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, 2020

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of November 2, 2020, there were 22,226,284 outstanding shares of the common stock of TFF Pharmaceuticals, Inc.

TFF PHARMACEUTICALS, INC.

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

TFF PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 41,617,891	$ 28,094,936
Prepaid assets and other current assets	595,016	1,092,462
Total current assets	42,212,907	29,187,398
Property and equipment, net	945,365	—
Total assets	$ 43,158,272	$ 29,187,398
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,573,384	$ 410,638
Total current liabilities	1,573,384	410,638
Accrued research and development expense (see Note 5)	—	1,132,013
Total liabilities	1,573,384	1,542,651
Commitments and contingencies (see Note 4)		
Stockholders' equity:		
Common stock; $0.001 par value, 45,000,000 shares authorized; 22,226,284 and 18,450,992 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	22,226	18,451
Additional paid-in capital	70,014,551	43,338,710
Accumulated other comprehensive loss	(67,663)	—
Accumulated deficit	(28,384,226)	(15,712,414)
Total stockholders' equity	41,584,888	27,644,747
Total liabilities and stockholders' equity	$ 43,158,272	$ 29,187,398

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

TFF PHARMACEUTICALS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Operating expenses:				
Research and development	$ 2,823,669	$ 2,563,528	$ 7,626,982	$ 5,554,046
General and administrative	2,254,912	300,640	5,147,639	1,721,691
Total operating expenses	5,078,581	2,864,168	12,774,621	7,275,737
Loss from operations	(5,078,581)	(2,864,168)	(12,774,621)	(7,275,737)
Other income:				
Interest income	20,546	25,865	102,809	67,699
Total other income	20,546	25,865	102,809	67,699
Net loss	(5,058,035)	(2,838,303)	(12,671,812)	(7,208,038)
Preferred stock dividend	—	(258,635)	—	(768,876)
Net loss applicable to common stock	(5,058,035)	(3,096,938)	(12,671,812)	(7,976,914)
Other comprehensive loss:				
Foreign currency translation adjustments	(28,172)	—	(67,663)	—
Comprehensive loss	$ (5,086,207)	$ (3,096,938)	$ (12,739,475)	$ (7,976,914)
Net loss applicable to common stock per share, basic and diluted	$ (0.24)	$ (0.70)	$ (0.61)	$ (1.81)
Weighted average common shares outstanding, basic and diluted	20,867,526	4,400,000	20,810,004	4,400,000

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

TFF PHARMACEUTICALS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2020 AND 2019

	Common Stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance, January 1, 2020	18,450,992	$ 18,451	$ 43,338,710	$ -	$ (15,712,414)	$ 27,644,747
Issuance of common stock for accrued research and development expense	220,666	221	1,131,792	-	-	1,132,013
Stock-based compensation	-	-	425,844	-	-	425,844
Foreign currency translation adjustment	-	-	-	(20,283)	-	(20,283)
Net loss	-	-	-	-	(3,797,198)	(3,797,198)
Balance, March 31, 2020	18,671,658	18,672	44,896,346	(20,283)	(19,509,612)	25,385,123
Stock-based compensation	-	-	295,356	-	-	295,356
Foreign currency translation adjustment	-	-	-	(19,208)	-	(19,208)
Net loss	-	-	-	-	(3,816,579)	(3,816,579)
Balance, June 30, 2020	18,671,658	18,672	45,191,702	(39,491)	(23,326,191)	21,844,692
Sale of common stock, net of offering costs	3,048,654	3,048	24,277,235	-	-	24,280,283
Issuance of common stock in connection with cashless warrant exercises	505,972	506	(506)	-	-	-
Stock-based compensation	-	-	546,120	-	-	546,120
Foreign currency translation adjustment	-	-	-	(28,172)	-	(28,172)
Net loss	-	-	-	-	(5,058,035)	(5,058,035)
Balance, September 30, 2020	22,226,284	$ 22,226	$ 70,014,551	$ (67,663)	$ (28,384,226)	$ 41,584,888
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	-	-	486,396	-	-	486,396
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)

