

As filed with the Securities and Exchange Commission on September 9, 2020

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

(State or other jurisdiction of
Incorporation or organization)

2834

(Primary Standard Industrial
Classification Code Number)

82-4344737

(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.
Sophia Shin, Esq.
Greenberg Traurig, LLP
18565 Jamboree Road, Suite 500
Irvine, California 92612
Telephone: (949) 732-6500**

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.

Large accelerated filer ☐

Non-accelerated filer ☒

Accelerated filer ☐

Smaller reporting company ☒

Emerging Growth Company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered ⁽¹⁾	Proposed maximum offering price per share ⁽²⁾	Proposed maximum aggregate offering price ⁽²⁾	Amount of registration fee
Common Stock, \$.001 par value per share	3,048,654 shares	\$ 13.00	\$ 39,632,502	\$ 5,144.30

- (1) All of the shares of common stock offered hereby are for the account of the selling stockholders named herein. In addition, pursuant to Rule 416 under the Securities Act of 1933, this Registration Statement includes an indeterminate number of additional shares as may be issuable as a result of stock splits or stock dividends which occur during this continuous offering.
- (2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933.

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 SEPTEMBER 9, 2020

3,048,654 Shares of Common Stock

TFF PHARMACEUTICALS, INC.

This prospectus relates to the resale of up to 3,048,654 shares of our common stock held by the selling stockholders named herein. We are not selling any shares of common stock and will not receive any proceeds from the sale of the shares by the selling stockholders under this prospectus.

These shares will be resold from time to time by the parties listed in the section titled "Selling Stockholders" beginning on page 9, which we refer to as the selling stockholders. The shares of common stock offered under this prospectus by the selling stockholders were issued in a private placement pursuant to the Securities Purchase Agreement, or the "Purchase Agreement," entered into by and among TFF Pharmaceuticals, Inc. and the selling stockholders, dated as of August 10, 2020. We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of securities by the selling stockholders.

The selling stockholders may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how a selling stockholder may sell its shares of common stock in the section titled "Plan of Distribution" on page 14. No underwriter or person has been engaged by us to facilitate the sale of shares in this offering. We will pay the expenses incurred in registering the securities covered by the prospectus, including legal and accounting fees.

Our common stock is listed on the NASDAQ Capital Market under the symbols "TFFP." On September 4, 2020, the last reported sale price of our common stock on the NASDAQ Capital Market was \$12.66 per share.

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.

The date of this prospectus is _____, 2020

TABLE OF CONTENTS

<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	7
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	8
<u>SELLING STOCKHOLDERS</u>	9
<u>ESTIMATED USE OF PROCEEDS</u>	11
<u>DESCRIPTION OF SECURITIES</u>	12
<u>PLAN OF DISTRIBUTION</u>	14
<u>LEGAL MATTERS</u>	16
<u>EXPERTS</u>	16
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	16
<u>INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE</u>	16
<u>INDEMNIFICATION OF DIRECTORS AND OFFICERS</u>	17

You should rely only on the information contained in this prospectus or in any free writing prospectus that we may specifically authorize to be delivered or made available to you. We have not, and the selling stockholders have not, authorized anyone to provide you with any information other than that contained in this prospectus. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus may only be used where it is legal to offer and sell our securities. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the selling stockholders are not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not and the selling stockholders have not 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 must inform themselves about, and observe any restrictions relating to, the offering of securities and the distribution of this prospectus outside the United States.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We believe that the data obtained from these industry publications and third-party research, surveys and studies are reliable.

This prospectus contains or incorporates by reference summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed or have been incorporated by reference as exhibits to the registration statement of which this prospectus forms a part, and you may obtain copies of those documents as described in this prospectus under

the heading “*Where You Can Find More Information.*”

Smaller Reporting Company – Scaled Disclosure

Pursuant to Item 10(f) of Regulation S-K promulgated under the Securities Act of 1933, as indicated herein, we have elected to comply with the scaled disclosure requirements applicable to “smaller reporting companies,” including providing two years of audited financial statements.

