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

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Quarterly Period Ended September 30, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to .

Commission file number: 001-39102

TFF PHARMACEUTICALS, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**82-4344737**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification no.)

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

(737) 802-1973
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock: Par value $.001	TFFP	Nasdaq Capital Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company (as defined in Rule 12b-2 of the Act):

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

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

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

As of December 9, 2019, there were 18,450,992 outstanding shares of the common stock of TFF Pharmaceuticals, Inc.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

TFF PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS

	As of September 30, 2019 (Unaudited)	As of December 31, 2018
Assets		
Current Assets		
Cash and cash equivalents	$ 10,550,569	$ 10,261,671
Prepaid assets and other current assets	20,297	12,065
Total Current Assets	10,570,866	10,273,736
Deferred offering costs	461,893	127,768
Total Assets	$ 11,032,759	$ 10,401,504
Liabilities and Stockholders' Deficit		
Current Liabilities		
Accounts payable	$ 691,105	$ 428,645
Accrued dividends payable	1,497,226	728,350
Total Liabilities	2,188,331	1,156,995
Commitments and Contingencies (see Note 4)		
Series A Preferred Stock		
Series A Preferred Stock, $0.001 par value, 10,000,000 shares authorized; 8,930,000 shares issued and outstanding as of September 30, 2019 and 5,662,000 shares issued and outstanding as of December 31, 2018, respectively (Liquidation Preference of $23,822,226)	19,684,197	12,485,971
Stockholders' Deficit:		
Common stock, $0.001 par value, 45,000,000 shares authorized; 4,000,000 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	4,000	4,000
Additional paid-in capital	206,455	596,724
Accumulated deficit	(11,050,224)	(3,842,186)
Total Stockholders' Deficit	(10,839,769)	(3,241,462)
Total Liabilities, Series A Preferred Stock and Stockholders' Deficit	$ 11,032,759	$ 10,401,504

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

TFF PHARMACEUTICALS, INC.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS

	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	January 24, 2018 to September 30, 2018	January 1, 2018 to January 23, 2018 (Predecessor)
Operating expenses					
Research and development	$ 2,563,528	$ 140,167	$ 5,554,046	$ 759,355	$ *
General and administrative	300,640	465,919	1,721,691	2,243,788	*
Total operating expenses	2,864,168	606,086	7,275,737	3,003,143	*
					*
Loss from operations	(2,864,168)	(606,086)	(7,275,737)	(3,003,143)	*
					*
Other income					*
Interest income	25,865	20,871	67,699	33,268	*
Total other income	25,865	20,871	67,699	33,268	*
					*
Net loss	(2,838,303)	(585,215)	(7,208,038)	(2,969,875)	*
					*
Preferred stock dividend	(258,635)	(219,498)	(768,876)	(505,516)	*
					*
Net loss applicable to common stock	$ (3,096,938)	$ (804,713)	$ (7,976,914)	$ (3,475,391)	$ *
Net loss applicable to common stock per share, basic and diluted	$ (0.70)	$ (0.18)	$ (1.81)	$ (0.79)	
Weighted average common shares outstanding, basic and diluted	4,400,000	4,400,000	4,400,000	4,400,000	

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

TFF PHARMACEUTICALS, INC.
UNAUDITED CONDENSED STATEMENTS OF STOCKHOLDERS' DEFICIT

	Common Stock		Additional Paid	Parent's Net	Accumulated	Total Stockholders'
	Shares	Amount	in Capital	Deficit	Deficit	Deficit
Balance, January 1, 2019	4,000,000	$ 4,000	$ 596,724	$ —	$ (3,842,186)	$ (3,241,462)
Stock-based compensation	—	—	121,226	—	—	121,226
Dividends on preferred stock	—	—	(221,279)	—	—	(221,279)
Net loss	—	—	—	—	(2,182,815)	(2,182,815)
Balance, March 31, 2019	4,000,000	4,000	496,671	—	(6,025,001)	(5,524,330)
Stock-based compensation	—	—	486,397	—	—	486,397
Dividends on preferred stock	—	—	(288,962)	—	—	(288,962)
Net loss	—	—	—	—	(2,186,920)	(2,186,920)
Balance, June 30, 2019	4,000,000	4,000	694,106	—	(8,211,921)	(7,513,815)
Stock-based compensation	—	—	(229,016)	—	—	(229,016)
Dividends on preferred stock	—	—	(258,635)	—	—	(258,635)
Net loss	—	—	—	—	(2,838,303)	(2,838,303)
Balance, September 30, 2019	4,000,000	$ 4,000	$ 206,455	$ —	$ (11,050,224)	$ (10,839,769)

	Common Stock		Additional Paid	Parent's Net	Accumulated	Total Stockholders'
	Shares	Amount	in Capital	Deficit	Deficit	Deficit
Balance, January 1, 2018 (predecessor)	—	$ —	$ —	$ (1,833)	$ —	$ (1,833)
Transfers from parent (predecessor)	—	—	—	1,833	—	1,833
Balance, January 24, 2018	—	—	—	—	—	—
Common stock issued to former parent	4,000,000	4,000	(4,000)	—	—	—
Net loss	—	—	—	—	(267,501)	(267,501)
Balance, March 31, 2018	4,000,000	4,000	(4,000)	—	(267,501)	(267,501)
Stock-based compensation	—	—	1,173,840		—	1,173,840
Dividends on preferred stock	—	—	(286,017)	—	—	(286,017)
Net Loss	—	—	—	—	(2,117,160)	(2,117,160)
Balance, June 30, 2018	4,000,000	4,000	883,823	—	(2,384,661)	(1,496,838)
Stock-based compensation	—	—	62,106		—	62,106
Dividends on preferred stock	—	—	(219,498)	—	—	(219,498)
Net Loss	—	—	—	—	(585,215)	(585,215)
Balance, September 30, 2018	4,000,000	$ 4,000	$ 726,431	$ —	$ (2,969,876)	$ (2,239,445)