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

TFF PHARMACEUTICALS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Nine Months Ended September 30, 2020	For the Nine Months Ended September 30, 2019
Cash flows from operating activities:		
Net loss	$ (12,671,812)	$ (7,208,038)
Adjustment to reconcile net loss to net cash used in operating activities:		
Stock based compensation	1,267,320	378,607
Changes in operating assets and liabilities:		
Prepaid assets	519,816	(261,204)
Accounts payable	501,877	181,307
Net cash used in operating activities	(10,382,799)	(6,909,328)
Cash flows from investing activities:		
Purchases of property and equipment	(293,243)	-
Net cash used in investing activities	(293,243)	-
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	24,280,283	-
Proceeds from issuance of preferred stock	-	7,198,226
Net cash provided by financing activities	24,280,283	7,198,226
Effect of exchange rate changes on cash and cash equivalents	(81,286)	-
Net change in cash and cash equivalents	13,522,955	288,898
Cash and cash equivalents at beginning of period	28,094,936	10,261,671
Cash and cash equivalents at end of period	$ 41,617,891	$ 10,550,569
Supplemental disclosure of non-cash investing and financing activities:		
Accrued offering costs	$ -	$ 81,153
Accrued dividend	$ -	$ 768,876
Cashless exercise of warrants	$ 506	$ -
Issuance of common stock for accrued research and development expense	$ 1,132,013	$ -
Purchases of property and equipment included in accounts payable	$ 652,122	$ -

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

TFF PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
For The Three and Nine Months Ended September 30, 2020 and 2019

NOTE 1 – ORGANIZATION AND DESCRIPTION OF BUSINESS

TFF Pharmaceuticals, Inc. (the "Company") was incorporated in the State of Delaware on January 24, 2018 by Lung Therapeutics, Inc. ("LTI"), at which time the Company and LTI entered into a Contribution and Subscription Agreement ("Contribution Agreement") pursuant to which LTI agreed to transfer to the Company certain of LTI's non-core intellectual property rights and other assets, including LTI's rights under a patent license agreement with the University of Texas at Austin (see Note 5), in exchange for 4,000,000 shares of the Company's common stock. The transactions under the Contribution Agreement closed in March 2018. LTI's basis in such assets were minimal. LTI is an early-stage biotechnology company focused on the development of certain technologies in the pulmonary field. The Company's initial focus is on the development of inhaled dry powder drugs to enhance the treatment of pulmonary diseases and conditions. In December 2019, the Company established a wholly-owned Australian subsidiary, TFF Pharmaceuticals Australia Pty Ltd ("TFF Australia"), in order to conduct clinical research. TFF Pharmaceuticals, Inc., along with TFF Australia, are collectively referred to as the "Company". The Company is in the development stage and is devoting substantially all of its efforts toward technology research and development.

October 2019 Initial Public Offering

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

August 2020 Private Placement

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

COVID-19

On March 11, 2020, the World Health Organization declared a novel strain of coronavirus disease ("COVID-19") a global pandemic. At this time, the United States and certain other countries are the subject of lock-downs and self-isolation procedures, which have significantly limited business operations and restricted internal and external meetings. The Company had expected to commence Phase I clinical trials of its thin film freezing, or TFF, formulation of Tacrolimus in Australia in the first quarter of 2020, and on March 13, 2020 the Company received the approval of the Alfred Hospital Human Research Ethics Committee to commence Phase I trials, however, later in March 2020, the Company's contract research organization in Australia informed the Company that because of the spread of the COVID-19 virus in Australia, there would be a delay in initiating the trial. During the second quarter of 2020, the Company was able to begin dosing in the Phase I Tacrolimus trial in Melbourne, Victoria, Australia. However, due to the resurgence of COVID-19 in the Melbourne area, in July 2020 the Phase I trials were delayed. With the flaring of COVID-19 in the Melbourne area and in order to remain dynamic, the Company opened a second clinical trial site in Brisbane, Queensland, Australia. and dosing in the Phase 1 clinical trial resumed in Australia during the third quarter 2020. The Company expects that dosing in this trial will be completed in the fourth quarter 2020. Any financial impact from the COVID-19 global pandemic cannot be reasonably estimated at this time, but may materially affect our business and financial condition. The extent to which COVID-19 impacts our results will

depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

NOTE 2 - LIQUIDITY AND MANAGEMENT'S PLANS

As of September 30, 2020, the Company had cash and cash equivalents of approximately $41,618,000 and a working capital of approximately $40,640,000. 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, 2020. Specifically, the Company expects increased spending on research and development activities and higher payroll expenses as it increases its professional and scientific staff and continues to prepare for anticipated manufacturing activities. The Company currently believes its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of these condensed consolidated financial statements.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial statements and with Form 10-Q and Article 10 of Regulation S-X of the United States Securities and Exchange Commission ("SEC"). 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 consolidated 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, 2020 and the results of operations, changes in stockholders' equity and cash flows for the periods presented. The results of operations for the three and nine months ended September 30, 2020 are not necessarily indicative of the operating results for the full fiscal year or any future period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019.

Principles of Consolidation

The consolidated financial statements include the accounts of TFF Pharmaceuticals, Inc. and its wholly-owned subsidiary, TFF Australia. All material intercompany accounts and transactions have been eliminated in consolidation.