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

TFF Pharmaceuticals, Inc. (NASDAQ: TFFP) is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative drug products based on our patented Thin Film Freezing, or TFF, technology platform. We believe, and early testing confirms, that our TFF platform can significantly improve the solubility of poorly water-soluble drugs, a class of drugs that makes up approximately 33% of the major pharmaceuticals worldwide, thereby improving the pharmacokinetic effect of those drugs. We believe that in the case of some new drugs that cannot be developed due to poor water-solubility, our TFF platform has the potential to improve the pharmacokinetic effect of the drug to a level allowing for its development and commercialization. In November 2019, we initiated Phase I human clinical trials of our lead product, TFF Vori, and in June 2020 we commenced Phase I human clinical trials of our TFF Tac-Lac product in Melbourne, Victoria, Australia, but in July 2020, the Phase I trials of our TFF Tac-Lac product were delayed due to a resurgence of COVID-19 in the Melbourne area. A second clinical trial site in Brisbane, Queensland, Australia is being opened and we expect to resume dosing in the Phase 1 clinical trials in Australia before the end of the third quarter 2020. As of the date of this prospectus, we have not progressed the development of any other of our drug candidates to human clinical trials and our efforts have focused on the formulation, early stage animal testing and formal toxicology studies of our initial drug candidates in preparation for our first clinical trials.

We intend to initially focus on the development of inhaled dry powder drugs for the treatment of pulmonary diseases and conditions. While 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 version of Voriconazole, generally considered to be the best antifungal drug used to treat invasive pulmonary aspergillosis, or IPA, a severe fungal pulmonary disease with a mortality rate that can reach 90% in some patient populations. In October 2019, we submitted to the U.S. Food and Drug Administration, or FDA, an Investigational New Drug Application, or IND, for our TFF Vori and initiated our Phase I human clinical trials in November 2019. In July 2020, we completed the clinical portion of the Phase I trial with both single ascending and multiple ascending dose phases with 32 healthy subjects enrolled in each part to evaluate the safety, tolerability and pharmacokinetic profile of TFF Vori. We believe, and our clinical testing to date confirms, that our TFF platform can be used to formulate a dry powder version of Voriconazole, 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. On September 26, 2019, we participated in a pre-IND meeting with the FDA for purposes of discussing our proposed regulatory pathway for TFF Tac-Lac and obtaining guidance from the FDA on the pre-clinical plan leading to the filing and acceptance of an IND application for TFF Tac-Lac. We were successful in gaining agreement that a 505(b)(2) approach would be appropriate for TFF Tac-Lac. We intend to conduct Phase I clinical trials for our TFF formulation of Tacrolimus in Australia, which we consider to be a highly desirable site to conduct human clinical trials. On March 13, 2020, we had received the approval of the Alfred Hospital Human Research Ethics Committee to commence Phase I trials in Melbourne, Victoria, Australia. However, later in March 2020, our contract research organization partner in Australia informed us that because of the spread of the COVID-19 virus in Australia, there would be a delay in initiating the trials. One contributing factor is that Tacrolimus is an immunosuppressant drug and, given the threat of the COVID-19 virus, concern exists that even though we would be dosing healthy volunteers the inhalation of an immunosuppressant could increase the risk of severe complications if a volunteer was to contract COVID-19. In June 2020, we were able to begin dosing in the Phase I trial our TFF Tac-Lac in Melbourne, however, in July 2020, due to the resurgence of COVID-19 in the Melbourne area, the Phase I trials were delayed. With the flaring of COVID-19 in the Melbourne area and in order to remain dynamic, a second clinical trial site in Brisbane, Queensland, Australia is being opened and we expect to resume dosing in the Phase I clinical trials before the end of the third quarter of 2020. As of the date of this prospectus, we intend to submit to the FDA an IND for TFF Tac-Lac upon completion of the Phase I clinical trials.

TFF Niclosamide is an inhaled dry powder formulation of Niclosamide. Niclosamide has been used to treat tapeworm infections in humans since the 1960s and was recently reported to be one of the most potent approved drugs in screens for antiviral activity against the SARS-CoV2 virus that causes the COVID-19 disease. Early testing confirmed that our TFF platform can be used to formulate a dry powder version of Niclosamide, which is no longer subject to patent protection. We believe a TFF prepared dry powder formulation of Niclosamide administered directly to the lungs can maximize both the prophylactic value for persons exposed to COVID-19 and for the treatment of patients with COVID-19 infections at risk for serious disease complications. TFF has also obtained the rights to a novel formulation that may enhance the bioavailability of Niclosamide through oral delivery under our license from the University of Texas. Systemically delivered Niclosamide has shown promise for the treatment of COVID -19 and various forms of cancer.

