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 March 31, 2022

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.)

1751 River Run, Suite 400
Fort Worth, Texas 76107
(Address of principal executive offices, including zip code)

(817) 438-6168
(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 $0.001	TFFP	The Nasdaq Global 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 ☒

The number of shares of the registrant's common stock outstanding as of May 9, 2022 was 25,373,818.

TFF PHARMACEUTICALS, INC.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

TFF PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,414,170	$ 33,794,672
Receivable due from collaboration agreement	1,776,583	1,628,703
Research and development tax incentive receivable	1,168,830	966,646
Prepaid assets and other current assets	2,164,451	2,447,930
Total current assets	31,524,034	38,837,951
Property and equipment, net	2,258,738	1,859,860
Total assets	$ 33,782,772	$ 40,697,811
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,028,779	$ 1,493,842
Accrued compensation	-	416,910
Deferred research grant revenue	168,000	50,000
Total liabilities	2,196,779	1,960,752
Commitments and contingencies (see Note 4)		
Stockholders' equity:		
Common stock; $0.001 par value, 45,000,000 shares authorized; 25,371,781 shares issued and outstanding	25,372	25,372
Additional paid-in capital	105,256,670	104,078,968
Accumulated other comprehensive loss	(1,687)	(48,921)
Accumulated deficit	(73,694,362)	(65,318,360)
Total stockholders' equity	31,585,993	38,737,059
Total liabilities and stockholders' equity	$ 33,782,772	$ 40,697,811

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

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Grant revenue	$ 67,435	$ 24,315
Operating expenses:		
Research and development	5,261,604	5,278,252
General and administrative	3,246,195	2,647,415
Total operating expenses	8,507,799	7,925,667
Loss from operations	(8,440,364)	(7,901,352)
Other income:		
Other income	57,177	231,278
Interest income	7,185	15,499
Total other income	64,362	246,777
Net loss	$ (8,376,002)	$ (7,654,575)
Net loss per share, basic and diluted	$ (0.33)	$ (0.33)
Weighted average common shares outstanding, basic and diluted	25,371,781	23,140,607

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Net loss	$ (8,376,002)	$ (7,654,575)
Other comprehensive loss:		
Foreign currency translation adjustments	47,234	(37,958)
Comprehensive loss	$ (8,328,768)	$ (7,692,533)

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 MONTHS ENDED MARCH 31, 2022 AND 2021

	Common Stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance, January 1, 2022	25,371,781	$ 25,372	$ 104,078,968	$ (48,921)	$ (65,318,360)	$ 38,737,059
Stock-based compensation	-	-	1,177,702	-	-	1,177,702

Foreign currency translation adjustment	-	-	-	47,234	-	47,234
Net loss	-	-	-	-	(8,376,002)	(8,376,002)
Balance, March 31, 2022	25,371,781	$ 25,372	$ 105,256,670	$ (1,687)	$ (73,694,362)	$ 31,585,993
Balance, January 1, 2021	22,534,874	$ 22,535	$ 71,648,453	$ (51,538)	$ (34,279,648)	$ 37,339,802
Sale of common stock, net of offering costs	2,140,000	2,140	28,021,424	-	-	28,023,564
Issuance of common stock for stock option exercises	244,656	245	655,008	-	-	655,253
Issuance of common stock for warrant exercises	444,751	444	179,768	-	-	180,212
Stock-based compensation	-	-	1,030,415	-	-	1,030,415
Foreign currency translation adjustment	-	-	-	(37,958)	-	(37,958)
Net loss	-	-	-	-	(7,654,575)	(7,654,575)
Balance, March 31, 2021	25,364,281	$ 25,364	$ 101,535,068	$ (89,496)	$ (41,934,223)	$ 59,536,713

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 Three Months Ended March 31, 2022	For the Three Months Ended March 31, 2021