Foreign Currency

The currency of TFF Australia, the Company's international subsidiary, is in Australian dollars. Foreign currency denominated assets and liabilities are translated into U.S. dollars using the exchange rates in effect at each balance sheet date. Results of operations and cash flows are translated using the average exchange rates throughout the period. The effect of exchange rate fluctuations on translation of assets and liabilities is included as a separate component of stockholders' equity in accumulated other comprehensive income (loss).

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. The Company calculates depreciation using the straight-line method over the estimated useful lives of the assets, which range from two to five years for furniture, fixtures, lab and computer equipment and software. Assets held within construction in progress are not depreciated. Construction in progress is related to the construction or development of property and equipment that have not yet been placed in service for its intended use. As of September 30, 2020, all of the Company's property and equipment consist of lab equipment that are considered construction in progress. Expenditures for repairs and maintenance of assets are charged to expense as incurred.

Fair Value of Financial Instruments

Authoritative guidance requires disclosure of the fair value of financial instruments. The Company's financial instruments consist of cash and cash equivalents and accounts payable, the carrying amounts of which approximate their estimated fair values primarily due to the short-term nature of the instruments or based on information obtained from market sources and management estimates. The Company measures the fair value of certain of its financial assets and liabilities on a recurring basis. A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value which

is not equivalent to cost will be classified and disclosed in one of the following three categories:

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

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

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

Basic and Diluted Earnings per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and dilutive share equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. Since the Company has had net losses for all periods presented, all potentially dilutive securities are anti-dilutive. Basic weighted average shares outstanding for the three and nine months ended September 30, 2020 and 2019 include 400,000 shares underlying a warrant to purchase common shares. As the shares underlying this warrant can be issued for little consideration (an aggregate exercise price of $0.01 per share), these shares are deemed to be issued for purposes of basic earnings per share.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, continued

For the nine months ended September 30, 2020 and 2019, 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:

	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Stock Options	2,871,123	1,341,094
Series A Convertible Preferred Stock*	—	9,568,700
Warrants	460,526	658,212
	3,331,649	11,568,006

* *On an as-converted basis*

Use of Estimates

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

Recent Accounting Standards

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)*. This ASU will require lessees to recognize a right-of-use asset and lease liability on the consolidated balance sheet for leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU No. 2016-02 supersedes the lease accounting requirements of ASC Topic 840, *Leases.* The Company adopted this standard on January 1, 2020, using the modified retrospective approach, which did not cause adjustments to prior comparative periods. The new standard provides a number of optional practical expedients in transition. The Company has elected the following "package of practical expedients" when assessing the transition impact as the lessee as of January 1, 2020: (1) not to reassess whether any expired or existing contracts, contain leases; (2) not to reassess the lease classification for any expired or existing leases; and (3) not to reassess initial direct costs for any existing leases. Leases with an initial term of 12 months or less are considered short-term leases and are not recorded on the balance sheet as the Company recognizes lease expense for these leases on a straight-line basis over the lease term. The Company has reviewed all contracts that may contain leases and have determined that there was no impact related to the adoption of ASU 2016-02 as the only contract that contains a lease is for office space in Doylestown, Pennsylvania, which is considered a short-term lease. See Note 4 for more information regarding the leased office space.

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, the Company exercised a one-year lease renewal in October 2019, and another one-year lease renewal in October 2020 that will expire on October 31, 2021. The lease has an additional one-year option for renewal, and the base rent is $36,000 per year. The Company has determined that the lease agreement is considered a short-term lease under ASC 842 and has not recorded a right-of-use asset or liability. Short-term lease expense for the three and nine months ended September 30, 2020 was $9,000 and $27,000, respectively.

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

Year ending December 31,	Amount
2020 – Remaining	$ 9,000
2021	30,000
Total	$ 39,000