We have identified a number of additional drug candidates that show promise upon initial evaluation, including dry powder formulations of:

Cannabidiol, or CBD, a controlled substance as defined in the federal Controlled Substances Act of 1970 that is reported to be used by some for the treatment of various epilepsy syndromes as well as anxiety, insomnia, and different types of pain. We are in the early stages of developing an inhaled dry powder form of CBD that could be used to support or to treat a variety of health issues that may benefit from CBD administration.

Vaccines containing aluminum salts, which make up approximately 35% of all vaccines. Aluminum salts are incorporated into many vaccine formulations as an adjuvant, which is a substance added to vaccines to enhance the immune response of vaccinated individuals. A major limitation with these vaccines is that they are fragile and to maintain their efficacy they must be formulated as liquid suspensions and kept in a cold chain (2 – 8°C) during transport and storage, which is burdensome and expensive. We have conducted drug and performance characterization activities of certain TFF formulated salt containing vaccines, which suggest that the salt containing vaccines can be successfully converted from liquid suspension into dry powder, and then later be reconstituted at the time of use without causing a decrease in efficacy.

As of the date of this prospectus, we intend to develop our dry powder formulations of CBD and salt containing vaccines with a pharmaceutical company active in the space and we do not intend to pursue the development of our dry powder formulation of CBD or salt containing vaccines beyond performance characterization and efficacy data through early animal testing until such time, if ever, as we obtain a development partner.

We are also focused on the joint development of dry powder formulations of proprietary drugs owned or licensed by other pharmaceutical companies. As of the date of this prospectus, we are at various stages of different feasibility studies of new chemical entities owned by international pharmaceutical companies. In addition, we recently commenced preliminary analysis and testing of dry powder formulations of certain drugs and vaccines through topical, ocular and nasal applications in connection with our participation in submissions made to certain government agencies for government contracts. Also, in May 2020, we authorized a third-party to conduct feasibility studies and market testing of dry powder formulations of cannabis and cannabis-derived products.

Our business model is to develop proprietary innovative drug product candidates that offer commercial or functional advantages, or both, to currently available alternatives. In our initial evaluation of the market, we have identified a number of potential drug candidates that show promise upon initial assessment. In most cases, these are off-patent drugs for which we would directly pursue the development of a dry powder formulation, however, we do not expect any dry powder formulation of a CBD drug product to be off-patent and our dry powder formulation of aluminum salt vaccines may not be off-patent. In those cases where our initial dry powder drug candidate will be established drugs that are off-patent, such as TFF Vori and TFF Tac-Lac, we believe that our drug product candidates may qualify for approval by the 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. Our dry powder formulation of a CBD drug candidate will likely require a full NDA through the FDA's 505(b)(1) regulatory pathway, however, a non-pharmaceutical CBD dry formulation, such as a dietary supplement, may not require FDA approval. We expect that our dry powder formulation of aluminum salt vaccines will require a biological license application, or BLA, which is very similar to a full NDA through the FDA's 505(b)(1) regulatory pathway. In addition, to the extent we claim that any of our off-patent drug product candidates target a new indication or offer improved safety compared to the existing approved products, and it is our present expectation that we will in many cases, it is likely that we will be required to conduct additional clinical trials in order to obtain marketing approval. For example, based on separate pre-IND meetings with the FDA concerning TFF Vori and TFF Tac-Lac, we believe we will need to conduct Phase I and Phase II studies prior to filing for marketing approval for TFF Vori and Phase I and Phase IIb/IIIa studies prior to filing for marketing approval for TFF Tac-Lac. However, there can be no assurance that the FDA will not ask for additional clinical data for either TFF Vori or TFF Tac-Lac.

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.

Recent Developments

On August 10, 2020, we entered into a Securities Purchase Agreement, or the Purchase Agreement, and a Registration Rights Agreement with certain institutional and other accredited investors, or the selling stockholders, pursuant to which we agreed to issue and sell, and the selling stockholders agreed to buy, 3,048,654 shares of our common stock at a price of \$8.50 per share for the approximate gross proceeds of \$25.91 million, before deducting placement agent and other offering expenses. The Purchase Agreement includes customary representations, warranties, and covenants by the selling stockholders and us, and an indemnity from us in favor of the selling stockholders. Pursuant to the terms of the Registration Rights Agreement, we agreed to prepare and file a resale registration statement with the SEC on or prior to September 12, 2020. The Registration Rights Agreement also provides that we must make certain payments as liquidated damages to the selling stockholders if we fail to timely file the registration statement or if the registration statement should become unavailable for the resale of the common shares, subject to certain exceptions. We have filed this registration statement on Form S-1 in fulfillment of our obligations under the Registration Rights Agreement.