Cash flows from operating activities:		
Net loss	$ (8,376,002)	$ (7,654,575)
Adjustment to reconcile net loss to net cash used in operating activities:		
Stock based compensation	1,177,702	1,030,415
Depreciation and amortization	77,028	1,495
Changes in operating assets and liabilities:		
Receivable due from collaboration agreement	(147,880)	-
Research and development tax incentive receivable	(108,097)	-
Prepaid assets and other current assets	237,646	534,612
Accounts payable	192,211	521,114
Accrued compensation	(416,910)	-
Deferred revenue	118,000	(24,315)
Net cash used in operating activities	(7,246,302)	(5,591,254)
Cash flows from investing activities:		
Purchases of property and equipment	(137,231)	(476,128)
Net cash used in investing activities	(137,231)	(476,128)
Cash flows from financing activities:		
Net proceeds from issuance of common stock	-	28,023,564
Proceeds from issuance of common stock for stock option exercises	-	655,253
Proceeds from issuance of common stock for warrant exercises	-	180,212
Net cash provided by financing activities	-	28,859,029
Effect of exchange rate changes on cash and cash equivalents	3,031	(37,330)
Net change in cash and cash equivalents	(7,380,502)	22,754,317
Cash and cash equivalents at beginning of period	33,794,672	35,300,805
Cash and cash equivalents at end of period	$ 26,414,170	$ 58,055,122
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of equipment included in accounts payable	$ 338,674	$ -
Cashless exercise of warrants	$ -	$ 416

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

TFF PHARMACEUTICALS, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
For The Three Months Ended March 31, 2022 and 2021

NOTE 1 – ORGANIZATION AND DESCRIPTION OF BUSINESS

TFF Pharmaceuticals, Inc. (the "Company") was incorporated in the State of Delaware on January 24, 2018. 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 and the human clinical trials of its initial product candidates.

COVID-19

As of the date of this report, the COVID-19 pandemic has had a relatively insignificant impact on the Company's operations and has not caused the Company to forego, abandon or materially delay any proposed activities. While the Company believes it has been able to effectively manage the disruption caused by the COVID-19 pandemic to date, there can be no assurance that its operations, including the development of its drug candidates, will not be disrupted or materially adversely affected in the future by the COVID-19 pandemic or an epidemic or outbreak of an infectious disease like the outbreak of COVID-19.

NOTE 2 - LIQUIDITY AND MANAGEMENT'S PLANS

As of March 31, 2022, the Company had cash and cash equivalents of approximately $26,414,000 and a working capital of approximately $29,327,000. The Company has not generated revenues from commercial operations 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 continue the pursuit of its product development.

The Company expects to further increase its research and development activities, which will increase the amount of cash utilized subsequent to March 31, 2022. 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. If the Company encounters unforeseen delays or expenses, it has the ability to curtail our presently planned level of operations. 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 March 31, 2022 and the results of operations, changes in stockholders' equity and cash flows for the periods presented. The results of operations for the three months ended March 31, 2022 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, 2021.

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 loss.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, continued

Cash and Cash Equivalents

The Company maintains its operating accounts in financial institutions in the U.S. and in Australia. The balances are insured 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. As of March 31, 2022 and December 31, 2021, the Company had cash in Australia of AUD$308,824 (US$231,447) and AUD$831,984 (US$604,944), respectively.

Revenue Recognition

The Company has entered into feasibility and material transfer agreements ("Feasibility Agreements") with third parties that provide the Company with funds in return for certain research and development activities. Revenue from the Feasibility Agreements is recognized in the period during which the related qualifying services are rendered and costs are incurred, provided that the applicable conditions under the Feasibility Agreements have been met.

The Feasibility Agreements are on a best-effort basis and do not require scientific achievement as a performance obligation. All fees received under the Feasibility Agreements are non-refundable. The costs associated with the Feasibility Agreements are expensed as incurred and are reflected as a component of research and development expense in the accompanying condensed consolidated statements of operations.