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

TFF PHARMACEUTICALS, INC.
UNAUDITED CONDENSED STATEMENTS OF CASH FLOWS

	For the Nine Months Ended September 30, 2019	January 24, 2018 to September 30, 2018	January 1, 2018 to January 23, 2018 (Predecessor)
Cash Flows from Operating Activities			
Net loss	$ (7,208,038)	$ (2,969,875)	—
Adjustment to reconcile net loss to net cash used in operating activities:			
Stock based compensation	378,607	1,235,946	—
Changes in operating assets and liabilities:			
Prepaid assets	(261,204)	(36,305)	—
Accounts payable	181,307	426,845	(1,833)
Net Cash Used In Operating Activities	(6,909,328)	(1,343,389)	(1,833)
Cash Flows From Investing Activities			
Net Cash Used in Investing Activities	—	—	—
Cash Flows From Financing Activities			
Net Transfers from parent	—	(6,542)	(1,833)
Proceeds from issuance of preferred stock	7,198,226	12,485,971	—
Net Cash Provided by Financing Activities	7,198,226	12,479,429	(1,833)
Net Increase in Cash and Cash Equivalents	288,898	11,136,040	—
Cash and Cash Equivalents – beginning of period	10,261,671	—	—
Cash and Cash Equivalents – end of period	$ 10,550,569	$ 11,136,040	—
Supplemental disclosure of non-cash investing and financing activities:			
Common stock issued to former parent for acquired assets	$ —	$ 4,000	—
Accrued offering costs	$ 81,153	$ 60,890	—
Accrued dividend	$ 768,876	$ 505,516	—

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

TFF PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS

Note 1 — Background and Basis of Presentation

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

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

In October 2019, the Company completed an initial public offering ("IPO"), selling 4,400,000 shares of common stock at an offering price of $5.00 per share. The Company received net proceeds of approximately $20,150,000, after deducting underwriting discounts and commissions and offering-related expenses (see Note 10). In addition, the Company granted the underwriter a 45-day option to purchase an additional 660,000 shares of common stock at the initial public offering price, less underwriting discounts and commissions. The option was exercised and the underwriter purchased an additional 479,300 shares of common stock and the Company received additional net proceeds of approximately $2,200,000.

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

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

Note 2 — Liquidity and Management's Plans

As of September 30, 2019, the Company had cash and cash equivalents of approximately $10,551,000 and a working capital surplus of approximately $8,383,000. The Company has not generated revenues since inception and has incurred recurring operating losses. The Company expects to continue incurring losses for the foreseeable future and may need to raise additional capital to pursue its product development.

The Company expects to further increase its research and development activities, which will increase the amount of cash utilized subsequent to September 30, 2019. Specifically, the Company expects increased spending on research and development activities and higher payroll expenses as it increases its professional and scientific staff and continues to prepare for anticipated manufacturing activities. The Company currently believes its existing cash and cash equivalents, together with the net cash proceeds received from the closing of its IPO in October 2019 and the exercise of the underwriter's option to purchase additional shares in November 2019 aggregating approximately $22,350,000 (see Note 10), will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of these financial statements.

Note 3 — Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial statements and with Form 10-Q and Article 8 of Regulation S-X of the United States Securities and Exchange Commission. Accordingly, they do not contain all information and footnotes required by GAAP for annual financial statements. In the opinion of the Company's management, the accompanying unaudited condensed financial statements contain all the adjustments necessary (consisting only of normal recurring accruals) to present the financial position of the Company as of September 30, 2019 and the results of operations, changes in stockholders' equity (deficit) and cash flows for the periods presented. The results of operations for the three and nine months ended September 30, 2019 are not necessarily indicative of the operating results for the full fiscal year or any future period. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and related disclosures of the Company as of December 31, 2018 and 2017 and for the years then ended.

Financial Statements

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

Deferred Offering Costs

The Company complies with the requirements of Accounting Standards Codification ("ASC") 340, *Other Assets and Deferred Costs*. Deferred offering costs of $461,893 and $127,768 as of September 30, 2019 and December 31, 2018, respectively, consist primarily of legal, accounting and filing fees incurred through the balance sheet date that are related to the Company's IPO and will be charged to capital upon completion of the IPO in October 2019.

Cash and Cash Equivalents

The Company maintains its operating accounts in a single financial institution. The balances are insured by the U.S. Federal Deposit Insurance Corporation ("FDIC") up to specified limits. The Company's cash is maintained in checking accounts and money market funds with maturities of less than three months when purchased, which are readily convertible to known amounts of cash, and which in the opinion of management are subject to insignificant risk of loss in value.

Fair Value of Financial Instruments

Authoritative guidance requires disclosure of the fair value of financial instruments. The Company's financial instruments consist of cash and cash equivalents and accounts payable, the carrying amounts of which approximate their estimated fair values primarily due to the short-term nature of the instruments or based on information obtained from market sources and management estimates. The Company measures the fair value of certain of its financial assets and liabilities on a recurring basis. A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value which is not equivalent to cost will be classified and disclosed in one of the following three categories:

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

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

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

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

Basic and Diluted Earnings per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and dilutive share equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. Since the Company has had net losses for all periods presented, all potentially dilutive securities are anti-dilutive. Accordingly, basic and diluted net loss per share are equal. Basic weighted average shares outstanding include the shares underlying a warrant to purchase 400,000 shares of common stock. As the shares underlying this warrant can be issued for little consideration (an aggregate exercise price of $0.01 per share), these shares are deemed to be issued for purposes of basic earnings per share.

