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 Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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.

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,			
	2022	2021	Favorable (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)

AMENDED AND RESTATED PATENT LICENSE AGREEMENT
AGREEMENT No. PM 2202501

This Amended and Restated Patent License Agreement (the "Patent License Agreement") is made and entered into as of April 20, 2022 ("Amendment Effective Date") by and between TFF Pharmaceuticals, Inc. ("Licensee") and The University of Texas at Austin, on behalf of the Board of Regents of the University of Texas System ("Licensor"), an agency of the State of Texas (collectively referred to as "**Parties**" or separately as "**Party**").

The Licensor and Lung Therapeutics, Inc. entered into a Patent License Agreement (UTA Agreement No. PM1504101-A) with an Effective Date of July 8, 2015, which was assigned by Lung Therapeutics, Inc. to Licensee on January 24, 2018 and consented to by Licensor on March 9, 2018, and was amended by Amendment #1 to the Patent License Agreement with an effective date of November 30, 2018, by Amendment # 2 to the Patent License Agreement with an effective date of September 6, 2019, by Amendment #3 to the Patent License Agreement with an effective date of May 5, 2020, by Amendment #4 to the Patent License Agreement with an effective date of June 12, 2020, by Amendment #5 to the Patent License Agreement with an effective date of July 27, 2020, and further amended by Amendment #6 to the Patent License Agreement with an effective date of November 13, 2020 (as amended, the "Original Patent License Agreement").

The Licensor and Licensee entered into a second Patent License Agreement (UTA Agreement No. PM1908501) with an Effective Date of August 30, 2019.

The Parties now wish to further amend the Original Patent License Agreement as set forth below and terminate the UTA Agreement No. PM1908501. UTA Agreement PM1908501 terminates automatically upon execution of this Patent License Agreement.

No new binding agreement between the Parties will exist until this Patent License Agreement has been signed by all Parties. Unsigned drafts of this Patent License Agreement shall not be considered offers.

Now, therefore, in consideration of the mutual covenants and premises herein contained, the Parties hereby amend and restate the Original Patent License Agreement in its entirety as follows:

Background

Licensor owns or controls Patent Rights. Licensee desires to secure the right and license to use, develop, manufacture, market, and commercialize the TFF Technology. Licensor has determined that such use, development, and commercialization of the TFF Technology is in the public's best interest and is consistent with Licensor's educational and research missions and goals. Licensor desires to have the Patent Rights developed and used for the benefit of Licensee, the inventors, Licensor, and the public.

The Terms and Conditions of Patent License attached hereto as Exhibit A are incorporated herein by reference in their entirety (the "Terms and Conditions"). In the event of a conflict between provisions of this Patent License Agreement and the Terms and Conditions, the provisions in this Patent License Agreement shall govern. Unless defined in this Patent License Agreement, capitalized terms used in this Patent License Agreement shall have the meanings given to them in the Terms and Conditions.

The section numbers used in the left hand column in the table below correspond to the section numbers in the Terms and Conditions.

1. Definitions

	Effective Date	Date of last signature
	Licensor	The University of Texas at Austin, on behalf of the Board of Regents of the University of Texas System, an agency of the State of Texas, whose address is 3925 W. Braker Lane, Suite 1.9A (R3500), Austin, Texas 78759.
	Licensee	TFF Pharmaceuticals, Inc., a Delaware Corporation, with its principal place of business at 1751 River Run, Suite 400, Fort Worth, Texas 76107.
	Contract Year and Contract Quarters	Contract Year is 12-month period ending on December 31 and Contract Quarters are 3-month periods ending on March 31, June 30, Sept. 30, Dec. 31.
	Territory	Worldwide
	Field	All fields
	Patent Rights	(See Exhibit B)
	TFF Technology	Thin film freezing or ultra rapid freezing technology that cannot be practiced without infringing any issued patents listed in Patent Rights.
	Know-how	Information and materials, including protocols, methods, processes, techniques, devices, models, designs, libraries and trade secrets owned by Licensor that (a) are necessary or advantageous for use in commercializing the technology described in the Patent Rights; and (b) University is not legally prevented from licensing; and (c) are either (1) developed pursuant to the Sponsored Research Agreement in the lab of Dr. Robert O. Williams III at the University of Texas at Austin, or (2) are learned or developed in the labs of Dr. Robert O. Williams III or Dr. Zhengrong Cui at the University of Texas at Austin or any successor lab.
	Mandatory Sublicensing	None
	USPTO Entity Status as of Effective Date	Check one box: ☒ Small ☐ Large

2.4. Diligence Milestones

	Milestones and deadlines	**Milestone Events**	**Deadlines**
		1. Receive $14 million in aggregate financing.	Complete
		2. Enter into a sponsored research agreement with the lab of Dr. Robert O. Williams III for $129,000.	Complete
		3. Enter into a sponsored research agreement with the lab of Dr. Robert O. Williams III for $200,000 with a start date after May 1, 2019.	Complete
		4. IND submission for TFF-VORI Licensed Product.	Complete
		5. Enter into a sponsored research agreement with the lab of Dr. Robert O. Williams III for $200,000, with a start date after May 1, 2020.	Complete
		6. Enroll first patient in Phase I FDA clinical trial for TFF-TAC Licensed Product.	Complete
		7. Enroll first patient in Phase II FDA clinical trial for TFF-VORI Licensed Product.	December 31, 2022
		8. Fund least $200,000 in research in the lab of Dr. Robert O. Williams III in the period between October 1, 2021 and December 31, 2022 under the Sponsored Research Agreement.	December 31, 2022
		9. Enroll first patient in Phase III FDA clinical trial for TFF-VORI Licensed Product.	December 31, 2023
		10. FDA regulatory approval for TFF-VORI Licensed Product.	December 31, 2025