Funds received from the Feasibility Agreements are recorded as revenue as the Company is the principal participant in the arrangement because the activities under the Feasibility Agreements are part of the Company's development programs. In those instances where the Company first receives consideration in advance of providing underlying services, the Company classifies such consideration as deferred revenue until (or as) the Company provides the underlying services. In those instances where the Company first provides the underlying services prior to its receipt of consideration, the Company records a grant receivable. During the three months ended March 31, 2022 and 2021, the Company rendered the related services and recognized revenue and research and development expenses of $67,435 and $24,315, respectively. As of March 31, 2022 and December 31, 2021, the Company had receivables due related to Feasibility Agreements of $55,435 and $11,996, respectively, which is included in prepaid assets and other current assets in the accompanying condensed consolidated balance sheets, and deferred grant revenue of approximately $168,000 and $50,000, respectively.

Collaborative Arrangements

The Company considers the nature and contractual terms of arrangements and assesses whether an arrangement involves a joint operating activity pursuant to which the Company is an active participant and is exposed to significant risks and rewards dependent on the commercial success of the activity. If the Company is an active participant and is exposed to significant risks and rewards dependent on the commercial success of the activity, the

Company accounts for such arrangement as a collaborative arrangement under Accounting Standards Codification ("ASC") 808, *Collaborative Arrangements*. ASC 808 describes arrangements within its scope and considerations surrounding presentation and disclosure, with recognition matters subjected to other authoritative guidance, in certain cases by analogy.

For arrangements determined to be within the scope of ASC 808 where a collaborative partner is not a customer for certain research and development activities, the Company accounts for payments received for the reimbursement of research and development costs as a contra-expense in the period such expenses are incurred. This reflects the joint risk sharing nature of these activities within a collaborative arrangement. The Company classifies payments owed or receivables recorded as other current liabilities or prepaid expenses and other current assets, respectively, in the Company's consolidated balance sheets. Please refer to Note 5, "Joint Development Agreement" for additional details regarding the Company's joint development agreement ("JDA") with Augmenta Bioworks, Inc. ("Augmenta").

If payments from the collaborative partner to the Company represent consideration from a customer in exchange for distinct goods and services provided, then the Company accounts for those payments within the scope of ASC 606, *Revenue from Contracts with Customers*. The Company does not currently have any collaborative arrangements that are accounted for under ASC 606.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, continued

Research and Development Tax Incentive

The Company is eligible to obtain a cash refund from the Australian Taxation Office for eligible research and development expenditures under the Australian R&D Tax Incentive Program (the "Australian Tax Incentive"). The Company recognizes the Australian Tax Incentive when there is reasonable assurance that the cash refund will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured. During the year ended December 31, 2021, the Company received its first cash refund under the Australian Tax Incentive, which was for expenditures incurred during 2020. Therefore, the Company recorded amounts received, or that it expects to receive, for expenditures incurred during 2020 as other income in the condensed consolidated statements of operations during the period ended March 31, 2021.

As the Company has determined that it has reasonable assurance that it will receive the cash refund for eligible research and development expenditures, beginning with expenditures incurred during the year ended December 31, 2021, the Company records the Australian Tax Incentive as a reduction to research and development expenses as the Australian Tax Incentive is not dependent on the Company generating future taxable income, the Company's ongoing tax status, or tax position. At each period end, management estimates the refundable tax offset available to the Company based on available information at the time. This percentage of eligible research and development expenses reimbursable under the Australian Tax Incentive is 43.5% for the three months ended March 31, 2022 and 2021. In addition, the Company is also eligible to receive amounts from the United States Internal Revenue Service ("IRS") related to research and development tax credits for expenditures.

The research and development incentive receivable represents amounts due in connection with the Australian Tax Incentive and from the IRS. The Company has recorded a research and development tax incentive receivable of $1,168,830 and $966,646 as of March 31, 2022 and December 31, 2021, respectively, in the condensed consolidated balance sheets. The Company has recorded other income of $57,177 and $231,278, in the condensed consolidated statements of operations for the three months ended March 31, 2022 and 2021, respectively, related to refundable

IRS and Australian research and development incentive program payments for expenditures incurred during 2020. The Company recorded a reduction to research and development expenses of $108,098 during the three months ended March 31, 2022 for expenditures incurred during 2022 and $0 during the three months ended March 31, 2021 for expenditures incurred during 2021.