For the nine months ended September 30, 2019 and the period January 24, 2018 to September 30, 2018, the Company had the following potential common stock equivalents outstanding which were not included in the calculation of diluted net loss per common share because inclusion thereof would be anti-dilutive:

	Period from January 1, 2019 to September 30, 2019	Period from January 24, 2018 to September 30, 2018
Stock Options	1,341,094	1,073,469
Series A Convertible Preferred Stock*	9,568,700	5,864,206
Warrants	658,212	658,212
	11,568,006	7,595,887

* *On an as-converted basis*

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

Use of Estimates

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

Recent Accounting Standards

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

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

Note 4 — Commitments and Contingencies

Operating leases

In October 2018, the Company entered into a lease agreement for office space in Doylestown, Pennsylvania. The lease commenced on October 15, 2018 and the Company exercised a one-year lease renewal in October 2019 that will expire on October 31, 2020. The lease has an additional one-year option for renewal, and the base rent is $36,000 per year.

Approximate future minimum lease payments required under the operating lease as of September 30, 2019, including the renewal exercised in October 2019, are as follows:

Years ending December 31,	**Amount**
2019 – Remaining	$ 9,500
2020	30,000
Total through October 31, 2020	$ 39,500

Note 4 — Commitments and Contingencies (cont.)

Legal

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

Note 5 — License and Agreements

In July 2015, the University of Texas at Austin ("UT") granted to TFF's former parent, LTI, an exclusive worldwide, royalty bearing license to the patent rights for the TFF platform in all fields of use, other than vaccines for which LTI received a non-exclusive worldwide, royalty bearing license to the patent rights for the TFF platform. In March 2018, LTI assigned to TFF all of its interest to the TFF platform, including the patent license agreement with UT, at which time the Company paid UT an assignment fee of $100,000 in accordance with the patent license agreement. In November 2018, TFF and UT amended the patent license agreement to expand TFF's exclusive patent rights to the TFF platform to all fields of use. The patent license agreement requires TFF to pay royalties and milestone payments and conform to a variety of covenants and agreements, and in the event of the Company's breach of agreement, UT may elect to terminate the agreement. For the nine months ended September 30, 2019, the Company did not achieve any of the milestones and, as such, was not required to make any milestone payments. As of the date of these financial statements, the Company is in compliance with the patent license agreement.

In June 2018, the Company entered into a one-year agreement with Patheon Development Services, Inc. to provide initial contract manufacturing services for the Company's drug product candidates. The fees payable for contract manufacturing services under this agreement total $270,000, with no minimum fee requirement. During the three and nine months ended September 30, 2019, the Company recorded costs associated with this agreement of $3,000 and $81,000, respectively. During the three and nine months ended September 2018, the Company recorded costs associated with this agreement of $52,450 as research and development costs. There is no additional work ongoing at this time.

In May 2018, the Company entered into a master services agreement and associated individual study contracts with ITR Canada, Inc. ("ITR") to provide initial contract pre-clinical research and development services for the Company's drug product candidates. The fees payable for pre-clinical research and development services under these study contracts totalled $1,790,000, with no minimum fee requirement. In January 2019, the Company cancelled all of the individual study contracts with ITR and entered into a contract with Canada Inc. (dba VJO Non-Clinical Development ("VJO")) to complete additional pre-clinical research and development services in order to take advantage of eligible Canadian Tax Credits. The services related to the contract with VJO were sub-contracted to ITR under substantially the same terms as the initial contract with ITR, with fees payable for the services under this contract totalling $4,104,000, as amended. During the three and nine months ended September 30, 2019, the Company recorded research and development costs of $843,280 and $2,596,535, respectively. During the three and nine months ended September 30, 2018, the Company recorded research and development costs of $7,525 and $495,409, respectively.

In April 2019, the Company entered into a master services agreement with Irisys, LLC to provide contract manufacturing services for one of the Company's drug product candidates, Voriconazole. The fees payable for contract manufacturing services under this agreement total $420,000, with additional pass-through costs. During the three and nine months ended September 30, 2019, the Company recorded costs associated with this agreement of $288,000 and $346,000, respectively, as research and development costs.

In June 2019, the Company entered into a master services agreement with CoreRx to provide contract manufacturing services for one of the Company's drug product candidates, Tacrolimus. The fees payable for contract manufacturing services under this agreement total $812,232, with additional pass-through costs. During the three and nine months ended September 30, 2019, the Company recorded costs associated with this agreement of $177,000 and $295,000, respectively, as research and development costs.

Note 5 — License and Agreements (cont.)

In August 2019, the Company entered into a master services agreement and associated individual study contracts with Conform Clinical Development, Inc. and its affiliate, Les Entreprises Envie Inc. (dba Envie Ventures), which sub-contracted with Inflamax Research Limited (dba Cliantha Research ("Cliantha")) to perform a Phase 1 study of one of the Company's drug candidates, Voriconazole. The fees payable for the services under this contract total approximately $1,258,000, as amended. During the three and nine months ended September 30, 2019, the Company recorded costs associated with this contract of $281,000, as research and development costs.