Legal

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

NOTE 5 - LICENSE AND AGREEMENTS

In July 2015, the University of Texas at Austin ("UT") granted to the Company's former parent, LTI, an exclusive worldwide, royalty bearing license to the patent rights for the TFF platform in all fields of use, other than vaccines for which LTI received a non-exclusive worldwide, royalty bearing license to the patent rights for the TFF platform. In March 2018, LTI completed an assignment to the Company all of its interest to the TFF platform, including the patent license agreement with UT, at which time the Company paid UT an assignment fee of $100,000 in accordance with the patent license agreement. In November 2018, the Company and UT entered into an amendment to the patent license agreement pursuant to which, among other things, the Company's exclusive patent rights to the TFF platform were expanded to all fields of use. The patent license agreement requires the Company to pay royalties and milestone payments and conform to a variety of covenants and agreements, and in the event of the Company's breach of agreement, UT may elect to terminate the agreement. During the year ended December 31, 2019, the Company achieved one milestone by gaining IND approval on first indication of a licensed product on November 24, 2019. The milestone fee associated with this achievement to be paid is $50,000 and the Company must issue UT common shares equal to 1% of the Company's outstanding shares of common stock, on a fully diluted basis, as of 30 days after IND approval, which was December 24, 2019. The total amount of common shares due and payable on December 31, 2019 to UT were 220,666 common shares, which have a fair value of approximately $1,132,000 based on the closing stock price of $5.13 on December 24, 2019. As of December 31, 2019, the Company had not paid the $50,000 or issued the shares and has included the $50,000 in accounts payable and the share amount due as a research and development expense payable. The Company paid the $50,000 and issued the shares in January 2020. As of the date of these condensed consolidated financial statements, the Company is in

compliance with the patent license agreement as all required amounts have been paid in accordance with the agreement.

In May 2018, the Company entered into a master services agreement and associated individual study contracts with ITR Canada, Inc. ("ITR") to provide initial contract pre-clinical research and development services for the Company's drug product candidates. The fees payable for pre-clinical research and development services under these study contracts totaled $1,790,000, with no minimum fee requirement. In January 2019, the Company cancelled all of the individual study contracts with ITR and entered into a contract with 11036114 Canada Inc. (initially dba VJO Non-Clinical Development and now dba Strategy Point Innovations ("SPI")) to complete additional pre-clinical research and development services in order to take advantage of eligible Canadian Tax Credits. The services related to the contract with SPI were sub-contracted to ITR under substantially the same terms as the initial contract with ITR, with fees payable for services under statements of work that are currently open totaling $3,607,000, as amended. During the three and nine months ended September 30, 2020, the Company recorded research and development costs of approximately $0 and $779,000, respectively. During the three and nine months ended September 30, 2019, the Company recorded research and development costs of approximately $843,000 and $2,597,000, respectively.

NOTE 5 - LICENSE AND AGREEMENTS, continued

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 approximately $3,089,000, as amended, with additional pass-through costs. During the three and nine months ended September 30, 2020, the Company recorded research and development costs of approximately $249,000 and $1,266,000, respectively. During the three and nine months ended September 30, 2019, the Company recorded research and development costs of approximately $288,000 and $346,000, respectively.

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 approximately $1,079,000, as amended, with additional pass-through costs. During the three and nine months ended September 30, 2020, the Company recorded research and development costs of approximately $384,000 and $626,000, respectively. During the three and nine months ended September 30, 2019, the Company recorded research and development costs of approximately $177,000 and $295,000, respectively.

In August 2019, the Company entered into a master services agreement and associated individual study contracts with Conform Clinical Development, Inc. and its affiliates, Les Entreprises Envie Inc. (dba Envie Ventures) and Desire Ventures LLC, which sub-contracted with Inflamax Research Limited (dba Cliantha Research) to perform a Phase I study of one of the Company's drug candidates, Voriconazole. The fees payable for the services under this contract total approximately $1,483,000, as amended. During the three and nine months ended September 30, 2020, the Company recorded research and development costs of approximately $709,000 and $934,000, respectively. During the three and nine months ended September 30, 2019, the Company recorded research and development costs of approximately $281,000.

In January 2020, TFF Australia entered into a master consultancy agreement with Novotech (Australia) Pty Ltd. (formally known as Clinical Network Services Pty Ltd.) to provide initial contract clinical research and development services for the Company's drug product candidates. The fees payable for clinical research and development services under these study contracts totaled AUD$1,942,981, as amended. During the three and nine months ended September 30, 2020, the Company recorded research and development costs of approximately AUD$139,000 (US$99,000) and AUD$323,000 (US$218,000), respectively.

In May 2020, TFF Australia entered into an amended clinical trial research agreement with Nucleus Network Pty Ltd. to provide a Phase I study of one of the Company's drug candidates, Tacrolimus. The fees payable for services under this contract totaled AUD$1,392,805, as amended. During the three and nine months ended September 30, 2020, the Company recorded research and development costs of approximately AUD$61,000 (US$44,000) and AUD$437,000 (US$295,000), respectively.

In August 2020, TFF Australia entered into a clinical trial research agreement with Q-Pharm Pty Ltd. to provide a Phase I study of one of the Company's drug candidates, Tacrolimus. The fees payable for services under this contract totaled AUD$704,600. During the three and nine months ended September 30, 2020, the Company recorded research and development costs of approximately AUD$327,000 (US$234,000).

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

approvals and/or the receipt of at least $25,000,000 of grant funding. The Company will receive a single-digit tiered royalty on net sales. The Company will also be entitled to receive sales-related milestone payments based on the commercial success of the licensed products.