3. Compensation

3.1(a)	**Milestone Fees**	**Milestone Events**	**Milestone Fees**
		IND Approval on first indication of Licensed Product.	$50,000 (paid)
		Submit IND (or foreign equivalent) on a first indication for a thin film freezing vaccine Licensed Product	$50,000
		Enroll first patient in Phase II clinical trial for first Licensed Product (FDA or foreign equivalent).	$100,000
		Enroll first patient in a Phase II clinical trial for a TFF-Vaccine Licensed Product (FDA or foreign equivalent)	$100,000
		Enroll first patient in Phase III clinical trial for first Licensed Product (FDA or foreign equivalent).	$250,000
		Enroll first patient in Phase III clinical trial for a thin film freezing vaccine Licensed Product (FDA or foreign equivalent).	$250,000
		Regulatory approval for a thin film freezing vaccine Licensed Product (FDA or foreign equivalent).	$250,000
		Regulatory approval for first Licensed Product (FDA or foreign equivalent).	$500,000
		Regulatory approval for second Licensed Product or second indication of first Licensed Product (FDA or foreign equivalent).	$500,000
3.1(b)	**Sublicense Fees**	7.5% of Non-Royalty Sublicense Consideration from a Sublicense Agreement executed before FDA regulatory approval of Licensed Product. 5% of Non-Royalty Sublicense Consideration from a Sublicense Agreement executed after FDA Regulatory approval of Licensed Product.	
3.2	**Running royalty rate (applies to Net Sales by Licensee, Affiliates and Sublicensees)**	2%	

18. Contact Information

	Licensee Contacts	**Licensor Contacts**
	Contact for Notice: Attn: Glenn Mattes 1751 River Run, Suite 400, Fort Worth, Texas 76107 Phone: 215-880-2632 E-mail: gmattes@tffpharma.com Accounting contact: Attn: Kirk Coleman 1751 River Run, Suite 400, Fort Worth, Texas 76107 Fax: N/A Phone: 817-989-6358 E-mail: kcoleman@tffpharma.com Patent prosecution contact: Attn: Kirk Coleman 1751 River Run, Suite 400, Fort Worth, Texas 76107 Fax: N/A Phone: 817-989-6358 E-mail: kcoleman@tffpharma.com Attn: Chris Cano 1751 River Run, Suite 400, Fort Worth, Texas 76107 Fax: N/A Phone: 609.933.3938 E-mail: ccano@tffpharma.com	Contact for Notice: Attn: Contract Manager 3925 W. Braker Lane, Suite 1.9A (R3500) Austin, TX 78759 Fax: 512.475.6894 Phone: 512.471.2995 E-mail: licensing@otc.utexas.edu Payment and reporting contact: Checks payable to “The University of Texas at Austin” Attn: Accounting/Compliance 3925 W. Braker Lane, Suite 1.9A (R3500) Austin, TX 78759 Fax: 512.475.6894 Phone: 512.471.2995 E-mail: accounting@otc.utexas.edu; compliance@otc.utexas.edu Patent prosecution contact: Attn: Patents 3925 W. Braker Lane, Suite 1.9A (R3500) Austin, TX 78759 Fax: 512.475.6894 Phone: 512.471.2995 E-mail: patents@otc.utexas.edu

20. Related Future Intellectual Property.

If Licensor receives an invention disclosure for an invention (i) developed pursuant to the Sponsored Research Agreement in the lab of Dr. Robert O. Williams III at the University of Texas at Austin, or (ii) that is jointly owned by Licensor and TFF Pharmaceuticals, Inc., or (iii) that could not be practiced without a license to any issued or pending claim within the Patent Rights, or (iv) that is developed in the lab of Dr. Robert O. Williams III at the University of Texas at Austin and directly related to thin film freezing or ultra rapid freezing technology, then Licensor shall provide a copy of such disclosure to Licensee for review, subject to the terms of the Sponsored Research Agreement, if applicable, and appropriate confidentiality restrictions.

After receiving such a disclosure, Licensee shall have thirty (30) days ("**Election Period**") to provide written notice to University of Licensee's election to add Board's rights to such disclosed invention(s) to Patent Rights under this Agreement. If Licensee elects to add such disclosed invention, Licensor, provided that it is not legally prevented from doing so, shall provide Licensee with an executable amendment to this Agreement to add Board's rights to such disclosed invention(s) to the Patent Rights under this Agreement, and all other terms of this Agreement shall apply.

If Licensee does not elect to add the disclosed invention(s) within thirty (30) days, Licensor shall have no further obligation to Licensee with respect to such disclosed invention(s).