Note 6 — Stockholders' Deficit

Series A Convertible Preferred Stock

The Company is authorized to issue up to 10,000,000 shares of preferred stock, $0.001 par value, all of which has been designated as Series A Convertible Preferred Stock ("Series A Preferred Stock") and has a stated value of $2.50 per share. As of September 30, 2019, 8,930,000 shares are issued and outstanding. The Series A Preferred Stock ranks senior to common stock with respect to dividends rights and liquidation preferences and has full voting rights. The Series A Preferred Stock accrues a dividend at a rate of 6% per annum, and such amount aggregated $1,497,226 and $728,350 as of September 30, 2019 and December 31, 2018, respectively. The Company recorded $258,635 and $768,875 of preferred dividends for the three and nine months ended September 30, 2019, respectively, and $219,498 and $505,516 for the three months ended September 30, 2018 and for the period from January 24, 2018 through September 30, 2018, respectively.

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

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

In addition to these methods of conversion, the agreement contained a feature that would have required the Company to repurchase all of the outstanding shares of the Series A Preferred Stock on July 1, 2020 at a redemption price of the product of two multiplied by the aggregate stated value of all of the Series A Preferred Stock then held by each holder, plus all accrued but unpaid dividends through the date of payment, if it was still outstanding as of that date.

Note 7 — Warrants

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

Note 7 — Warrants (cont.)

On March 13, 2018 and March 22, 2018, the Company issued to National Securities Corporation warrants to purchase shares of the Company's common stock in an amount equal to 10% of the shares of common stock issuable upon conversion of 5,662,000 shares of the Company's Series A Preferred Stock at an exercise price equal to the conversion price of the Series A Preferred Stock. Upon the conversion of the Series A Preferred Stock in October 2019 (see, Note 6), the warrant adjusted to provide for the purchase of 619,879 shares of common stock at an exercise price of $2.50 per share. The warrants represented placement agent compensation in connection with the 2018 Private Placement. The fair value of the warrants on the grant date was estimated using the Black-Scholes-Merton option pricing model with a common stock value of $1.67 per share, a contractual life of 2.5 years, a dividend yield of 0%, a volatility of 102.4% and an assumed risk-free interest rate of 2.36%. The fair value of the warrants was determined to be $480,485 and is included in general and administrative expenses in the statement of operations.

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

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

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

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

A summary of warrant activity for the nine months ended September 30, 2019 is as follows:

	Number of Shares	Range of Exercise Prices	Weighted-Average Exercise Prices	Weighted-Average Remaining Life
Outstanding at December 31, 2018	1,058,212	$ 0.01 – $2.50	$ 1.56	4.6
Issued	326,800	2.50	2.50	5.0
Forfeited	(326,800)	2.50	2.50	5.0
Outstanding at September 30, 2019	1,058,212	$ 0.01 – $2.50	$ 1.56	3.9

The warrants outstanding at September 30, 2019 had an aggregate intrinsic value of approximately $664,000.

Note 8 — Stock Based Compensation

In January 2018, the Company's board of directors approved its 2018 Stock Incentive Plan ("2018 Plan"). The 2018 Plan provides for the grant of non-qualified stock options and incentive stock options to purchase shares of the Company's common stock, the grant of restricted and unrestricted share awards and grant of restricted stock units. The 2018 Plan provides for the issuance of 1,630,000 shares of common stock. All of the Company's employees and any subsidiary employees (including officers and directors who are also employees), as well as all of the Company's nonemployee directors and other consultants, advisors and other persons who provide services to the Company will be eligible to receive incentive awards under the 2018 Plan.

The following table summarizes the stock-based compensation expense recorded in the Company's results of operations during the periods ended September 30, 2019 and 2018 for stock options and warrants:

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019	Three Months Ended September 30, 2018	Period From January 24, 2018 to September 30, 2018
Research and development	$ —	$ —	$ —	$ —
General and administrative	(229,016)	378,607	62,106	1,235,946
	$ (229,016)	$ 378,607	$ 62,106	$ 1,235,946

As of September 30, 2019, there was approximately $1,167,042 of total unrecognized compensation expense related to non-vested share-based compensation arrangements that are expected to vest. This cost is expected to be recognized over a weighted-average period of 2.9 years.

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

The Company estimated the fair value of employee and non-employee stock options using the Black-Scholes option pricing model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service periods of the respective awards. The fair value of employee stock options issued was estimated using the following weighted-average assumptions:

	Nine months Ended September 30, 2019
Weighted average exercise price	$ 2.55
Weighted average grant date fair value	$ 1.16
Assumptions	
Expected volatility	88-89%
Expected term (in years)	6.3
Risk-free interest rate	1.72-2.31%
Expected dividend yield	0.00%

Note 8 — Stock Based Compensation (cont.)

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

The fair value of the common stock was determined by the board of directors based on a variety of factors, including valuations prepared by third parties, the Company's financial position, the status of development efforts within the Company, the current climate in the marketplace and the prospects of a liquidity event, among others.

The following table summarizes stock option activity during the nine months ended September 30, 2019:

	Number of Shares	Weighted-Average Exercise Prices	Weighted-Average Remaining Contractual Term (In Years)	Intrinsic Value
Outstanding at December 31, 2018	1,073,082	$ 2.50	9.64	—
Granted	268,012	2.55	—	—
Outstanding at September 30, 2019	1,341,094	$ 2.51	9.01	$ —
Exercisable at September 30, 2019	370,906	$ 2.50	8.88	$ —

Note 9 — Related Party Transactions

On March 22, 2018, the Company raised financing through a private placement of Series A Preferred Stock (as further discussed in Note 6). Certain of the Company's officers and directors participated in the private placement in the aggregate amount of $125,000, representing 0.88% of the Series A Preferred Stock sold by the Company.