On August 12, 2020, we entered into a licensing and collaboration agreement, or the License Agreement, with UNION therapeutics A/S, or UNION, pursuant to which UNION acquired an option to obtain a worldwide exclusive license for our TFF technology in combination with niclosamide. Pursuant to the terms of the License Agreement, UNION can exercise its option to obtain the license within 45 days after the complete data has been received by UNION from investigator-initiated trials. Upon exercise of the option, UNION shall be responsible to pay all expenses incurred in the development of any licensed products. We will be eligible to receive certain milestone payments based on the development the licensed products, sales-based payments based on sales of the licensed products and a single-digit tiered royalty on net sales.

Corporate Information

We were incorporated under the laws of the state of Delaware on January 24, 2018. 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 in our Annual Report on Form 10-K for the year ended December 31, 2019 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.”

Additional Information

For additional information related to our business and operations, please refer to the reports incorporated herein by reference, including our Annual Report on Form 10-K for the year ended December 31, 2019 as filed with the SEC on March 27, 2020, or the 2019 Form 10-K, our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2020 and June 30, 2020 as filed with the SEC on May 14, 2020 and August 13, 2020, or the 2020 Forms 10-Q, and our Current Reports on Form 8-K as filed with the SEC, as described in the section entitled “*Incorporation of Certain Documents by Reference*” in this prospectus.

The Offering

Common stock offered by the selling stockholders	3,048,654 shares
Common stock to be outstanding prior to this offering	22,286,224 shares
Terms of the offering	The selling stockholders and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares covered hereby on The Nasdaq Capital Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. See "Plan of Distribution."
NASDAQ symbol	"TFFP"
Risk factors	Investment in our securities involves a high degree of risk and could result in a loss of your entire investment. See "Risk Factors" beginning on page 7 and the similarly entitled sections in the documents incorporated by reference into this prospectus.
Use of proceeds	We will not receive any proceeds from the sale of the shares by the selling stockholders under this prospectus.

The number of shares of our common stock to be outstanding after this offering is based on 22,286,224 shares of common stock outstanding as of the date of this prospectus, and excludes:

2,792,623 shares of our common stock issuable upon exercise of outstanding options, with a weighted average exercise price of \$4.94 per share, granted pursuant to our 2018 Equity Incentive Plan, or the 2018 Plan;

approximately 860,526 shares of our common stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of \$2.86 per share; and

491,857 shares of our common stock reserved for future grants under our 2018 Plan.

Market Information

Our common stock has traded on the NASDAQ Capital Market under the symbol "TFFP," since our initial public offering on October 25, 2019. Since then, our common stock common stock has been relatively thinly traded at times and has experienced, and is expected to experience in the future, significant price and volume volatility. The following table shows the reported high and low closing prices per share for our common stock based on information provided by the NASDAQ Capital Market for the periods indicated.

Fiscal Year Ended December 31, 2019	High	Low
Fourth Quarter (commencing on October 25, 2019)	\$ 5.40	\$ 4.71
Fiscal Year Ending December 31, 2020	High	Low
First Quarter	\$ 5.36	\$ 3.51
Second Quarter	\$ 6.08	\$ 3.79
Third Quarter (through September 4, 2020)	\$ 14.06	\$ 5.86



RISK FACTORS

Investing in our securities involves a high degree of risk. Before investing in our securities, you should carefully consider the risks, uncertainties and assumptions contained in this prospectus and discussed under the heading “Risk Factors” included in the 2019 Form 10-K, as revised or supplemented by subsequent filings, which are on file with the SEC and are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. Our business, financial condition, results of operations and future growth prospects could be materially and adversely affected by any of these risks. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the reports incorporated by reference, contain 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;
- our ability to raise additional capital as and when needed;
- the effects of market conditions on our stock price and operating results;
- our ability to maintain, protect and enhance our intellectual property;
- the effects of increased competition in our market and our ability to compete effectively;
- costs associated with initiating and defending intellectual property infringement and other claims;
- the attraction and retention of qualified employees and key personnel;
- future acquisitions of or investments in complementary companies or technologies; and
- our ability to comply with evolving legal standards and regulations, particularly concerning requirements for being a public company.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading “Risk Factors” included in the 2019 Form 10-K 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, the reports incorporated by reference 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.