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.

For the three months ended March 31, 2022 and 2021, 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:

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Stock Options	2,976,090	2,375,839
Warrants	389,233	389,233
	3,365,323	2,765,072

* *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

There have been no recent accounting pronouncements, changes in accounting pronouncements or recently adopted accounting guidance during the three months ended March 31, 2022 that are of significance or potential significance to the Company.

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 expires on October 31, 2022, as amended. 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. The Company rents another office space on a month-to-month basis with no long-term commitment, which is considered a short-term lease as well. Short-term lease expense for the three months ended March 31, 2022 and 2021 was approximately $21,000 and $15,000, respectively.

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

	Amount
Year Ending December 31, 2022	$ 21,000

Legal

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

NOTE 5 - LICENSE AND AGREEMENTS

In July 2015, the University of Texas at Austin ("UT") granted to the Company's former parent, LTI, an exclusive worldwide, royalty bearing license to the patent rights for the TFF platform in all fields of use, other than vaccines for which LTI received a non-exclusive worldwide, royalty bearing license to the patent rights for the TFF platform. In March 2018, LTI completed an assignment to the Company all of its interest to the TFF platform, including the patent license agreement with UT, at which time the Company paid UT an assignment fee of $100,000 in accordance with the patent license agreement. In November 2018, the Company and UT entered into an amendment to the patent license agreement pursuant to which, among other things, the Company's exclusive patent rights to the TFF platform were expanded to all fields of use. The patent license agreement requires the Company to pay royalties and milestone payments and conform to a variety of covenants and agreements, and in the event of the Company's breach of agreement, UT may elect to terminate the agreement. For the period ended December 31, 2018, the Company did not achieve any of the milestones and, as such, was not required to make any milestone payments. During the ended December 31, 2019, the Company achieved one milestone by gaining IND approval on first indication of a licensed product on November 24, 2019 and the Company satisfied the milestone payment of $50,000 and issuance of shares in accordance with the agreement. 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. In January 2019, the Company cancelled all of the individual study contracts with ITR and entered into contracts with 11036114 Canada Inc. (initially dba VJO Non-Clinical Development and now dba Strategy Point Innovations ("SPI")) and 11035835 Canada Inc., (dba Periscope Research) 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 and others under substantially the same terms as the initial contract with ITR. Desire Ventures, LLC facilitates the invoicing for the various affiliates. The accounts payable due in connection with this agreement was approximately $472,000 and $0 as of March 31, 2022 and December 31, 2021, respectively. During the three months ended March 31, 2022 and 2021, the Company recorded research and development costs of approximately $1,585,000 and $1,812,000, respectively, pertaining to this agreement.

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 accounts payable

due in connection with this agreement was approximately $35,000 and $21,000 as of March 31, 2022 and December 31, 2021, respectively. During the three months ended March 31, 2022 and 2021, the Company recorded research and development costs of approximately $446,000 and $494,000, respectively, pertaining to this agreement.

NOTE 5 - LICENSE AND AGREEMENTS, continued

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 accounts payable due in connection with this agreement was approximately AUD$179,000 (US$134,000) and AUD$138,000 (US$100,000) as of March 31, 2022 and December 31, 2021, respectively. During the three months ended March 31, 2022 and 2021, the Company recorded research and development costs of approximately AUD$347,000 (US$251,000) and AUD$705,000 (US$545,000), respectively, pertaining to this agreement.

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 accounts payable due in connection with this agreement was approximately $0 and AUD$161,000 (US$117,000) as of March 31, 2022 and December 31, 2021, respectively. During the three months ended March 31, 2022 and 2021, the Company recorded research and development costs of approximately $0 and AUD$244,000 (US$188,000), respectively, pertaining to this agreement.

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.