Note 10 — Subsequent Events

The Company has performed an evaluation of events occurring subsequent to September 30, 2019 through the filing date of this Quarterly Report. Based on its evaluation, nothing other than the events described below need to be disclosed.

In October 2019, the Company completed its IPO, selling 4,400,000 shares of common stock at an offering price of $5.00 per share. The Company received net proceeds of approximately $20,150,000, after deducting underwriting discounts and commissions and offering-related expenses. In addition, the Company granted the underwriter a 45-day option to purchase an additional 660,000 shares of common stock at the initial public offering price, less underwriting discounts and commissions. The option was exercised and the underwriter purchased an additional 479,300 shares of common stock and the Company received additional net proceeds of approximately $2,200,000.

In conjunction with the IPO, the Company's outstanding shares of Series A Preferred Stock automatically converted into 9,571,692 shares of its common stock. Warrants for 317,155 shares of the Company's common stock were issued to the IPO underwriter at an exercise price of $6.25 per share as part of the underwriter's compensation for the IPO.

In conjunction with the issuance of shares in the IPO, the Company granted options to officers and directors to purchase 627,984 shares of common stock at an exercise price of $5.00. In addition, the Company granted warrants to an entity affiliated with a director to purchase 47,417 shares of common stock at an exercise price of $5.00.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Cautionary Statement

The following discussion and analysis should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto contained elsewhere in this report. The information contained in this quarterly report on Form 10-Q is not a complete description of our business or the risks associated with an investment in our common stock. We urge you to carefully review and consider the various disclosures made by us in this report and in our other filings with the Securities and Exchange Commission, or SEC, including our Prospectus dated October 24, 2019 filed with the SEC on October 25, 2019.

In this report we make, and from time to time we otherwise make written and oral statements regarding our business and prospects, such as projections of future performance, statements of management's plans and objectives, forecasts of market trends, and other matters that are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements containing the words or phrases "will likely result," "are expected to," "will continue," "is anticipated," "estimates," "projects," "believes," "expects," "anticipates," "intends," "target," "goal," "plans," "objective," "should" or similar expressions identify forward-looking statements, which may appear in our documents, reports, filings with the SEC, and news releases, and in written or oral presentations made by officers or other representatives to analysts, stockholders, investors, news organizations and others, and in discussions with management and other of our representatives.

Our future results, including results related to forward-looking statements, involve a number of risks and uncertainties, including those risks included below in Part II, Item 1 "Risk Factors". No assurance can be given that the results reflected in any forward-looking statements will be achieved. Any forward-looking statement speaks only as of the date on which such statement is made. Our forward-looking statements are based upon assumptions that are sometimes based upon estimates, data, communications and other information from suppliers, government agencies and other sources that may be subject to revision. Except as required by law, we do not undertake any obligation to update or keep current either (i) any forward-looking statement to reflect events or circumstances arising after the date of such statement or (ii) the important factors that could cause our future results to differ materially from historical results or trends, results anticipated or planned by us, or which are reflected from time to time in any forward-looking statement.

General

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, however, as of the date of this report, we have not progressed the development of any other of our drug candidates to human clinical trials and our efforts have focused on the formulation, early stage animal testing and formal toxicology studies of our initial drug candidates in preparation for our first clinical trials.

We intend to initially focus on the development of inhaled dry powder drugs for the treatment of pulmonary diseases and conditions. While 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. We believe, and early testing 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 report, the Clinical Practice Guidelines released by the Infectious Diseases Society of America recommend Voriconazole as first-line monotherapy for IPA. However, since the registration of Vfend in Europe and the U.S. in 2002, several studies have examined the exposure-response relationship with Voriconazole, identifying a relationship between low Voriconazole exposure and higher rates of treatment failure, as well as a higher propensity for neurotoxicity at higher exposures. 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 plan on submitting an IND for TFF Tac-Lac in the first quarter of 2020.

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 report, 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.

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

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

On October 29, 2019, we closed our initial public offering of 4,400,000 share of common stock at a public offering price of $5.00 per share. After the payment of underwriter discounts and offering expenses, and after giving effect to the underwriters' exercise of its overallotment option on November 20, 2019 to purchase an additional 479,300 shares of our common stock at the offering price of $5.00 per share, we received net proceeds of approximately $22.4 million.

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 report, and you should not consider any information contained in, or that can be accessed through, our website as part of this report or in deciding whether to purchase our common stock.

Results of Operations

We were formed in January 2018 and have not commenced revenue-producing operations. To date, our operations have consisted of the development and early-stage testing of our initial product candidates. In connection with our organization on January 24, 2018, we entered into a Contribution and Subscription Agreement with Lung Therapeutics, Inc., or LTI, our former parent, pursuant to which we agreed to acquire from LTI certain of LTI's non-core intellectual property rights and other assets, or the Acquired Assets, all of which relate to our Thin Film Freezing technology. We closed on the acquisition of the Acquired Assets concurrent with the close of the initial Series A preferred stock financing in March 2018. The operations surrounding the Acquired Assets are deemed to be our accounting predecessor and the results of operations in the financial summary below for the period January 1, 2018 through January 23, 2018 reflect the results of operations of the Acquired Assets, which were immaterial, as our predecessor.