NOTE 6 – STOCKHOLDERS' EQUITY

Series A Convertible Preferred Stock

Prior to the close of the Company's IPO, the Company was authorized to issue up to 10,000,000 shares of preferred stock, $0.001 par value, all of which had been designated as Series A Preferred Stock and had a stated value of $2.50 per share. All outstanding shares of Series A Preferred Stock converted to shares of the Company's common stock, and all authorized and unissued shares of Series A Preferred Stock was extinguished, upon the close of the Company's IPO in October 2019. As of September 30, 2020 and December 31, 2019, there are no shares of Series A Preferred Stock authorized, issued or outstanding. The Series A Preferred Stock ranked senior to common stock with respect to dividends rights and liquidation preferences and had full voting rights. The Series A Preferred Stock accrued a dividend at a rate of 6% per annum with no amounts outstanding as of September 30, 2020 and December 31, 2019. The Company recorded $258,635 and $768,875 of preferred dividends during the three and nine months ended September 30, 2019, respectively.

Common Stock

UT Agreement

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

NOTE 6 – STOCKHOLDERS' EQUITY, continued

August 2020 Private Placement

On August 10, 2020, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement") with certain institutional and other accredited investors pursuant to which the Company issued and sold to the investors 3,048,654 shares of the Company's common stock at a price of $8.50 per share for the approximate gross proceeds of $25.91 million, before deducting placement agent and other offering expenses. After deducting the placement agent and other offering expenses, the Company received net proceeds of approximately $24.28 million. The Purchase Agreement included customary representations, warranties, and covenants by the investors and the Company, and an indemnity from the Company in favor of the investors. Jefferies LLC acted as placement agent for the private placement and the private placement closed on August 13, 2020. Pursuant to the terms of the Registration Rights Agreement, the Company file a resale registration statement on Form S-1 with the SEC on September 9, 2020.

NOTE 7 – STOCK BASED COMPENSATION

In January 2018, the Company's board of directors approved its 2018 Stock Incentive Plan ("2018 Plan"). The 2018 Plan provides for the grant of non-qualified stock options and incentive stock options to purchase shares of the Company's common stock, the grant of restricted and unrestricted share awards and grant of restricted stock units. The Company initially reserved 1,630,000 shares of its common stock under the 2018 Plan; however, upon completion of the Company's IPO the number of shares reserved for issuance under the 2018 Plan increased to 3,284,480, representing 15% of the Company's outstanding shares of common stock calculated on a fully diluted basis upon the close of the IPO. All of the Company's employees and any subsidiary employees (including officers and directors who are also employees), as well as all of the Company's nonemployee directors and other consultants, advisors and other persons who provide services to the Company will be eligible to receive incentive awards under the 2018 Plan.

The following table summarizes the stock-based compensation expense recorded in the Company's results of operations during the periods ended September 30, 2020 and 2019 for stock options and warrants:

	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Research and development	$ 34,430	$ 78,035	$ —	$ —
General and administrative	511,690	1,189,285	(229,016)	378,607
	$ 546,120	$ 1,267,320	$ (229,016)	$ 378,607

As of September 30, 2020, there was approximately $9,546,000 of total unrecognized compensation expense related to non-vested options and warrants that are expected to vest. This cost is expected to be recognized over a weighted-average period of 2.6 years.

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

The Company estimated the fair value stock options using the Black-Scholes option pricing model. The fair value of

stock options is being amortized on a straight-line basis over the requisite service periods of the respective awards. The fair value of stock options issued was estimated using the following weighted-average assumptions:

	Nine Months Ended September 30, 2020
Weighted average exercise price	$ $10.13
Weighted average grant date fair value	$ $9.02
Assumptions	
Expected volatility	87-91%
Expected terms (in years)	6.3-10
Risk-free interest rate	0.36-1.47%
Expected dividend yield	0.00%

NOTE 7 – STOCK BASED COMPENSATION, continued

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

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

The following table summarizes stock option activity during the nine months ended September 30, 2020:

	Number of Shares	Weighted-Average Exercise Prices	Weighted-Average Remaining Contractual Term (In Years)	Intrinsic Value
Outstanding at January 1, 2020	2,139,078	$ 3.46	9.17	$ 4,052,512
Granted	752,045	10.13	—	—
Cancelled	(20,000)	5.24	—	—
Outstanding at September 30, 2020	2,871,123	$ 5.19	8.75	$38,128,217
Exercisable at September 30, 2020	750,355	$ 2.51	7.90	$11,979,107

NOTE 8 – SUBSEQUENT EVENTS

Augmenta Bioworks Agreement

On November 1, 2020, the Company entered into a joint development and collaboration agreement (the "Agreement") with Augmenta Bioworks, Inc. ("Augmenta" pursuant to which the parties have agreed to collaborate on the joint development of novel commercial products incorporating Augmenta's human-derived monoclonal antibodies ("mAbs") for potential COVID-19 therapeutics. Under the terms of the Agreement, both companies will collaborate to develop one or more commercial therapeutics utilizing the Company's Thin-Film Freezing technology to manufacture dry powder formulations of Augmenta's mAbs for inhalation delivery directly to the lungs of patients.