SELLING STOCKHOLDERS

This prospectus relates to the offering and sale, from time to time, of up to 3,048,654 shares of our common stock, held by the stockholders named in the table below. All of the selling stockholders named below acquired their shares of our common stock directly from us in a private placement of shares of our common stock conducted by us in August 2020.

On August 10, 2020, we entered into a Securities Purchase Agreement, or the Purchase Agreement, and a Registration Rights Agreement with certain institutional and other accredited investors, or the selling stockholders, pursuant to which we agreed to issue and sell, and the selling stockholders agreed to buy, 3,048,654 shares of our common stock at a price of \$8.50 per share for the approximate gross proceeds of \$25.91 million, before deducting placement agent and other offering expenses. The Purchase Agreement includes customary representations, warranties, and covenants by the selling stockholders and us, and an indemnity from us in favor of the selling stockholders. Pursuant to the terms of the Registration Rights Agreement, we agreed to prepare and file a resale registration statement with the SEC on or prior to September 12, 2020. The Registration Rights Agreement also provides that we must make certain payments as liquidated damages to the selling stockholders if we fail to timely file the registration statement or if the registration statement should become unavailable for the resale of the common shares, subject to certain exceptions. We have filed this registration statement on Form S-1 in fulfillment of our obligations under the Registration Rights Agreement.

Except as indicated below, none of the selling stockholders has held a position as an officer or director of our company, nor has any selling stockholder had any material relationship of any kind with us or any of our affiliates. Except as otherwise indicated in the footnotes to the table, the selling stockholders possess sole voting and investment power with respect to the shares shown, and no selling stockholder is a broker-dealer or an affiliate of a broker-dealer. All information with respect to share ownership has been furnished by the selling stockholders. The shares being offered are being registered to permit public secondary trading of the shares and each selling stockholder may offer all or part of the shares owned for resale from time to time.

The following table sets forth certain information known to us as of September 4, 2020 with respect to the beneficial ownership of our common stock by the selling stockholders who participated in the private placement mentioned above. Except as indicated below, the share amounts under the column "Maximum Number of Shares Offered" consist of the shares of our common stock sold by us in the private placement described above. The share amounts under the column "Shares Beneficially Owned after the Offering" assume all of the offered shares are sold pursuant to this prospectus.

Name of Beneficial Owner	Shares Beneficially Owned Before the Offering		Maximum Number of Shares Offered	Shares Beneficially Owned After the Offering ¹	
	Number	%		Number	%
The Precept Fund, L.P. ²	235,294	1.06%	235,294	0	*
683 Capital Partners, LP ³	117,647	*	117,647	0	*
Corriente Master Fund II, LP ⁴	1,058,823	4.75%	1,058,823	0	*
Brian and Dorothy Gagnon JTWROS ⁵	2,354	*	2,354	0	*
The Darwin Partnership (DL) ^{5 6}	14,706	*	14,706	0	*
The Darwin Partnership (NG) ^{5 7}	17,647	*	17,647	0	*
Dwight Lee ⁵	2,941	*	2,941	0	*
Hank and Phyllis Beinstein JTWROS ⁵	9,412	*	9,412	0	*
Upland Associates L.P. ^{5 6}	23,529	*	23,529	0	*
Gagnon Investment Associates ^{5 7}	176,471	*	176,471	0	*
Catalysis Partners, LLC ⁸	457,647	2.05%	117,647	340,000	1.53%
Weintraub Capital Management, L.P. ⁹	29,412	*	29,412	0	*
Nantahala Capital Partners Limited Partnership ¹⁰	129,906	*	72,189	57,717	*
Nantahala Capital Partners II Limited Partnership ¹⁰	377,696	1.69%	219,960	157,736	*
Nantahala Capital Partners SI, LP	967,337	4.34%	553,583	413,754	1.86%
NCP QR LP ¹⁰	157,772	*	93,342	64,430	*
Blackwell Partners LLC - Series A ¹⁰	303,182	1.36%	180,441	122,741	*
Silver Creek CS SAV, L.L.C. ¹⁰	97,095	*	56,956	40,139	*
NFS/FMTC Rollover IRA FBO Robert C. Clifford ^{5 11}	407,156	1.81%	30,000	377,156	1.68%
NFS/FMTC SEP IRA FBO Daniel P. Landry ^{5 12}	358,813	1.60%	12,000	346,813	1.54%
NFS/FMTC IRA FBO Christopher D. Jennings ^{5 13}	356,864	1.59%	9,400	347,464	1.55%
The Blair Family Trust U/A 3/21/11 ^{5 14}	33,288	*	9,000	24,288	*
NFS/FMTC SEP IRA FBO Ankur Desai ^{5 15}	262,764	1.17%	5,900	256,864	1.15%