21. **No Other Promises and Agreements; Representation by Counsel**. Licensee expressly warrants and represents and does hereby state and represent that no promise or agreement which is not herein expressed has been made to Licensee in executing this Patent License Agreement except those explicitly set forth herein and in the Terms and Conditions, and that Licensee is not relying upon any statement or representation of Licensor or its representatives. Licensee is relying on Licensee's own judgment and has had the opportunity to be represented by legal counsel. Licensee hereby warrants and represents that Licensee understands and agrees to all terms and conditions set forth in this Patent License Agreement and said Terms and Conditions.

22. **Deadline for Execution by Licensee**. If this Patent License Agreement is executed first by the Licensor and is not executed by the Licensee and received by the Licensor at the address and in the manner set forth in Section 18 of the Terms and Conditions within 30 days of the date of signature set forth under the Licensor's signature below, then this Patent License Agreement shall be null and void and of no further effect.

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Patent License Agreement.

LICENSOR: THE UNIVERSITY OF TEXAS AT AUSTIN
ON BEHALF OF THE BOARD OF REGENTS OF THE
UNIVERSITY OF TEXAS SYSTEM

By: */s/ Les Nichols*
Les Nichols
Director, Office of Technology Commercialization
Date: May 9, 2022

LICENSEE: TFF Pharmaceuticals, Inc

By: /s/ Glenn Mattes
Glenn Mattes
CEO, TFF Pharmaceuticals, Inc.
Date: May 6, 2022

EXHIBIT A

Terms and Conditions of Patent License

These Terms and Conditions of Patent License ("Terms and Conditions") are incorporated by reference into the Patent License Agreement to which they are attached. All Section references in these Terms and Conditions shall be references to provisions in these Terms and Conditions unless explicitly stated otherwise.

1. Definitions

"**Affiliate**" means any business entity more than 50% owned by Licensee, any business entity which owns more than 50% of Licensee, or any business entity that is more than 50% owned by a business entity that owns more than 50% of Licensee.

"**Agreement**" means collectively (i) these Terms and Conditions, and (ii) the Patent License Agreement.

"**Contract Quarter**" means the three-month periods indicated as the Contract Quarter in Section 1 of the Patent License Agreement, or any stub period thereof at the commencement of the Agreement or the expiration or termination of the Agreement.

"**Contract Year**" means the 12-month periods indicated as the Contract Year in Section 1 of the Patent License Agreement, or any stub period thereof at the commencement of the Agreement or the expiration or termination of the Agreement.

"**Effective Date**" means the date indicated as the Effective Date in Section 1 of the Patent License Agreement.

"**Fair Market Value**" means the cash consideration an unaffiliated, unrelated buyer would pay in an arm's length sale of a substantially identical item sold in the same quantity, under the same terms, and at the same time and place.

"**Field**" means all fields.

"**Government**" means any agency, department or other unit of the United States of America or the State of Texas.

"**Gross Consideration**" means all cash and non-cash consideration (e.g., securities).

"**Licensed Process**" means a method or process whose practice or use is covered by a Valid Claim.

"**Licensed Product**" means any product or component (i) whose manufacture, use, sale, offer for sale or import is covered by any Valid Claim, or (ii) which is made using a Licensed Process or another Licensed Product.

"**Licensed Service**" means performance of a service for any consideration using a Licensed Product, or the practice of a Licensed Process. For clarity, research and development of Licensed Products by Licensee, its Affiliates, or a Sublicensee does not constitute a Licensed Service.

"**Licensee**" means the Party identified as the Licensee in Section 1 of the Patent License Agreement.

"**Licensor**" means the Party identified as the Licensor in Section 1 of the Patent License Agreement.

"**Milestone Fees**" means all fees identified as Milestone Fees in Section 3.1(a) of the Patent License Agreement.

"**Net Product Sales**" means the Gross Consideration from the Sale of Licensed Products less the following items directly attributable to the Sale of such Licensed Products that are specifically identified on the invoice for such Sale and borne by the Licensee, Affiliates, or Sublicensees as the seller: (a) discounts and rebates actually granted; (b) sales, value added, use and other taxes and government charges actually paid, excluding income taxes; (c) import and export duties actually paid; (d) freight, transport, packing and transit insurance charges actually paid or allowed; and (e) other amounts actually refunded, allowed or credited due to rejections or returns, but not exceeding the original invoiced amount.

Additionally, if Licensee, its Affiliates or Sublicensees use a Licensed Product or a Licensed Process for its own internal purposes or otherwise in a situation that does not involve a Sale for which a royalty is paid under Section 3.2, then Net Product Sales shall also include an amount equal to the customary sale price charged to a third party for the same Licensed Product or Licensed Process, except for a reasonable quantity used internally solely for testing or quality control purposes, marketing or demonstration purposes, or seeking governmental approval (e.g., U.S. Food and Drug Administration clinical trial). If there is no customary sale price, then the Net Product Sales shall be an amount equal to the Fair Market Value.

"**Net Sales**" means the total of Net Product Sales and Net Service Sales.

"**Net Service Sales**" means the Gross Consideration received from the Sale of Licensed Services less the following items, directly attributable to the Sale of such Licensed Services that are specifically identified on the invoice for such Sale and borne by the Licensee, Affiliates, or Sublicensees as the seller: (a) discounts and rebates actually granted; (b) sales, value added, use and other taxes and government charges actually paid, excluding income taxes; and (c) other amounts actually refunded, allowed or credited due to rejections or re-works, but not exceeding the original invoiced amount.