In January 2021, the Company entered into a master services agreement with Experic to provide contract manufacturing services for one of the Company's drug product candidates, Voriconazole. The accounts payable due in connection with this agreement was approximately $87,000 and $313,000 as of March 31, 2022 and December 31, 2021, respectively. During the three months ended March 31, 2022 and 2021, the Company recorded research and development costs of approximately $318,000 and $196,000, respectively, pertaining to this agreement.

In January 2022, the Company entered into a Letter of Intent with Synteract, Inc. to provide contract research and development services while negotiating a Master Services Agreement for one of the Company's drug product candidates, Voriconazole. The accounts payable due in connection with this agreement was approximately $14,000 as of March 31, 2022. During the three months ended March 31, 2022, the Company recorded research and development costs of approximately $226,000 pertaining to this agreement.

Joint Development Agreement

On November 2, 2020, the Company and Augmenta entered into the JDA pursuant to which the Company and Augmenta (collectively the "Parties") agreed to work jointly to develop one or more novel commercial products incorporating Augmenta's human derived monoclonal antibody for the treatment of patients with COVID-19 and the Company's patented Thin Film Freezing technology platform. Each party retains full ownership over its existing assets.

The Parties will share development costs with each party funding its fifty-percent-share at specified times. In the event that one of the Parties fails to make its pro rata share payment, the other party may terminate the JDA. In lieu of terminating the JDA, the non-defaulting party may elect to continue the JDA by paying the delinquent amount and each party's pro rata share of the JDA will automatically adjust by the amount paid. In addition, in the event Augmenta experiences a default on its required payment, Augmenta will have the one-time right to elect to require the Company to purchase Augmenta's interest in the JDA ("Put Right") for a one-time fee of $500,000. Upon exercise of the Put Right and payment by the Company, Augmenta will grant the Company an exclusive, worldwide, royalty-free, transferable, sublicensable license to the Augmenta antibody and Augmenta's rights to the property developed under the JDA. The Company has determined that the likelihood of the Put Right being exercised to be remote.

The JDA is within the scope of ASC 808 as the Company and Augmenta are both active participants in the research and development activities and are exposed to significant risks and rewards that are dependent on commercial success of the activities of the arrangement. The research and development activities are a unit of account under the scope of ASC 808 and are not promises to a customer under the scope of ASC 606.

The Company records its portion of the research and development expenses as the related expenses are incurred. All payments received or amounts due from Augmenta for reimbursement of shared costs are accounted for as an offset to research and development expense. During the three months ended March 31, 2022 and 2021, the Company recorded research and development expenses of $147,880 and $76,200, respectively, and has recorded a receivable of $1,776,583 and $1,628,703 for reimbursement due from Augmenta as of March 31, 2022 and December 31, 2021, respectively.

NOTE 6 – 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.

In September 2021, the Company's board of directors approved its 2021 Stock Incentive Plan ("2021 Plan"), which was also approved by the stockholders of the Company at the Company's annual meeting of stockholders held on November 4, 2021. The 2021 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 has 4,200,000 shares of its common stock reserved under the 2021

Plan. 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 2021 Plan.

The following table summarizes the stock-based compensation expense recorded in the Company's results of operations during the three months ended March 31, 2022 and 2021 for stock options and warrants:

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Research and development	$ 205,809	$ 67,279
General and administrative	971,893	963,136
	$ 1,177,702	$ 1,030,415

As of March 31, 2022, there was approximately $8,135,000 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 2.4 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:

	Three Months March 31, 2022
Weighted average exercise price	$ 6.90
Weighted average grant date fair value	$ 5.20
Assumptions	
Expected volatility	96%-97%
Expected term (in years)	6.3
Risk-free interest rate	1.79%-2.41%
Expected dividend yield	0.00%

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

NOTE 6 – STOCK BASED COMPENSATION, continued

The following table summarizes stock option activity during the three months ended March 31, 2022:

	Number of Shares	Weighted-Average Exercise Prices	Weighted-Average Remaining Contractual Term (In Years)	Intrinsic Value
Outstanding at January 1, 2022	2,893,839	$ 6.48	8.05	$ 9,932,413
Granted	100,000	6.90	—	—
Cancelled	(17,749)	11.09	—	—
Outstanding at March 31, 2022	2,976,090	$ 6.47	7.87	$ 4,435,685
Exercisable at March 31, 2022	1,411,441	$ 5.00	7.24	$ 3,196,095

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had strike prices lower than the fair value of the Company's common stock.

