purchase shares of its common stock in an amount equal to 10% of the shares of common stock issuable upon conversion of the 3,268,000 shares of its Series A Preferred Stock sold in the 2019 Private Placement. The warrants are exercisable at per share price equal to the lesser of (i) 50% of the price of the common stock sold in the Company's IPO or (ii) $2.50 (subject to proportional adjustment in the events of combinations, subdivisions or the like) and expire five years from the date of grant.

During the second quarter of 2019, the Company granted options under its 2018 Plan to purchase a total 250,512 shares of its common stock, exercisable at $2.50 per share over a period of ten years from the date of grant. The options include options to purchase 150,000 common shares granted to Kirk Coleman in connection with his employment agreement as Chief Financial Officer and options to purchase 92,012 common shares granted to Randy Thurman in connection his appointment to the Company's Board of Directors. The remaining options to purchase 8,500 common shares were granted to a consultant to the Company.

During the second quarter of 2019, the Company also granted to a consultant options under its 2018 Plan to purchase 10,000 shares of its common stock, exercisable at $3.20 per share over a period of ten years from the date of grant.

Shares of Common Stock

TFF Pharmaceuticals, Inc.

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PROSPECTUS

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National Securities Corporation

, 2019

Through and including , 2019 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the various expenses to be incurred in connection with the sale and distribution of our common stock being registered hereby, all of which will be borne by us (except any underwriting discounts and commissions and expenses incurred for brokerage, accounting, tax or legal services or any other expenses incurred in disposing of the shares). All amounts shown are estimates except the SEC registration fee.

SEC Filing Fee		*
FINRA Fee		*
Underwriter's Legal Fees and Expenses		*
Nasdaq Fee		*
Printing Expenses		*
Accounting Fees and Expenses		*
Legal Fees and Expenses		*
Transfer Agent and Registrar Expenses		*
Miscellaneous		*
Total	$	*

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* To be provided by amendment.

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS

The following summary is qualified in its entirety by reference to the complete text of any statutes referred to below and the amended and restated certificate of incorporation of TFF Pharmaceuticals, Inc., a Delaware corporation.

Section 145 of the General Corporation Law of the State of Delaware (the "DGCL") permits a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful.

In the case of an action by or in the right of the corporation, Section 145 of the DGCL permits a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any

claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses that the Court of Chancery or such other court shall deem proper.

Section 145 of the DGCL also permits a Delaware corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under Section 145 of the DGCL.

Article Sixth of our Amended and Restated Certificate of Incorporation states that to the fullest extent permitted by the DGCL our directors shall not be personally liable to us or to our stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL is amended after the date hereof to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Article Seventh of our Amended and Restated Certificate of Incorporation requires us, to the fullest extent permitted by applicable law, to provide indemnification of (and advancement of expenses to) our directors and officers, and authorizes us, to the fullest extent permitted by applicable law, to provide indemnification of (and advancement of expenses to) to other employees and agents (and any other persons to which the DGCL permits us to provide indemnification) through bylaw provisions, agreements with such directors, officers, employees, agents or other persons, vote of stockholders or disinterested directors or otherwise, subject only to limits created by the DGCL with respect to actions for breach of duty to our corporation, our stockholders and others.

Article Seventh of our Amended and Restated Certificate of Incorporation provides that we shall, to the maximum extent and in the manner permitted by the DGCL, indemnify each of our directors, officers and all other persons we have the power to indemnify under Section 145 of the DGCL against expenses (including attorneys' fees), judgments, fines, settlements and other amounts actually and reasonably incurred in connection with any proceeding, arising by reason of the fact that such person is or was a director of the Company. We may maintain insurance, at our expense, to protect the Company and any of our directors, officers, employees or agents against any such expense, liability or loss, whether or not we have the power to indemnify such person.

Prior to the closing of this offering we plan to enter into an underwriting agreement, which will provide that the underwriters are obligated, under some circumstances, to indemnify our directors, officers and controlling persons against specified liabilities.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

Issuances of capital stock

The following list sets forth information regarding all unregistered securities sold by us since January 24, 2018 (inception) through the date of the prospectus that forms a part of this registration statement.

In January 2018, we issued a warrant to purchase an aggregate of 400,000 shares of our common stock to Liquid Patent Advisors, LLC at an exercise price of $0.01 per share.

In March 2018, we issued 4,000,000 shares of our common stock to Lung Therapeutics, Inc. in consideration of its contribution of certain licensed patent rights to us.

In March 2018, we issued an aggregate of 5,662,000 shares of our Series A preferred stock to 228 accredited investors at a purchase price of $2.50 per share for aggregate consideration of approximately $14.2 million.

In March 2018, we issued warrants to National Securities Corporation, as placement agent compensation in connection with our March 2018 placement of Series A preferred stock, to purchase shares of our common stock equal to 10% of our common stock issuable upon conversion of our Series A preferred stock sold in the placement by National Securities Corporation, at an exercise price equal to the lesser of (i) 50% of the initial public offering price or (ii) $2.50 (subject to proportional adjustment in the events of combinations, subdivisions or the like).

In April 2018, we issued options to purchase an aggregate of 60,000 shares of our common stock to two members of our Board of Directors and a warrant to purchase 10,000 shares of our common stock to an entity affiliated with a third member of our Board of Directors. The options and warrant vest on the one-year anniversary of the date of grant, provided that one-half of the options and warrants will vest immediately upon the close of our initial public offering if sooner. The exercise price of the options and warrant is $2.50 per share.