During the three months ended September 30, 2019 and 2018, we incurred $2,563,528 and $140,167 of research and development expenses and $300,640 and $465,919 of general and administrative expenses, respectively. The increase in research and development expenses during 2019 was due to the ramp-up of research and development activities following the completion of our funding in May 2019. The decrease in general and administrative expenses in third fiscal quarter of 2019 from the prior year period was due to a higher level of activity in stock-based compensation in 2018 compared to 2019. We incurred a net loss applicable to common stockholders of $3,096,939 and $804,713 for three months ended September 30, 2019 and 2018, respectively.

For the nine months ended September 30, 2019 and 2018, we incurred $5,554,046 and $759,355 of research and development expenses, respectively. The increase in research and development expenses in 2019 was due to the ramp-up of research and development activities. For the nine months ended September 30, 2019 and 2018, we incurred $1,721,691 and $2,243,788 of general and administrative expenses, respectively. The decrease in general and administrative expenses in 2019 was due to a higher level of activity in stock-based compensation in 2018 compared to 2019. We incurred a net loss applicable to common stockholders of $7,976,914 and $3,475,391 for the nine months ended September 30, 2019 and 2018, respectively. The increase in net loss in 2019 was due to the increase in research and development offset by a decrease in general corporate activities. We expect our research and development expenses as well as our general and administrative expenses to continue to increase in accordance with our business plan.

Financial Condition

As of September 30, 2019, we had total assets of approximately $11 million and working capital of approximately $8.4 million. As of September 30, 2019, our liquidity included approximately $10.6 million of cash and cash equivalents. The foregoing does not give effect to our receipt of approximately $22.4 million of net proceeds from our initial public offering completed in October 2019. We believe that our cash on-hand as of the date of this report, which includes the proceeds of our IPO, is sufficient to fund our proposed operating plan for, at least, the 12 months following the date of this report. However, as of the date of this report, we believe that we will need additional capital to fund our operations through to the marketing approval for TFF Vori and TFF Tac-Lac, assuming such approval can be obtained at all, and to engage in the substantial development of any other of our drug candidates, such as formulation, early stage animal testing and formal toxicology studies. We intend to seek additional funds through various financing sources, including the sale of our equity and debt securities, licensing fees for our technology and co-development and joint ventures with industry partners, with a preference towards licensing fees for our technology and co-development and joint ventures with industry partners. In addition, we will consider alternatives to our current business plan that may enable to us to achieve revenue producing operations and meaningful commercial success with a smaller amount of capital. However, there can be no guarantees that such funds will be available on commercially reasonable terms, if at all. If such financing is not available on satisfactory terms, we may be unable to further pursue our business plan and we may be unable to continue operations, in which case you may lose your entire investment.

Off Balance Sheet Transactions

We do not have any off-balance sheet transactions.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15 of the Securities Exchange Act of 1934. Based upon their evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were not effective as of September 30, 2019 because we have a small number of employees, as a result of our limited operations, which prohibits a segregation of duties. As we grow and expand our operations, we intend to engage additional employees and experts as needed. However, there can be no assurance that our operations will expand.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three-month period ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1A. Risk Factors

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

Risks Related to Our Business

We are a clinical-stage biopharmaceutical company with limited operating history. We are a biopharmaceutical company, newly-formed in January 2018, and have limited operating history. We have not commenced revenue-producing operations. In November 2019, we initiated Phase I human clinical trials for our TFF Vori product candidate, however, to date, our operations have otherwise consisted of preliminary research and development, drug formulation and characterization and testing of our initial product candidates. Our limited operating history makes it difficult for potential investors to evaluate our technology or prospective operations. As a development stage biopharmaceutical company, we are subject to all the risks inherent in the organization, financing, expenditures, complications and delays involved with a new business. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical-stage biopharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we may be unable to:

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

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

We have a history of significant operating losses and anticipate continued operating losses for the foreseeable future. For the fiscal years ended December 31, 2018 and 2017, and for the nine months ended September 30, 2019, we incurred a net loss applicable to common stockholders of $4.6 million, $178,605 and $8.0 million, respectively. As of September 30, 2019, we had an accumulated deficit of $11.1 million. We expect to continue to incur substantial expenses without any corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize at least one of our product candidates. However, there can be no assurance we will be able to obtain regulatory approval for any of our product candidates. Even if we are able to obtain regulatory approval and subsequently commercialize our product candidates, there can be no assurance that we will generate significant revenues or ever achieve profitability.

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

We expect we will need additional financing to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all. As of September 30, 2019, we had total assets of approximately $11 million and working capital of approximately $8.4 million. As of September 30, 2019, our liquidity included approximately $10.5 million of cash and cash equivalents. The foregoing does not give effect to our receipt of approximately $22.4 million of net proceeds from our initial public offering completed in October 2019. We believe that our cash on-hand as of the date of this report, which includes the proceeds of our IPO, is sufficient to fund our proposed operating plan for, at least, the 12 months following the date of this report. However, as of the date of this report, we believe that we will need additional capital to fund our operations through to the marketing approval for TFF Vori and TFF Tac-Lac, assuming such approval can be obtained at all, and to engage in the substantial development of any other of our drug candidates, such as formulation, early stage animal testing and formal toxicology studies. We intend to seek additional funds through various financing sources, including the sale of our equity and debt securities, licensing fees for our technology and co-development and joint ventures with industry partners, with a preference towards licensing fees for our technology and co-development and joint ventures with industry partners. In addition, we will consider alternatives to our current business plan that may enable to us to achieve revenue producing operations and meaningful commercial success with a smaller amount of capital. However, there can be no guarantees that such funds will be available on commercially reasonable terms, if at all. If such financing is not available on satisfactory terms, we may be unable to further pursue our business plan and we may be unable to continue operations, in which case you may lose your entire investment.