Letter of Intent with Felix Biotechnology

On November 2, 2020, the Company signed a Letter of Intent with Felix Biotechnology, Inc. ("Felix") reflecting the parties' non-binding agreement in principle to negotiate and enter into a collaboration, development and license agreement. Under the proposed agreement, Felix will obtain a non-exclusive license to the Company's Thin-Film freezing technology to develop and manufacture dry powder formulations of specified Felix bacteriophage products for inhalation delivery directly to the lungs of patients. Felix would agree to pay the Company an upfront payment, development milestones, commercial milestones and royalties on net sales of the Felix phage products.

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 2019 Annual Report on Form 10-K filed with the SEC on March 27, 2020 and Amendment No. 1 to the 2019 Annual Report on Form 10-K filed with the SEC on April 29, 2020.

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 in Part I, Item 1 "Risk Factors" in our 2019 Annual Report on Form 10-K filed with the SEC on March 27, 2020. 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, and in June 2020 we commenced Phase I human clinical trials of our TFF Tac-Lac product in Melbourne, Victoria, Australia, but in July 2020, the Phase I trials of our TFF Tac-Lac product were delayed due to a resurgence of COVID-19 in the Melbourne area. A second clinical trial site in Brisbane, Queensland, Australia was opened and dosing in the Phase 1 clinical trial resumed in Australia during the third quarter 2020. We expect that dosing in this trial will be completed in the fourth quarter 2020. 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. In July 2020, we completed the clinical portion of the Phase I trial with both single ascending and multiple ascending dose phases with 32 healthy subjects enrolled in each part to evaluate the safety, tolerability and pharmacokinetic profile of TFF Vori. We believe, and our clinical testing to date confirms, that our TFF platform can be used to formulate a dry powder version of Voriconazole, which is no longer subject to patent protection. Voriconazole is currently marketed in Australia, Europe and the U.S. as Vfend. As of the date of this 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 intend to conduct Phase I clinical trials for our TFF formulation of Tacrolimus in Australia, which we consider to be a highly desirable site to conduct human clinical trials. On March 13, 2020, we had received the approval of the Alfred Hospital Human Research Ethics Committee to commence Phase I trials in Melbourne, Victoria, Australia. However, later in March 2020, our contract research organization partner in Australia informed us that because of the spread of the COVID-19 virus in Australia, there would be a delay in initiating the trials. One contributing factor is that Tacrolimus is an immunosuppressant drug and, given the threat of the COVID-19 virus, concern exists that even though we would be dosing healthy volunteers the inhalation of an immunosuppressant could increase the risk of severe complications if a volunteer was to contract COVID-19. In June 2020, we were able to begin dosing in the Phase I trial our TFF Tac-Lac in Melbourne, however, in July 2020, due to the resurgence of COVID-19 in the Melbourne area, the Phase I trials were delayed. With the flaring of COVID-19 in the Melbourne area and in order to remain dynamic, a second clinical trial site in Brisbane, Queensland, we opened a second clinical trial site in Brisbane, Queensland, Australia. and dosing in the Phase 1 clinical trial resumed in Australia during the third quarter 2020. We expect that dosing in this trial will be completed in the fourth quarter 2020As of the date of this report, we intend to submit to the FDA an IND for TFF Tac-Lac upon completion of the Phase I clinical trials.

TFF Niclosamide is an inhaled dry powder formulation of Niclosamide. Niclosamide has been used

to treat tapeworm infections in humans since the 1960s and was recently reported to be one of the most potent approved drugs in screens for antiviral activity against the SARS-CoV2 virus that causes the COVID-19 disease. Early testing confirmed that our TFF platform can be used to formulate a dry powder version of Niclosamide, which is no longer subject to patent protection. We believe a TFF prepared dry powder formulation of Niclosamide administered directly to the lungs can maximize both the prophylactic value for persons exposed to COVID-19 and for the treatment of patients with COVID-19 infections at risk for serious disease complications. TFF has also obtained the rights to a novel formulation that may enhance the bioavailability of Niclosamide through oral delivery under our license from the University of Texas. Systemically delivered Niclosamide has shown promise for the treatment of COVID -19 and various forms of cancer. On August 12, 2020, we entered into a licensing and collaboration agreement with UNION therapeutics A/S in which UNION acquired an option to obtain a worldwide exclusive license for the TFF technology in combination with niclosamide.