"**Non-Royalty Sublicensing Consideration**" means the Gross Consideration received by the Licensee or its Affiliate from a Sublicensee in consideration of the grant of a sublicense under the Patent Rights (including, without limitation, license or option or distribution fees, fees to maintain license rights, and bonus/milestone payments), but excluding amounts received as running royalties, a profit share, or other revenue sharing based on Net Product Sales or Net Service Sales for which Licensor receives a running royalty under Section 3.2. For the avoidance of doubt, Non-Royalty Sublicensing Consideration shall not include bona fide: (a) running royalties received by Licensee or an Affiliate based on Net Product Sales or Net Service Sales that are royalty-bearing to Licensor under Section 3.2, (b) purchase price for Licensee's stock or other securities not in excess of Fair Market Value, and (iii) amounts paid and used exclusively for research and development of Licensed Products or Licensed Services by Licensee.

"**Patent License Agreement**" means the particular Patent License Agreement to which these Terms and Conditions are attached and incorporated into by reference.

"**Patent Rights**" means the Licensor's rights in (a) the patents and patent applications listed in Section 1 of the Patent License Agreement; (b) all non-provisional patent applications that claim priority to any provisional application listed in Section 1 of the Patent License Agreement; and (c) all divisionals, continuations, and such claims of continuations-in-part as are entitled to claim priority to the aforesaid patents and/or patent applications, and all reissues, reexaminations, extensions of, and foreign counterparts; and (d) any patents that issue with respect to the aforesaid patent applications. From time to time during the term of the Agreement, upon written agreement by both parties, Licensee and Licensor shall update the list of all patent applications and patents within the Patent Rights.

"**Phase I**" means a human clinical trial of a Licensed Product, including the initial introduction into humans, the principal purpose of which is to obtain sufficient information about the Product's pharmacokinetics and pharmacological effects to permit the design of further clinical trials, and be generally consistent with 21 CFR § 312.21(a). Said trial may be conducted in any country.

"**Phase II**" means a human clinical trial of a Licensed Product the principal purpose of which is to make a preliminary determination that such Product is safe in a patient population for its intended use and to obtain sufficient information about such Product's efficacy to permit the design of further clinical trials, and be generally consistent with 21 CFR § 312.21(b). Said trial may be conducted in any country.

"**Phase III**" means a human clinical trial of a Licensed Product, which trial is designed to: (a) establish that a Licensed Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed; (c) support regulatory approval of such Licensed Product; and (d) be generally consistent with 21 CFR § 312.21(c). Said trial may be conducted in any country.

"**Prosecution Counsel**" means the law firm or attorney who is handling the prosecution of the Patent Rights. Prosecution Counsel as of the Effective Date is identified in Section 1 of the Patent License Agreement.

"**Quarterly Payment Deadline**" means the day that is 30 days after the last day of any particular Contract Quarter.

"**Regulatory Approval**" means the approval by the Regulatory Authority needed for a particular national jurisdiction to market, sell and use a Licensed Product in that national jurisdiction.

"**Regulatory Authority**" means the governmental authority responsible for granting any necessary licenses or approvals for the marketing, sale and use of a Licensed Product or Licensed Service in a particular national jurisdiction, including without limitation, the FDA, European Medicines Agency or Koseisho (i.e. the Japanese Ministry of Health and Welfare)

"**Sell, Sale or Sold**" means any transfer or other disposition of Licensed Products or Licensed Services for which consideration is received by Licensee, its Affiliates or Sublicensees. A Sale of Licensed Products or Licensed Services will be deemed completed at the time Licensee or its Affiliate or its Sublicensee receives such consideration.

"**Sponsored Research Agreement**" means that certain Sponsored Research Agreement UTA18-000556 dated May 17, 2018, as the same may be amended from time to time, between Licensor and Licensee.

"**Sublicense Agreement**" means any agreement or arrangement pursuant to which Licensee (or an Affiliate or Sublicensee) grants to any third party any license rights of Licensee under the Agreement.

"**Sublicense Fee**" means the fee specified in Section 3.1(b) of the Patent License Agreement.

"**Sublicensee**" means any entity to whom an express sublicense has been granted under the Patent Rights. For clarity, a third party wholesaler or distributor who has no significant responsibility for marketing and promotion of the Licensed Product or Licensed Services within its distribution territory or field (i.e., the third party simply functions as a reseller), and who does not pay any consideration to Licensee or an Affiliate for such wholesale or distributor rights, shall not be deemed a Sublicensee; and the resale by such a wholesaler or distributor shall not be treated as royalty bearing Net Sales by a Sublicensee provided that a royalty is being paid by Licensee for the initial transfer to the wholesaler or distributor pursuant to Section 3.2. This definition does not limit Licensee's rights to grant or authorize sublicenses under the Agreement.

"**Territory**" means the territory so indicated as the Territory in Section 1 of the Patent License Agreement.