Option Modification

Effective March 21, 2022, one of the members of the Company's board of directors, Dr. Brian Windsor, resigned. As part of his resignation from the board of directors, modifications were made to Dr. Windsor's vested and non-vested stock option awards including acceleration of certain non-vested option awards and the extension of the post-termination exercise period of certain stock option awards. During the three months ended March 31, 2022, in accordance with ASC Topic 718, *Compensation—Stock Compensation,* the Company recorded a one-time, non-cash incremental compensation expense net of the required reversal of previously recognized compensation attributed to non-vested shares in the amount of approximately $339,000, which is included in general and administrative expense in the accompanying condensed consolidated statements of operations.

NOTE 7 – SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to March 31, 2022 through the filing date of this Quarterly Report. Based on its evaluation, there are no events that need to be disclosed.

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 2021 Annual Report on Form 10-K filed with the SEC on March 24, 2022.

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 2021 Annual Report on Form 10-K filed with the SEC on March 24, 2022. 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 increase the pharmacokinetic effect of the drug to a level allowing for its development and commercialization.

As of the date of this report, we have three product candidates under development, TFF Voriconazole Inhalation Powder, or TFF Vori; TFF Tacrolimus Inhalation Powder, or TFF Tac-Lac; and TFF Niclosamide Inhalation Powder, or TFF Niclo. In July 2020, we completed Phase I human clinical trials of our lead product, TFF Vori, and completed the enrollment of a Phase 1b clinical trial of TFF Vori in asthma patients in December 2021. Dosing of TFF Vori in patients with invasive pulmonary aspergillosis in a Phase 2 clinical trial is expected to begin in 2022. Dosing of a patient in a Compassionate Use Study commenced in the first quarter of 2022 for a lung transplant patient with a pulmonary fungal infection. In September 2021, we completed Phase 1 human clinical trials of our TFF Tac-Lac product in Australia. Dosing of TFF Tac-Lac in lung transplant patients in a Phase 2 clinical trial is expected to begin in 2022. In November 2021, we commenced dosing of TFF Niclosamide in a Phase 1 human clinical trial in Canada and completed dosing the Phase 1 trial in January 2022. 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 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 engaged in the joint development of an inhaled SARS-CoV2 Monoclonal Antibody in collaboration with Augmenta BioWorks and a dry powder formulation of niclosamide in collaboration agreement with UNION therapeutics A/S. We are also actively engaged in the analysis and testing of dry powder formulations of several drugs and vaccines through topical, ocular and nasal applications pursuant to feasibility studies and material transfer agreements with U.S. and international pharmaceutical companies and certain government agencies.

We intend to initially focus on the development of inhaled dry powder drugs for the treatment of pulmonary diseases and conditions. While the TFF platform was designed to improve solubility of poorly water-soluble drugs generally, the researchers at University of Texas at Austin, or UT, found that the technology was

particularly useful in generating dry powder particles with properties which allow for superior inhalation delivery, especially to the deep lung, which is an area of extreme interest in respiratory medicine. We believe that our TFF platform can significantly increase the number of pulmonary drug products that can be delivered by way of breath-actuated inhalers, which are generally considered to be the most effective and patient-friendly means of delivering medication directly to the lungs. Our dry powder drug products will be designed for use with dry powder inhalers, which are generally considered to be the most effective of all breath-actuated inhalers. We plan to focus on developing inhaled dry powder formulations of existing off-patent drugs intended for lung diseases and conditions, which we believe includes dozens of potential drug candidates, many of which have a potential market ranging from $100 million to over $500 million.