* Less than 1%

¹ Assumes that all securities offered are sold.

² The selling stockholder indicated to us that D. Blair Baker has voting and investment power over the shares it is offering for resale.

³ The selling stockholder indicated to us that Ari Zweiman, Managing Member of 683 Capital Partners, LP, has voting and investment power over the shares it is offering for resale.

⁴ The selling stockholder indicated to us that Matthew Gilman, Chief Financial Officer of Corriente Advisors, LLC, the General Partner of the stockholder, has voting and investment power over the shares it is offering for resale.

⁵ The selling stockholder identified itself to us as an affiliate of a broker-dealer. It has indicated to us that it purchased the shares through the ordinary course of business, and at the time of the purchase of the shares to be resold, had no agreements or understandings, directly or indirectly, with any person to distribute the

shares.

- 6 The selling stockholder indicated to us that Dwight Lee has voting and investment power over the shares it is offering for resale.
- 7 The selling stockholder indicated to us that Neil Gagnon has voting and investment power over the shares it is offering for resale.
- 8 The selling stockholder indicated to us that John P. Francis, the Managing Member of Francis Capital Management, LLC, the Managing Member of the stockholder, has voting and investment power over the shares it is offering for resale.
- 9 The selling stockholder indicated to us that Jerald M. Weintraub, President of Weintraub Capital Management, L.P. has voting and investment power over the shares it is offering for resale.
- 10 Nantahala Capital Management, LLC is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of such securities on behalf of the selling stockholder as a General Partner or Investment Manager and would be considered the beneficial owner of such securities. The above shall not be deemed to be an admission by the record owners or the selling stockholder that they are themselves beneficial owners of these securities for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any other purpose. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the selling stockholder.
- 11 The selling stockholder indicated to us that Robert Clifford has voting and investment power over the shares it is offering for resale.
- 12 The selling stockholder indicated to us that Daniel P. Landry has voting and investment power over the shares it is offering for resale.
- 13 The selling stockholder indicated to us that Christopher D. Jennings has voting and investment power over the shares it is offering for resale.
- 14 The selling stockholder indicated to us that Kevin Blair has voting and investment power over the shares it is offering for resale.
- 15 The selling stockholder indicated to us that Ankur Desai has voting and investment power over the shares it is offering for resale.

ESTIMATED USE OF PROCEEDS

We will not receive any proceeds upon the sale of the shares by the selling stockholders in this offering.

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 the date of this prospectus, we had 22,286,224 shares of common stock outstanding and held by 36 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.

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 3,284,480 shares of our common stock under the 2018 Plan. The purpose of the 2018 Plan is to provide eligible participants with an opportunity to acquire an ownership interest in our company. 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 to purchase an aggregate of 2,792,623 shares of our common stock at an average exercise price of \$4.94 per share.

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 bylaws. 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 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.

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 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 is Philadelphia Stock Transfer, Inc., located at 2320 Haverford Road, Suite 230, Ardmore, Pennsylvania 19003; telephone (484) 416-3124.

PLAN OF DISTRIBUTION

The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

short sales effected after the date the registration statement of which this prospectus is a part is declared effective by the SEC;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale; and

any other method permitted by applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, as amended, or the Securities Act, amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares

offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, provided that they meet the criteria and conform to the requirements of that rule.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be “underwriters” within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling stockholders who are “underwriters” within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934, as amended, may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, to the extent applicable, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed with the selling stockholders to use commercially reasonable efforts to cause the registration statement of which this prospectus constitutes a part effective and to remain continuously effective until the earlier of (1) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with such registration statement or (2) the date on which all of the shares may be sold without restriction pursuant to Rule 144 of the Securities Act.