In September 2018, we issued options to purchase an aggregate of 629,058 shares of our common stock to three members of our Board of Directors and a warrant to purchase 82,012 shares of our common stock to an entity affiliated with a fourth member of our Board of Directors. The options and warrant vest as to one quarter of the underlying shares on the first anniversary of the date of grant, with the remaining shares vesting in 12 equal quarterly installments thereafter. The exercise price of the options and warrant is $2.50 per share.

In December 2018, we issued options to purchase an aggregate of 184,024 shares of our common stock to two members of our Board of Directors, and in April 2019, we issued options to purchase 92,012 shares of our common stock to one member of our Board of Directors. The options vest as to one quarter of the underlying shares on the first anniversary of the date of grant, with the remaining shares vesting in 12 equal quarterly installments thereafter. The exercise price of the options is $2.50 per share.

In May 2019, we issued an aggregate of 3,268,000 shares of our Series A preferred stock to 229 accredited investors at a purchase price of $2.50 per share for aggregate consideration of approximately $8.2 million.

In May 2019, we issued warrants to National Securities Corporation, as placement agent compensation in connection with our May 2019 placement of Series A Preferred Stock, to purchase shares of our common stock equal to 10% of our common stock issuable upon conversion of our Series A preferred stock sold in the placement by National Securities Corporation, at an exercise price equal to the lesser of (i) 50% of the initial public offering price or (ii) $2.50 (subject to proportional adjustment in the event of combinations, subdivisions or the like).

We believe the offers, sales and issuances of the above securities by us were exempt from registration under the Securities Act by virtue of Section 4(a)(2) of the Securities Act as transactions not involving a public offering. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates, notes and warrants issued in these transactions. All recipients had adequate access, through their relationships with us, to information about our Company. The sales of these securities were made without any general solicitation or advertising.

ITEM 16. EXHIBITS

Exhibit No.	Description of Document
1.1*	Form of Underwriting Agreement
3.1	Second Amended and Restated Certificate of Incorporation of the Registrant
3.2**	Bylaws of the Registrant
3.3	Amended and Restated Bylaws of the Registrant effective immediately following the closing of this offering
4.1*	Specimen Certificate representing shares of common stock of Registrant
4.2**	Warrant dated January 24, 2018 issued to Liquid Patent Advisors, LLC
4.3**	Warrant dated March 13, 2018 issued to National Securities Corporation
4.4**	Warrant dated March 22, 2018 issued to National Securities Corporation
4.5	Warrant dated May 16, 2019 issued to National Securities Corporation
4.6	Warrant dated May 23, 2019 issued to National Securities Corporation
5.1*	Opinion of Greenberg Traurig, LLP regarding the validity of the common stock being registered
10.1	Engagement Agreement dated January 26, 2018 between Liquid Patent Advisors, LLC and the Registrant
10.2**	Securities Purchase Agreement dated March 13, 2018 by and among the Registrant and the Buyers named therein
10.3	Amended and Restated Registration Rights Agreement dated May 16, 2019 by and among the Registrant and certain of its stockholders
10.4**	Contribution and Subscription Agreement dated January 24, 2018 between the Registrant and Lung Therapeutics, Inc.
10.5**	Patent License Agreement dated July 8, 2015 between Lung Therapeutics, Inc. and The

	University of Texas at Austin
10.6+**	TFF Pharmaceuticals, Inc. 2018 Stock Incentive Plan
10.7+	Amended and Restated Consulting Agreement dated December 20, 2018 between Robert Mills and the Registrant
10.8+**	Consulting Agreement dated February 12, 2018 between Dr. Brian Windsor and the Registrant
10.9+**	Consulting Agreement dated April 23, 2018 between Glenn Mattes and the Registrant

Exhibit No.	Description of Document
10.10	Lease Agreement dated October 19, 2018
10.11+	Executive Employment Agreement dated December 20, 2018 between Glenn Mattes and the Registrant
10.12	Securities Purchase Agreement dated May 16, 2019 by and among the Registrant and the Buyers named therein
10.13	Amendment No.1 to Patent License Agreement dated November 30, 2018 between the Registrant and The University of Texas at Austin
10.14+	Employment Agreement, dated February 15, 2019, by and between the Registrant and Kirk Coleman
21.1	List of Subsidiaries
23.1*	Consent of Marcum LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Greenberg Traurig, LLP (included in Exhibit 5.1)
24.1	Power of Attorney

_____

* To be submitted by amendment
** Previously submitted
\+ Indicates management compensatory plan, contract or arrangement

ITEM 17. UNDERTAKINGS

The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus as filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Austin, Texas on this _____ day of July, 2019.

	TFF PHARMACEUTICALS, INC.
	Glenn Mattes Chief Executive Officer and Director (Principal Executive Officer)

Each person whose signature appears below constitutes and appoints Glenn Mattes, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, any subsequent registration statements pursuant to Rule 462 of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof. This power of attorney may be executed in counterparts.

Pursuant to the requirements of the Securities Act of 1933, this registration statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

Signature	**Title**	**Date**
Glenn Mattes	President, Chief Executive Officer and Director *(Principal Executive Officer)*	July __, 2019
Kirk Coleman	Chief Financial Officer, Treasurer and Secretary *(Principal Financial and Accounting Officer)*	July __, 2019
Aaron Fletcher, Ph.D.	Chairman of the Board	July __, 2019
Brian Windsor, Ph.D.	Director	July __, 2019
Robert S. Mills, Jr.	Director	July __, 2019
	Director	July __, 2019

Stephen Rocamboli		
	Director	July __, 2019
Harlan Weisman, M.D.		
	Director	July __, 2019
Randy Thurman		