TFF mAb therapies is intended to be a dry powder formulation of a COVID-19 monoclonal antibody therapy. On November 1, 2020, the Company entered into a joint development and collaboration agreement (the "Agreement") with Augmenta Bioworks, Inc. ("Augmenta" pursuant to which the parties have agreed to collaborate on the joint development of novel commercial products incorporating Augmenta's human-derived monoclonal antibodies ("mAbs") for potential COVID-19 therapeutics. Under the terms of the Agreement, both companies will collaborate to develop one or more commercial therapeutics utilizing the Company's Thin-Film Freezing technology to manufacture dry powder formulations of Augmenta's mAbs for inhalation delivery directly to the lungs of patients.

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.

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

Our business model is to develop proprietary innovative drug product candidates that offer commercial or functional advantages, or both, to currently available alternatives. In our initial evaluation of the market, we have identified a number of potential drug candidates that show promise upon initial assessment. In most cases, these are off-patent drugs for which we would directly pursue the development of a dry powder formulation, however, we do not expect any dry powder formulation of a CBD drug product to be off-patent and our dry powder formulation of aluminum salt vaccines may not be off-patent. In those cases where our initial dry powder drug candidate will be established drugs that are off-patent, such as TFF Vori and TFF Tac-Lac, we believe that our drug product candidates may qualify for approval by the FDA through the FDA's 505(b)(2) regulatory pathway and in corresponding regulatory paths in other foreign jurisdictions. The 505(b)(2) pathway sometimes does not require clinical trials other than a bioequivalence trial. Our dry powder formulation of a CBD drug candidate will likely require a full NDA through the FDA's 505(b)(1) regulatory pathway, however, a non-pharmaceutical CBD dry formulation, such as a dietary supplement, may not require FDA approval. We expect that our dry powder formulation of aluminum salt vaccines will require a biological license application, or BLA, which is very similar to a full NDA through the FDA's 505(b)(1) regulatory pathway. In addition, to the extent we claim that any of our off-patent drug product candidates target a new indication or offer improved safety compared to the existing approved products, and it is our present expectation that we will in many cases, it is likely that we will be required to conduct additional clinical trials in order to obtain marketing approval. For example, based on separate pre-IND meetings with the FDA concerning TFF Vori and TFF Tac-Lac, we believe we will need to conduct Phase I and Phase II studies prior to filing for marketing approval for TFF Vori and Phase I and Phase IIb/IIIa studies prior to filing for marketing approval for TFF Tac-Lac. However, there can be no assurance that the FDA will not ask for additional clinical data for either TFF Vori or TFF Tac-Lac.

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

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.

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 $21.8 million.

On August 13, 2020, we conducted a private placement of 3,048,654 shares of ours common stock, at a purchase price per share of $8.50, for aggregate gross proceeds to us of approximately $25,914,000, before deducting selling commissions and other offering expenses payable by us.

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.

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

On March 11, 2020, the World Health Organization declared a novel strain of coronavirus disease ("COVID-19") a global pandemic. We had expected to commence Phase I clinical trials our TFF formulation of Tacrolimus in Australia in the first quarter of 2020, and on March 13, 2020 we had received the approval of the Australian Human Research Ethics Committee to commence Phase I trials, however later in March 2020 our contract research organization in Australia informed us that because of the spread of the COVID-19 virus in Australia, there would be a delay in initiating the trial. During the second quarter of 2020, we were able to begin dosing in the Phase I Tacrolimus trial in Melbourne, Victoria, Australia. However, due to the resurgence of COVID-19 in the Melbourne area, in July 2020 the Phase I trials were delayed. With the flaring of COVID-19 in the Melbourne area and in order to remain dynamic, we opened a second clinical trial site in Brisbane, Queensland, Australia. and dosing in the Phase 1 clinical trial resumed in Australia during the third quarter 2020. We expect that dosing in this trial will be completed in the fourth quarter 2020. Any financial impact cannot be reasonably estimated at this time, but may materially affect our business and financial condition. The extent to which COVID-19 impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

During the three months ended September 30, 2020 and 2019, we incurred $2,823,669 and $2,563,528 of research and development expenses and $2,254,912 and $300,640 of general and administrative expenses, respectively. The increase in research and development expenses during 2020 was due to the ramp-up of research and development activities following the completion of IPO in October 2019. The ramp up includes our preliminary analysis and testing of dry powder formulations of certain drugs and vaccines we believe have the potential to become product candidates. We expect our spending on research and development activities to continue to increase in upcoming quarters. The increase in general and administrative expenses in 2020 from the prior year period was mainly a result of public-company related increases in expenses of approximately $196,000, increased expenses related to consulting and business development activities of approximately $825,000, payroll and related expense increases of approximately $144,000 and an increase in stock-based compensation of approximately $741,000. We incurred a net loss applicable to common stockholders of $5,058,035 and $3,096,938 for three months ended September 30, 2020 and 2019, respectively.