We 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 and prevent 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 product and initiated our Phase I human clinical trials in November 2019. In July 2020, we completed Phase I human clinical trials of TFF Vori, and completed the enrollment of a Phase 1b clinical trial of TFF Vori in asthma patients in December 2021. Dosing of TFF Vori in patients with invasive pulmonary aspergillosis in a Phase 2 clinical trial is expected to begin in 2022. 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 acute and 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 that are required for effective immunosuppression in the lung. 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. In September 2021, we completed Phase 1 human clinical trials of our TFF Tac-Lac product in Australia. As of the date of this report, dosing of TFF Tac-Lac in lung transplant patients in a Phase 2 clinical trial is expected to begin in 2022, and we intend to submit to the FDA an IND for TFF Tac-Lac in 2022.

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, including the UK B.1.1.7 and South African B.1.351 variants. 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. Orally 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 In November 2021, we commenced dosing of TFF Niclosamide in a Phase 1 human clinical trial in Canada and completed dosing subjects in the Phase 1 trial in January 2022.

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. Furthermore, TFF has evaluated formulation and delivery of vaccines that do not contain aluminum salts and reported positive animal data for a universal influenza candidate vaccine formulation in collaboration with the University of Georgia. In addition, TFF and USAMRIID have a CRADA agreement to evaluate monoclonal antibody vaccines to prevent a number of viral infections. We are also collaborating with Albert Einstein College of Medicine on certain VSV vaccine candidates.

As of the date of this report, we intend to focus on the development of dry powder formulations of CBD and salt containing vaccines in partnership with pharmaceutical companies. Our intent is for TFF to be involved

only through performance characterization of the formulations and early animal efficacy trials. Beyond that work, if successful, we will transfer further development and commercialization responsibility to the partner as part of a negotiated licensing transaction.

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. These efforts have resulted in refinement of specific formulations that we believe could achieve a positive position in the marketplace.

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.

Based on the February 2019 pre-Investigational New Drug Application, or IND, meeting with the FDA, and a March 2022 post-Phase 1 meeting with the FDA concerning TFF Vori, we believe we will need to conduct one Phase 2 study and may need a second Phase 2 or a Phase 2b/3a study prior to filing for marketing approval for TFF Vori. Concerning TFF Tac-Lac, based on a pre-IND meeting with the FDA, we believe we will need to conduct Phase 1 and Phase 2b/3a 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, such as designated for TFF Tac-Lac. 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.

We were incorporated under the laws of the state of Delaware on January 24, 2018. Our principal executive offices are located at 1751 River Run, Suite 400, Fort Worth, Texas 76107 and our telephone number is (817) 438-6168. 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 and Phase 1 human clinical trials of our initial product candidates.

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

As of the date of this report, the COVID-19 pandemic has had a relatively insignificant impact on our operations and has not caused us to forego, abandon or materially delay any proposed activities. While we believe we have been able to effectively manage the disruption caused by the COVID-19 pandemic to date, there can be no assurance that our operations, including the development of our drug candidates, will not be disrupted or materially adversely affected in the future by the COVID-19 pandemic or an epidemic or outbreak of an infectious disease like the outbreak of COVID-19.

The following table summarizes our results of operations with respect to the items set forth below for the three months ended March 31, 2022 and 2021 together with the percentage change for those items.

	Three months ended March 31,			
	2022	2021	Favorable (Unfavorable)	Change
Grant revenue	$ 67,435	$ 24,315	$ 43,120	177%
Research and development expense	$ 5,261,604	$ 5,278,252	$ 16,648	0%
General and administrative expense	3,246,195	2,647,415	(598,780)	(23)%
Total operating expense	$ 8,507,799	$ 7,925,667	$ (582,132)	(7)%

We have entered into feasibility and material transfer agreements with third parties that provide us with funds in return for certain research and development activities. During the three months ended March 31, 2022 and 2021, we recognized $67,435 and $24,315, respectively, of grant revenue.