"**Valid Claim**" means a claim of (i) an issued and unexpired patent included within the Patent Rights unless the claim has been held unenforceable or invalid by the final, un-reversed, and un-appealable decision of a court or other government body of competent jurisdiction, has been irretrievably abandoned or disclaimed, or has otherwise been finally admitted or determined to be invalid, un-patentable or unenforceable, whether through reissue, reexamination, disclaimer or otherwise, or (ii) a pending patent application within the Patent Rights to the extent the claim continues to be prosecuted in good faith.

2. License Grant and Commercialization

2.1 Grant

(a) Licensor grants to Licensee a royalty-bearing exclusive license under the Patent Rights to manufacture, have manufactured, distribute, have distributed, use, offer for Sale, Sell, lease, loan and/or import Licensed Products in the Field in the Territory and to perform Licensed Services in the Field in the Territory. Licensor grants to Licensee a non-exclusive royalty-bearing license under the Know-How to manufacture, have manufactured, offer for sale, sell, lease and/or import Licensed Products in the Licensed Field in the Licensed Territory.

(b) This grant is subject to (i) the payment by Licensee to Licensor of all consideration required under the Agreement, (ii) any rights of, or obligations to, the Government as set forth in Section 11.2 (Government Rights), and (iii) rights retained by Licensor to:

(2) Publish the scientific findings from research related to the Patent Rights in compliance with the confidentiality and pre-publication review provisions of any other agreements between the Parties;

(2) Make and use the technology claimed in the Patent Rights solely for non-commercial purposes limited to teaching, research, and education, except to the extent consented to by Licensee; and

(3) Grant rights to, and transfer material embodiments of, the Patent Rights to other academic institutions or non-profit research institutions for the purposes identified in clauses (1) and (2) above.

(c) Licensor reserves all rights not expressly granted in the Agreement and disclaims the grant of any implied rights to Licensee.

2.2 Affiliates

Licensee may extend the license granted herein to any Affiliate provided that the Affiliate agrees in writing to be bound by the Agreement to the same extent as Licensee.

2.3 Sublicensing

Licensee has the right to grant Sublicense Agreements under the Patent Rights and Know-how consistent with the terms of the Agreement, subject to the following:

(a) A Sublicense Agreement shall not exceed the scope and rights granted to Licensee hereunder.

(b) Sublicense Agreements shall be consistent with the terms and conditions of this Agreement, including, but not necessarily limited to;

(1) All payments, fees, and royalties under Section 3.1 and 3.2.

(2) Sublicensee's acknowledgment of the disclaimer of warranty and limitation on Licensor's liability, as provided by Section 11.3 and 12 below.

(3) Provisions under which the Sublicensee accepts duties at least equivalent to those accepted by the Licensee in the following Sections: Section 11.3 (Licensor Disclaimers); Section 12 (Limitation of Liability); Section 13 (Indemnification); Section 14.1 (Insurance Requirements); Section 17 (Use of Name); and Section 19.10 (Sovereign Immunity, if applicable).

(c) In the event of termination of the Agreement, continued sublicense rights shall be governed by Section 7.5(a) (Effect of Termination).

(d) Licensee may grant a Sublicensee the right to grant further sub-Sublicense Agreements, in which case such sub-Sublicense Agreements shall be treated as "Sublicense Agreements" and such sub-Sublicensees shall be treated as "Sublicensees" for purposes of the Agreement.

(e) Licensee shall deliver to Licensor a true, complete, and correct copy of each Sublicense Agreement granted by Licensee, Affiliate or Sublicensee, and any modification or termination thereof, within 30 days following the applicable execution, modification, or termination of such Sublicense Agreement. If the Sublicense Agreement is not in English, Licensee shall provide Licensor an accurate English translation in addition to a copy of the original agreement.

(f) Notwithstanding any such Sublicense Agreement, Licensee will remain primarily liable to Licensor for all of the Licensee's duties and obligations contained in the Agreement, including without limitation the payment of running royalties due under Section 3.2 whether or not paid to Licensee by a Sublicensee. Any act or omission of a Sublicensee that would be a breach of the Agreement if performed by Licensee will be deemed to be a breach by Licensee unless Licensee complies with the remaining provisions of this paragraph. Each Sublicense Agreement will contain a right of termination by Licensee in the event that the Sublicensee breaches the payment or reporting obligations affecting Licensor or any other terms and conditions of the Sublicense Agreement that would constitute a breach of the Agreement if such acts were performed by Licensee. In the event of a Sublicensee breach, and if after a reasonable opportunity to cure as provided in any such Sublicense Agreement, such Sublicensee fails to cure such Sublicensee breach, then the Licensee shall in Licensee's discretion either terminate the Sublicense Agreement or shall continue to be responsible for all payments and reports owed to Licensor as a result of Sublicensee's activities under such Sublicense Agreement.

(g) If a Sublicensee initiates any proceeding or action to challenge the validity, enforceability, or scope of one or more of the Patent Rights, Licensor shall provide written notice of such action to Licensee, and Licensee shall immediately terminate such Sublicense.