During the nine months ended September 30, 2020 and 2019, we incurred $7,626,982 and $5,554,046 of research and development expenses and $5,147,639 and $1,721,691 of general and administrative expenses, respectively. The increase in research and development expenses during 2020 was due to the ramp-up of research and development activities following the completion of IPO in October 2019. The ramp up includes our preliminary analysis and testing of dry powder formulations of certain drugs and vaccines we believe have the potential to become product candidates. The increase in general and administrative expenses in 2020 from the prior year period was mainly a result of public-company related increases in expenses of approximately $933,000, increased expenses related to consulting and business development activities of approximately $1,200,000, payroll and related expense increases of approximately $480,000 and an increase in stock-based compensation of approximately $811,000. We incurred a net loss applicable to common stockholders of $12,671,812 and $7,976,914 for nine months ended September 30, 2020 and 2019, respectively.

Financial Condition

As of September 30, 2020, we had total assets of approximately $43.2 million and working capital of approximately $40.6 million. As of September 30, 2020, our liquidity included approximately $41.6 million of cash and cash equivalents. We believe that our cash on-hand as of the date of this report is sufficient to fund our proposed operating plan for, at least, the 12 months following the date of this report. However, as of the date of this report, we believe that we will need additional capital to fund our operations through to the marketing approval for TFF Vori and TFF Tac-Lac, assuming such approval can be obtained at all, and to engage in the substantial development of any other of our drug candidates, such as formulation, early stage animal testing and formal toxicology studies. We intend to seek additional funds through various financing sources, including the sale of our equity and debt securities, licensing fees for our technology and co-development and joint ventures with industry partners, with a preference towards licensing fees for our technology and co-development and joint ventures with industry partners. In addition, we will consider alternatives to our current business plan that may enable to us to achieve revenue producing operations and meaningful commercial success with a smaller amount of capital. However, there can be no guarantees that such funds will be available on commercially reasonable terms, if at all. If such financing is not available on satisfactory terms, we may be unable to further pursue our business plan and we may be unable to continue operations, in which case you may lose your entire investment.

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 effective as of September 30, 2020.

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, 2020 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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Those forward-looking statements include our expectations, beliefs, intentions and strategies regarding the future. You should carefully consider the risk factors discussed in Part I, Item 1A. "Risk Factors" in our 2019 Annual Report on Form 10-K filed with the SEC on March 27, 2020 as, in light of those risks, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in our forward-looking statements. There have been no material changes in the risk factors included in our 2019 Annual Report on Form 10-K. The risk factors described in our 2019 Annual Report on Form 10-K are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.

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

2020 Private Placement

On August 10, 2020, we entered into a Securities Purchase Agreement (the "Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement") with certain institutional and other accredited investors pursuant to which we issued and sold to the investors 3,048,654 shares of our common stock at a price of $8.50 per share for the approximate gross proceeds of $25.91 million, before deducting placement agent and other offering expenses. The shares were offered and sold in transactions exempt from registration under the Securities Act of 1933, as amended ("Securities Act"), in reliance on Section 4(a)(2) thereof and Regulation D thereunder. Each of the investors represented that it was an "accredited investor," as defined in Regulation D, and is acquiring the shares for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof. The Purchase Agreement included customary representations, warranties, and covenants by the investors and us, and an indemnity from us in favor of the investors. Jefferies LLC acted as placement agent for the private placement and the private placement closed on August 13, 2020. Pursuant to the terms of the Registration Rights Agreement, we filed a resale registration statement on Form S-1 with the SEC on September 9, 2020.

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 pursuant to a registration statement on Form S-1 (File No. 333-233378), which was declared effective by the SEC on October 24, 2019. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on December 12, 2014 pursuant to Rule 424(b)(4). Pending the uses described in our definitive prospectus, 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.

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.
10.1	Form of Securities Purchase Agreement, dated August 10, 2020, between the Company and Investors named therein	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on August 11, 2020
10.2	Form of Registration Rights Agreement dated August 10, 2020 between the Company and investors named in the Securities Purchase Agreement	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on August 11, 2020
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

* Indicates management compensatory plan, contract or arrangement.

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: November 5, 2020

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

Date: November 5, 2020

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