During the three months ended March 31, 2022 and 2021, we incurred $5.3 million and $5.3 million of research and development expenses and $3.2 million and $2.6 million of general and administrative expenses, respectively. The change in research and development expenses during 2022 was mainly due to increased manufacturing costs of approximately $299,000, which includes approximately $72,000 related to the Augmenta monoclonal antibody, clinical expenses of approximately $990,000 related to Niclosamide, TFF Vori and TFF Tac-Lac, payroll and related expense of approximately $292,000 and stock-based compensation of approximately $139,000, offset by a decrease in preclinical expenses of approximately $1.8 million. The change in research and development expenses also includes our preliminary analysis and testing of dry powder formulations of several drugs and vaccines owned or licensed by third parties we believe may lead to the out-licensing of our TFF technology for the development of dry powder product candidates. We expect our spending on research and development activities to increase in upcoming quarters due primarily to clinical trial activity.

The increase in general and administrative expenses in 2022 from the prior year was mainly a result of increases in insurance and investor relation expenses of approximately $523,000 and payroll and related expenses of approximately $90,000, offset by decreased consulting and business development expenses of approximately $148,000. While we expect our general and administrative expenses to continue to increase over the next few years, we anticipate the rate of increase has begun to decrease.

The following table summarizes our other income and interest income for the three months ended March 31, 2022 and 2021 together with the percentage change for those items.

	Three months ended March 31,	
		Favorable

	2022	2021	(Unfavorable)	Change
Other income	$ 57,177	$ 231,278	$ (174,101)	(75)%
Interest income	$ 7,185	$ 15,499	$ (8,314)	(54)%

Other income consists of refundable United States Internal Revenue Services and Australian research and development incentive program payments for expenditures incurred during 2020. Interest income decreased during fiscal 2022 due to lower balances in interest-bearing accounts.

We incurred a net loss of $8.4 million and $7.7 million for the three months ended March 31, 2022 and 2021, respectively.

Financial Condition

As of March 31, 2022, we had total assets of approximately $33.8 million and working capital of approximately $29.3 million. As of March 31, 2022, our liquidity included approximately $26.4 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. If we encounter unforeseen delays or expenses, we may require additional capital in order to fund our current level of ongoing costs over the next twelve months. 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.

Critical Accounting Policies

During the three months ended March 31, 2022, there were no material changes to our critical accounting policies previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates. There were no material changes to our critical accounting estimates as reported in our Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the SEC on March 24, 2022.

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 March 31, 2022.

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 March 31, 2022 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 2021 Annual Report on Form 10-K filed with the SEC on March 24, 2022 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 2021 Annual Report on Form 10-K. The risk factors described in our 2021 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 5. Other Information.

On May 9, 2022, we entered into an Amended and Restated Patent License Agreement, or the Amended PLA, with University of Texas at Austin, or UT. The Amended PLA is an amendment to the Patent License Agreement, or the Original PLA, originally entered into in July 2015 and pursuant to which we hold the exclusive rights to approximately 127 patents held by UT concerning the TFF technology. We initiated the discussions leading to the Amended PLA for purposes of strengthening our licensed rights to the TFF technology and patents held by UT. The principal changes to the Original PLA made by way of the Amended PLA are to:

Grant us the exclusive license rights to any future UT patents relating to the TFF technology;

Grant us the license rights to the know-how developed by UT concerning the TFF technology; and

Allow us to assign the Amended PLA, without the consent of UT, in the event of a sale of our company.

Except as set forth above, the material terms of the Original PLA remain unchanged and in effect.

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	Amended and Restated Patent License Agreement dated April 20, 2022 between the Registrant and The University of Texas at Austin	Filed electronically herewith
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	Inline XBRL Instance Document	Filed electronically herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	Filed electronically herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed electronically herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed electronically herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed electronically herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed electronically herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	

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: May 11, 2022

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

Date: May 11, 2022

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