LEGAL MATTERS

Greenberg Traurig, LLP, Irvine, California, will pass upon the validity of the shares of common stock offered by this prospectus.

EXPERTS

The consolidated financial statements as of and for the fiscal years ended December 31, 2019 and 2018, incorporated by reference into this prospectus supplement from the Company's Annual Report on Form 10-K for the year ended December 31, 2019 have been so incorporated in reliance on the report of Marcum, LLP, an independent registered public accounting firm, as stated in their report which is incorporated by reference herein, and has been so incorporated in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

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. In addition, we file annual, quarterly and current reports and proxy statements and other information with the SEC. 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. Copies of certain information filed by us with the SEC are also available on our website at <https://ir.tffpharma.com/financial-information/sec-filings>. We have not incorporated by reference into this prospectus the information on our website and it is not a part of this document.

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.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to another document that we have filed separately with the SEC. You should read the information incorporated by reference because it is an important part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus, while information that we file later with the SEC will automatically update and supersede the information in this prospectus. We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC (Commission File No. 001-39102):

Our Annual Report on [Form 10-K](#) for the fiscal year ended December 31, 2019 filed with the SEC on March 27, 2020;

Our Annual Report on [Form 10-K/A](#) for the fiscal year ended December 31, 2019 filed with the SEC on April 29, 2020;

Our Quarterly Report on [Form 10-Q](#) for the quarter ended March 31, 2020 filed with the SEC on May 14,

2020;

Our Quarterly Report on [Form 10-Q](#) for the quarter ended June 30, 2020 filed with the SEC on August 13, 2020;

Our Current Reports on Form 8-K filed with the SEC on [January 31, 2020](#) and [August 11, 2020](#);

Our definitive Proxy Statement on [Schedule 14A](#) filed with the SEC on August 28, 2020; and

The description of our common stock set forth in our registration statement on [Form 8-A12B](#) filed with the SEC on October 22, 2019.

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act made after the effective date of this registration statement of which this prospectus is a part and until we terminate this offering. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

We will furnish without charge to each person, including any beneficial owner, to whom a prospectus is delivered, upon written or oral request, a copy of any or all of the reports or documents incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits that are specifically incorporated by reference into such documents. You can access the reports and documents incorporated by reference into this prospectus at <https://ir.tffpharma.com/financial-information/sec-filings>. You may also direct any requests for reports or documents to:

TFF Pharmaceuticals, Inc.
2600 Via Fortuna, Suite 360
Austin, Texas 78746
Attention: Corporate Secretary
Telephone: (737) 802-1973
Email: investorinfo@tffpharma.com

You should rely only on information contained in, or incorporated by reference into, this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus or incorporated by reference into this prospectus. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

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 and we have entered into indemnification agreements with each of our directors and executive officers.

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.

3,048,654 Shares of Common Stock

TFF Pharmaceuticals, Inc.

PROSPECTUS

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	5,144.30
Printing Expenses	1,000.00
Accounting Fees and Expenses	5,000.00
Legal Fees and Expenses	20,000.00
Transfer Agent and Registrar Expenses	1,000.00
Miscellaneous	1,000.00
Total	<u>\$ 33,144.30</u>

* 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.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

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.

On 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 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 August 2020, we issued an aggregate of 3,048,654 shares of our common stock to 23 accredited investors, at a price of \$8.50 per share for the approximate gross proceeds of \$25.91 million.

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

Number	Exhibit Description	Method of Filing
1.1	<u>Form of Underwriting Agreement</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on September 27, 2019.
3.1	<u>Second Amended and Restated Certificate of Incorporation of the Registrant</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
3.2	<u>Amended and Restated Bylaws of the Registrant</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
4.1	<u>Specimen Certificate representing shares of common stock of Registrant</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on September 27, 2019.
4.2	<u>Warrant dated January 24, 2018 issued to Liquid Patent Consulting, LLC</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
4.3	<u>Warrant dated March 13, 2018 issued to National Securities Corporation</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
4.4	<u>Warrant dated March 22, 2018 issued to National Securities Corporation</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
4.5	<u>Warrant dated May 16, 2019 issued to National Securities Corporation</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
4.6	<u>Warrant dated May 23, 2019 issued to National Securities Corporation</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
4.7	<u>Warrant dated October 29, 2019 issued to National Securities Corporation</u>	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 27, 2020.
4.8	<u>Warrant dated November 20, 2019 issued to National Securities Corporation</u>	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 27, 2020.
5.1	<u>Opinion of Greenberg Traurig, LLP</u>	Filed electronically herewith.