Our business model is entirely dependent on certain patent rights licensed to us from the University of Texas at Austin, and the loss of those license rights would, in all likelihood, cause our business, as presently contemplated, to fail. In July 2015, the University of Texas at Austin, or UT, granted to our former parent, LTI, an exclusive worldwide, royalty bearing license to the patent rights for the TFF platform in all fields of use, other than vaccines. In March 2018, LTI assigned to us all of its interest to the TFF platform, including the patent license agreement with UT. In November 2018, we and UT amended the patent license agreement such that our exclusive patent rights to the TFF platform were expanded to all fields of use. Our current business model, which focuses exclusively on the development of drugs using the TFF technology, is based entirely on the availability of the patent rights licensed to us by UT under the patent license agreement. The patent license agreement requires us to pay royalties and milestone payments and conform to a variety of covenants and agreements, and in the event of our breach of the agreement, UT may elect to terminate the agreement. As of the date of this report, we believe we are in compliance with the patent license agreement and consider our relationship with UT to be excellent. However, in the event of our breach of the patent license agreement for any reason, and our inability to cure such breach within any cure period or obtain a waiver from UT, we could lose the patent license agreement, which would result in our loss of all rights to the TFF technology.

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

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

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

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

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

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

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

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

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

- decreased demand for any of our product candidates or any future products that we may develop;
- injury to our reputation;
- failure to obtain regulatory approval for our product candidates;
- withdrawal of participants in our clinical trials;
- costs associated with our defense of the related litigation;
- a diversion of our management's time and our resources;

- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize some or all of our product candidates; and
- a decline in the value of our stock.

As of the date of this report, we have procured insurance coverage for our human clinical trials, which we consider adequate for our current level of clinical testing and development, however we do not carry product liability insurance. We intend to obtain product liability insurance at the time we commence commercial sale of our initial product. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. Although we will endeavor to obtain and maintain such insurance in coverage amounts we deem adequate, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies would also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. As a result, we may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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

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

Risks Related to Product Regulation

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

Because our initial dry powder drug candidates, TFF Vori and TFF Tac-Lac, will be established drugs that are off-patent, we believe that our initial drug product candidates will qualify for FDA approval through the FDA's 505(b)(2) regulatory pathway and in corresponding regulatory paths in other foreign jurisdictions. The 505(b)(2) pathway sometimes does not require clinical trials other than a bioequivalence trial; however, to the extent we claim that our drug product candidates target a new indication or offer improved safety compared to the existing approved products, and it is our present expectation that we will do so in many cases, it is likely that we will be required to conduct additional clinical trials in order to obtain marketing approval. For example, based on separate pre-IND meetings with the FDA concerning TFF Vori and TFF Tac-Lac, we believe we will need to conduct Phase I and Phase II studies prior to filing for marketing approval for TFF Vori and Phase I and Phase IIb/IIIa studies prior to filing for marketing approval for TFF Tac-Lac. However, there can be no assurance that the FDA will not ask for additional clinical data for either TFF Vori or TFF Tac-Lac.

Our business model is to pursue the development of off-patent drugs for which we would directly pursue the development of a dry powder formulation through the FDA's 505(b)(2) regulatory pathway; however, not all of our product candidates will target off-patent drugs and, at least in the case of a dry powder formulation of CBD, our product candidate may not be a drug. We do not expect any dry powder formulation of a CBD drug product to be off-patent and our proposed dry powder formulation of aluminum salt vaccines may not be off-patent. We also expect that our dry powder formulation of a CBD drug product will likely require a full NDA through the FDA's 505(b)(1) regulatory pathway; however, a non-pharmaceutical CBD dry powder formulation may not require FDA approval. We expect that our dry powder formulation of aluminum salt vaccines will require a biological license application, or BLA, which is very similar to a full NDA through the FDA's 505(b)(1) regulatory pathway.

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

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

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

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Our business model depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. In November 2019, we initiated Phase I human clinical trials for our TFF Vori product candidate and we had a pre-IND meeting for TFF Tac-Lac in September 2019 and plan on submitting an IND for that product candidate in the first quarter of 2020. However, as of the date of this report, we have not otherwise progressed any of our product candidates beyond performance characterization and animal testing. We may not be successful in obtaining approval from the FDA or comparable foreign regulatory authorities to start clinical trials for any other of our product candidates. If we do not obtain such approvals as presently planned, the time in which we expect to commence clinical programs for any product candidate will be extended and such extension will increase our expenses, delay our potential receipt of any revenues, and increase our need for additional capital. Moreover, there is no guarantee that we will receive approval to commence human clinical trials or, if we do receive approval, that our clinical trials will be successful or that we will continue clinical development in support of an approval from the FDA or comparable foreign regulatory authorities for any indication. We note that most product candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. Therefore, our business currently depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur.

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

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

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

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidates not commercially viable. For example, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for any of our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the drug. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates.