2.4 Diligent Commercialization

Licensee by itself or through its Affiliates and Sublicensees will use diligent efforts to make Licensed Products or Licensed Services commercially available in the Field in the Territory. Without limiting the foregoing, Licensee will (a) maintain a reasonably funded, ongoing and active research, development, manufacturing, regulatory, marketing or sales program required to make License Products or Licensed Services commercially available, and (b) fulfill the milestone events specified in Section 2.4 of the Patent License Agreement by the deadlines indicated therein and (c) use diligent and commercially reasonable efforts to perform and complete the plans described in the annual report submitted pursuant to Section 4.2 (Annual Written Progress Report). If the obligations under this Section 2.4 are not fulfilled, Licensor may treat such failure as a breach in accordance with Section 7.3(b).

3. Compensation

In consideration of rights granted to Licensee, Licensee will pay Licensor the following fees and royalties. All fees and royalties are not refundable and are not creditable against other fees and royalties except as explicitly set forth herein. Each payment will reference the Patent License Agreement number and will be sent to Licensor's payment and accounting contact in Section 18 (Notices) of the Patent License Agreement.

3.1 Non-Royalty Payments due from Licensee

(a) *Milestone Fees*. Licensee will pay the Milestone Fees indicated in Section 3.1(a) of the Patent License Agreement by the Quarterly Payment Deadline for the Contract Quarter in which the milestone events set forth in Section 3.1(a) of the Patent License Agreement are achieved.

(b) *Sublicense Fees*. Licensee will pay the Sublicense Fees indicated in Section 3.1(b) of the Patent License Agreement on or before the Quarterly Payment Deadline for the Contract Quarter.

3.2 Royalties

Licensee will pay a running royalty at the rate set forth in Section 3.2 of the Patent License Agreement on Net Sales in each Contract Quarter, payable on or before the Quarterly Payment Deadline for such Contract Quarter, subject to the following:

(a) No more than one royalty shall be paid to Licensor hereunder with respect to the Sale of any one unit of Licensed Product or Licensed Service, whether or not more than one patent or Valid Claim is applicable to the Licensed Product or Licensed Service, or the development, manufacture, or performance thereof.

(b) No royalty shall be payable under this Section 3.2 with respect to (i) Sales to an Affiliate or Sublicensee of a particular unit of Licensed Product that is used by such Affiliate or Sublicensee to perform a Licensed Service if Licensor is paid a royalty on the Sale of such Licensed Service, (ii) the Sale of Licensed Products between or among Licensee, its Affiliates, and Sublicensees for re-sale purposes, provided Licensor is paid a royalty with respect to the re-sale, or (iii) payments that constitute Non-Royalty Sublicensing Consideration.

3.3 Non-cash Consideration

If Licensee receives or anticipates receipt of non-cash consideration from Sales or Sublicenses, the manner in which Licensor will receive its compensation under the Agreement with respect to such non-cash consideration will be negotiated in good faith and timely agreed to by the Parties.

4. Reports and Plans

The reports specified in this Section 4 will be sent to Licensor's payment and reporting contact identified in Section 18 (Notices) of the Patent License Agreement. If Licensor requests to have information submitted in a particular format, Licensee will use reasonable efforts to comply with such request.

4.1 Quarterly Payment and Milestone Reports

On or before each Quarterly Payment Deadline, Licensee will deliver to Licensor a true and accurate report, certified by an officer of Licensee, giving such particulars of the business conducted by Licensee, its Affiliates and its Sublicensees (including copies of reports provided by Sublicensees and Affiliates to Licensee) during the preceding Contract Quarter under the Agreement as necessary for Licensor to account for Licensee's payments hereunder, even if no payments are due. The reports shall continue to be delivered after the termination or expiration of the Agreement until such time as all Licensed Products permitted to be Sold after termination or expiration have been Sold or destroyed. Licensee shall provide information in sufficient detail to enable the royalties payable hereunder to be determined and to calculate all of the amounts payable under the Agreement. The report shall include:

(a) The name of the Licensee, the Patent License Agreement number, and the period covered by the report;

(b) The name of any Affiliates and Sublicensees whose activities are also covered by the report;

(c) Identification of each Licensed Product and Licensed Service for which any royalty payments have become payable;

(d) Net Product Sales and Net Service Sales segregated on a product-by-product basis, and a country-by-country basis, or an affirmative statement that no Sales were made. The report shall also itemize the permitted deductions from the Gross Consideration used to arrive at the resulting Net Product Sales and Net Service Sales, on a product-by-product and country-by-country basis;

(e) The applicable royalty rate;

(f) An affirmative statement of whether any milestones with deadlines in that Contract Quarter under Section 2.4 and any milestones under Section 3.1(a) were met or not, and the resulting Milestone Fee payable;

(g) Non-Royalty Sublicensing Consideration received by Licensee segregated on a Sublicense-by-Sublicense basis, or an affirmative statement that none was received;

(h) If any consideration was received in currencies other than U.S. dollars, the report shall describe the currency exchange calculations; and

(i) Any changes in accounting methodologies used to account for and calculate the items included in the report since the previous report.