Number	Exhibit Description	Method of Filing
10.1	<u>Patent License Agreement dated July 8, 2015 between Lung Therapeutics, Inc. and The University of Texas at Austin</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.2*	<u>TFF Pharmaceuticals, Inc. 2018 Stock Incentive Plan</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.3*	<u>Amended and Restated Consulting Agreement dated December 20, 2018 between Robert Mills and the Registrant</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.4*	<u>Consulting Agreement effective as of January 24, 2018 between Dr. Brian Windsor and the Registrant, as amended on December 20, 2018 and September 26, 2019</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on September 27, 2019
10.5*	<u>Consulting Agreement dated April 23, 2018 between Glenn Mattes and the Registrant</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.6	<u>Lease Agreement dated October 19, 2018</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.7*	<u>Executive Employment Agreement dated December 20, 2018 between Glenn Mattes and the Registrant</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.8	<u>Securities Purchase Agreement dated May 16, 2019 by and among the Registrant and the Buyers named therein</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.9	<u>Amended and Restated Registration Rights Agreement dated May 16, 2019 by and among the Registrant and certain of its stockholders</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.10	<u>Amendment No. 1 to Patent License Agreement dated November 30, 2018 between the Registrant and The University of Texas at Austin</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.11*	<u>Employment Agreement dated February 15, 2019, by and between the Registrant and Kirk Coleman</u>	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
10.12*	<u>Form of Securities Purchase Agreement dated August 10, 2020 between the Company and investors named therein</u>	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on August 11, 2020.
10.13	<u>Form of Registration Rights Agreement dated August 10, 2020 between the Company and investors named in the Securities Purchase</u>	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on August 11, 2020.

Agreement

10.14*	<u>Amendment No. 1 Dated May 14, 2020 to Executive Employment Agreement Between Glenn Mattes and Registrant</u>	Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q filed on August 13, 2020.
--------	---	---

Number	Exhibit Description	Method of Filing
21.1	<u>List of Subsidiaries</u>	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 27, 2020.
23.1	<u>Consent of Marcum, LLP</u>	Filed electronically herewith.
23.2	<u>Consent of Greenberg Traurig, LLP</u>	Filed as part of Exhibit 5.1 above.
24.1	<u>Power of Attorney</u>	Included on signature page hereto.
31.1	<u>Certification under Section 302 of the Sarbanes-Oxley Act of 2002.</u>	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 27, 2020.
31.2	<u>Certification under Section 302 of the Sarbanes-Oxley Act of 2002.</u>	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 27, 2020.
32.1	<u>Certifications Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350.</u>	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 27, 2020.

* Indicates management compensatory plan, contract or arrangement.

ITEM 17. UNDERTAKINGS

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "*Calculation of Registration Fee*" table in the effective registration statement; and
- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (i), (ii) and (iii) do not apply if the registration statement is on Form S-1 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment 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.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act of 1934 that is incorporated by reference in the registration statement 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.

(6) Insofar as indemnification for liabilities arising under the Securities Act 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.

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 9th day of September 2020.

TFF PHARMACEUTICALS, INC.

/s/ Glenn Mattes

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
<u>/s/ Aaron Fletcher, Ph.D.</u> Aaron Fletcher, Ph.D.	Chairman of the Board	September 9, 2020
<u>/s/ Glenn Mattes</u> Glenn Mattes	President, Chief Executive Officer and Director (Principal Executive Officer)	September 9, 2020
<u>/s/ Kirk Coleman</u> Kirk Coleman	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	September 9, 2020
<u>/s/ Brian Windsor, Ph.D.</u> Brian Windsor, Ph.D.	Director	September 9, 2020
<u>/s/ Robert S. Mills, Jr.</u> Robert S. Mills, Jr.	Director	September 9, 2020
<u>/s/ Stephen Rocamboli</u> Stephen Rocamboli	Director	September 9, 2020
<u>/s/ Harlan Weisman, M.D.</u> Harlan Weisman, M.D.	Director	September 9, 2020

/s/ Randy Thurman
Randy Thurman

Director

September 9, 2020

/s/ Malcolm Fairbairn
Malcolm Fairbairn

Director

September 9, 2020