Even if we obtain marketing approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates. Even if we obtain regulatory approval for any of our product candidates for an indication, the FDA or foreign equivalent may still impose significant restrictions on their indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Our product candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current cGMPs, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

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

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

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

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

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

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

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

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

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

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

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

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

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

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

The Health Care Reform Law remains subject to legislative efforts to repeal, modify or delay the implementation of the law. If the Health Care Reform Law is repealed or modified, or if implementation of certain aspects of the Health Care Reform Law are delayed, such repeal, modification or delay may materially adversely impact our business, strategies, prospects, operating results or financial condition. We are unable to predict the full impact of any repeal, modification or delay in the implementation of the Health Care Reform Law on us at this time. Due to the substantial regulatory changes that will need to be implemented by Centers for Medicare & Medicaid Services, or CMS, and others, and the numerous processes required to implement these reforms, we cannot predict which healthcare initiatives will be implemented at the federal or state level, the timing of any such reforms, or the effect such reforms or any other future legislation or regulation will have on our business.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Relating to Our Intellectual Property Rights

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

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

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

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

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

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

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts. Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third-party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize any of our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may:

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

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

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

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

Risks Related to this Offering and Owning Our Common Stock

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

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

Future capital raises may dilute your ownership and/or have other adverse effects on our operations. If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced and these stockholders may experience substantial dilution. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our intellectual property or candidate products, or to grant licenses on terms that are not favorable to us.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Initial Public Offering

On October 29, 2019, we completed our initial public offering, or IPO, of 4,400,000 shares of our common stock, and on November 20, 2019 we closed on the sale and issuance of an additional 479,300 shares of common stock from the partial exercise of the option to purchase additional shares granted to the underwriters, at a price to the public of $5.00 per share. The offer and sale of all of the shares in our IPO were registered under the Securities Act of 1933 ("Securities Act") pursuant to a registration statement on Form S-1 (File No. 333-233378), which was declared effective by the SEC on October 24, 2019. The offering commenced on October 25, 2019 and the initial closing took place on October 29, 2019. The offering terminated in connection with the closing of the underwriters' exercise of their over-allotment option on November 20, 2019.

National Securities Corporation acted as the sole underwriter for the offering. The aggregate offering price for shares sold in the offering was approximately $24,396,500. We raised approximately $22.4 million in net proceeds from the offering, after deducting underwriter discounts and commissions of $1,829,738 and other offering expenses of approximately $160,000. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries. Pending the uses described in our definitive prospectus filed with the SEC on October 24, 2019, we have invested the net proceeds from the offering in short-term, investment-grade interest-bearing securities such as money market accounts, certificates of deposit, commercial paper, and guaranteed obligations of the U.S. government.

Unregistered Sales of Equity Securities

In March 2018, we conducted a private placement of 5,662,000 shares of our Series A preferred stock, at an offering price of $2.50 per share, for the gross proceeds of approximately $14.2 million, and in May 2019 we conducted a private placement of 3,268,000 shares of our Series A preferred stock, at an offering price of $2.50 per share, for the gross proceeds of approximately $8.2 million. The shares of our Series A preferred stock accumulated dividends at the rate of 6% per annum. At of the initial close of our IPO on October 29, 2019, the shares of Series A preferred stock, including all accrued but unpaid dividends on the Series A preferred stock, which totaled $1,603,709, automatically converted into 9,571,692 shares of our common stock. The common shares were issued pursuant to the exemption from registration at Section 4(a)(2) of the Securities Act and Rule 506 thereunder.

Each holder of Series A preferred stock was an accredited investor, as such term is defined in Rule 501 under the Securities Act. The Series A preferred stockholders 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 issued in the note conversions. All Series A preferred stockholders had adequate access, through their relationships with us, to information about our Company. The issuance of the common shares was made without any general solicitation or advertising.

Item 6. Exhibits

Exhibit No.	Description	Method of Filing
3.1	Second Amended and Restated Certificate of Incorporation of the Registrant	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
3.2	Amended and Restated Bylaws of the Registrant	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
31.1	Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed electronically herewith
31.2	Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed electronically herewith
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).	Filed electronically herewith
101.INS	XBRL Instance Document	Filed electronically herewith
101.SCH	XBRL Taxonomy Extension Schema Document	Filed electronically herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed electronically herewith
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	Filed electronically herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed electronically herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed electronically herewith

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TFF PHARMACEUTICALS, INC.

Date: December 9, 2019

By: /s/ *Glenn Mattes*
Glenn Mattes,
President and Chief Executive Officer
(Principal Executive Officer)

Date: December 9, 2019

By: */s/ Kirk Coleman*
Kirk Coleman,
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATIONS

I, Glenn Mattes, certify that:

(1) I have reviewed this Form 10-Q of TFF Pharmaceuticals, Inc. (the "Company");

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

(4) The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; And

(5) The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

TFF PHARMACEUTICALS, INC.

Date: December 9, 2019

By: /s/ *Glenn Mattes*
Glenn Mattes, Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Kirk Coleman, certify that:

(1) I have reviewed this Form 10-Q of TFF Pharmaceuticals, Inc. (the "Company");

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

(4) The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; And

(5) The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

TFF PHARMACEUTICALS, INC.

Date: December 9, 2019

By: */s/ Kirk Coleman*
Kirk Coleman, Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

**CERTIFICATION PURSUANT TO 18
U.S.C. 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of TFF Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Glenn Mattes, the Chief Executive Officer, and Kirk Coleman, the Chief Financial Officer, of the Company, respectively, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ *Glenn Mattes* Dated: December 9, 2019
Glenn Mattes,
Title: President and Chief Executive Officer

By: /s/ *Kirk Coleman* Dated: December 9, 2019
Kirk Coleman,
Title: Chief Financial Officer

This certification is made solely for the purposes of 18 U.S.C. Section 1350, subject to the knowledge standard contained therein, and not for any other purpose.