4.2 Annual Written Progress Report and Commercialization Plan

Within 45 days following the end of each Contract Year, Licensee will deliver to Licensor a true and accurate written progress report and commercialization plan, certified by an officer of Licensee, that summarizes (i) Licensee's efforts and accomplishments during the Contract Year to diligently commercialize Licensed Products and Licensed Services, and (ii) Licensee's development and commercialization plans with respect to Licensed Products and Licensed Services for the next Contract Year. The report shall also cover such activities by Affiliates and Sublicensees. The report shall contain the following information to the extent relevant to the activities under the Agreement:

(a) The name of the Licensee, the Patent License Agreement number, the names of any Affiliates and Sublicensees, and the products and services being developed and/or commercialized;

(b) The progress toward completing and the plans for completing the applicable milestone events pursuant to Section 2.4, Section 3.1(a) and Exhibit C;

(c) The research and development activities, including status and plans for obtaining any necessary governmental approvals, performed during the past year, and the plans for research and development activities for the next year; and

(d) The marketing activities for the past year and planned for the next year, and Licensee's internal estimate for Sales for the next year.

4.3 Government and Economic Development Reporting

If Licensor requests, Licensee will provide information required by the Government for Licensor's Government and economic development reporting purposes.

5. Payment, Records, and Audits

5.1 Payments

All amounts referred to in the Patent License Agreement are expressed in U.S. dollars without deductions for taxes, assessments, fees, or charges of any kind. Each payment will reference the agreement number set forth at the beginning of the Patent License Agreement. All payments to Licensor will be made in U.S. dollars by check or wire transfer (Licensee to pay all wire transfer fees) payable to the payee identified in Section 18 of the Patent License Agreement and sent to the payment and reporting contact in Section 18 (Notices) of the Patent License Agreement.

5.2 Sales Outside the U.S.

If any currency conversion shall be required in connection with the calculation of payments hereunder, such conversion shall be made using the rate used by Licensee for its financial reporting purposes in accordance with Generally Accepted Accounting Principles (or foreign equivalent) or, in the absence of such rate, using the average of the buying and selling exchange rate for conversion between the foreign currency and U.S. Dollars, for current transactions as reported in *The Wall Street Journal* on the last business days of the Contract Quarter to which such payment pertains. Licensee may not make any tax withholdings from payments to Licensor, but Licensor agrees to supply to Licensee, upon written request, appropriate evidence from appropriate U.S. governmental agencies showing that Licensor is a resident of the United States of America for purposes of the U.S. income tax laws and is tax-exempt under such income tax laws.

5.3 Late Payments

Amounts that are not paid when due will accrue a late charge from the due date until the date paid, at a rate equal to 1.0% per month (or the maximum allowed by law, if less).

5.4 Records

For a period of six years after the Contract Quarter to which the records pertain, Licensee agrees that it and its Affiliates and Sublicensees will each keep complete and accurate records of their Sales, Net Product Sales, Net Service Sales, Milestone Fees, and Non-Royalty Sublicensing Consideration in sufficient detail to enable such payments to be determined and audited.

5.5 Auditing

Licensee and its Affiliates will permit Licensor or its representatives, at Licensor's expense, to annually examine books, ledgers, and records during regular business hours, at Licensee's or its Affiliate's place of business, on at least 30 days advance written notice, to the extent necessary to verify any payment or report required under the Agreement. For each Sublicensee, Licensee shall obtain such audit rights for itself, and will, within 30 days of Licensor's written request, conduct an audit of the Sublicensee's records, and Licensee will furnish to Licensor a copy of the findings from such audit. No more than one audit of Licensee, each Affiliate, and each Sublicensee shall be conducted under this Section 5.5 in any calendar year. If any amounts due Licensor have been underpaid, then Licensee shall immediately pay Licensor the amount of such underpayment plus accrued interest due in accordance with Section 5.3. If the amount of underpayment is equal to or greater than 5% of the total amount due for the records so examined, Licensee will pay the cost of such audit. Such audits may, at Licensor's sole discretion, consist of a self-audit conducted by Licensee at Licensee's expense and certified in writing by an authorized officer of Licensee. All information examined pursuant to this Section 5.5 shall be deemed to be the Confidential Information of the Licensee.

6. Patent Expenses and Prosecution

6.1 Patent Expenses

Licensee shall pay for all past documented, out-of-pocket expenses incurred by Licensor for filing, prosecuting, enforcing, defending and maintaining Patent Rights and related patent searches through the Effective Date of the Agreement. Licensee shall pay all expenses incurred by Licensor for actions instructed or approved by Licensee, or that are otherwise necessary for the maintenance of the Patent Rights after the effective date, for so long as, and in such countries as the Agreement remains in effect. Licensee will pay all patent expenses within 30 days after Licensee's receipt of an invoice. Patent expense payment delinquencies (whether owed directly to Prosecution Counsel or to Licensor) will be considered a payment default under Section 7.3(a).

6.2 Direction of Prosecution

Licensor will confer with Licensee to develop a strategy for the prosecution and maintenance of Patent Rights. Licensor will request that copies of all documents prepared by the Prosecution Counsel for submission to governmental patent offices be provided to Licensee for review and comment prior to filing. At its discretion, Licensor may allow Licensee to instruct Prosecution Counsel directly, provided, that (a) Licensor will maintain final authority in all decisions regarding the prosecution and maintenance of the Patent Rights, (b) Licensor may revoke this authorization to instruct Prosecution Counsel directly at any time, and (c) the Prosecution Counsel remains counsel to the Licensor with an appropriate contract (and shall not jointly represent Licensee unless requested by Licensee and approved by Licensor, and an appropriate engagement letter and conflict waiver are in effect). If Licensee wishes to instruct Prosecution Counsel directly or change Prosecution Counsel, Licensee may request to do so by following the Licensor's procedures for such. Licensor reserves in its sole discretion the ability to change Prosecution Counsel and to approve or disapprove any requested changes by Licensee. The Parties agree that they share a common legal interest to get valid enforceable patents and that Licensee will maintain as privileged all information received pursuant to this Section.

6.3 Ownership

The ownership of all patent applications and patents filed after the effective date will be determined in accordance with U.S. patent law. No payments due under the Agreement will be reduced as the result of co-ownership interests in the Patent Rights by Licensee or any other party.

6.4 Foreign Filings

In addition to the U.S., the Patent Rights shall, subject to applicable bar dates, be pursued in such foreign countries as Licensee so designates in writing to Licensor in sufficient time to reasonably enable the preparation of such additional filings, and in those foreign countries in which Licensor has filed applications prior to the Effective Date. If Licensee does not choose to pursue patent rights in a particular foreign country and Licensor chooses to do so, Licensor shall provide written notice to Licensee and thereafter said patent application or patent shall no longer be included in the Patent Rights and Licensee shall have no further rights thereto. Licensor shall have the right to make alternative arrangements with Licensee for upfront payment of foreign patent expenses.

6.5 Withdrawal from Paying Patent Costs

If at any time Licensee wishes to cease paying for any costs for any particular Patent Rights or for patent prosecution in a particular jurisdiction, Licensee must give Licensor at least 90 days prior written notice (the "Notice Period") and Licensee will continue to be obligated to pay for the patent costs which reasonably accrue during said Notice Period. Thereafter, said patent application or patent shall no longer be included in the Patent Rights and Licensee shall have no further rights thereto.

6.6 U.S. Patent and Trademark Office Entity Size Status

Licensee represents that as of the Effective Date the entity size status of Licensee in accordance with the regulations of the U.S. Patent and Trademark Office is as set forth in Section 1 of the Patent License Agreement. Licensee will inform Licensor in writing on a timely basis of any change in its U.S. Patent and Trademark Office entity size status.

6.7 Extension of Patent Term

If a Licensed Product is eligible for extending the term of any patent in the Patent Rights under the Drug Price Competition and Patent Term Restoration Act of 1984 and/or any European, Japanese, or other foreign counterparts of this law, then Licensee shall take all necessary steps with the appropriate regulatory authorities to apply in a timely manner for such an extension of the term for such patent. For example, such application must be made to the USPTO within sixty (60) days after the US FDA approves a commercial marketing application for said Licensed Product. Licensee shall prepare and file all documents needed for the application; and Licensee shall take all reasonable actions as may be appropriate to further obtain patent term extension. Licensor shall cooperate and sign such documents as may be reasonably requested by Licensee for the application.

Licensee shall keep Licensor informed as to Licensee's efforts to prepare and file said application, including giving a written report within thirty (30) days after Licensee obtains the applicable marketing approval from the FDA (or foreign counterpart). If Licensee fails to make this required application, then Licensor shall have the option but not the obligation to do so; and if Licensor does elect to file the application, then Licensee shall cooperate and sign such documents as may be needed; and Licensee shall reimburse Licensor's costs incurred for said application.

7. Term and Termination

7.1 Term

Unless earlier terminated as provided herein, the term of the Agreement as to Patent Rights will commence on the Effective Date and continue until the last date of expiration or termination of the Patent Rights, but shall continue for another ten years as to the Know-How with the running royalty rate being reduced by half during that period.

7.2 Termination by Licensee

Licensee, at its option, may terminate the Agreement by providing Licensor written notice of intent to terminate, which such termination effective will be 90 days following receipt of such notice by Licensor.

7.3 Termination by Licensor

Licensor, at its option, may immediately terminate the Agreement, or any part of Patent Rights, or any part of Field, or any part of Territory, or the exclusive nature of the license grant, upon delivery of written notice to Licensee of Licensor's decision to terminate, if any of the following occur:

(a) Licensee becomes more than $5,000 in arrears in any payments due under the Agreement, and Licensee fails to make the required payment within 60 days after delivery of written notice from Licensor; or

(b) Licensee is in material breach of any non-payment provision of the Agreement, and does not cure such breach within 60 days after delivery of written notice from Licensor; or

(c) Licensee or its Affiliate initiates any proceeding or action to challenge the validity, enforceability, or scope of one or more of the Patent Rights, or assist a third party in pursuing such a proceeding or action.

7.4 Other Conditions of Termination

The Agreement will terminate:

(a) Immediately without the necessity of any action being taken by Licensor or Licensee, (i) if Licensee becomes bankrupt or insolvent, or (ii) Licensee's Board of Directors elects to liquidate its assets or dissolve its business, or (iii) Licensee ceases its business operations, or (iv) Licensee makes an assignment for the benefit of creditors or (v) if the business or assets of Licensee are otherwise placed in the hands of a receiver, assignee or trustee, whether by voluntary act of Licensee or otherwise; or

(b) At any time by mutual written agreement between Licensee and Licensor.

7.5 Effect of Termination

If the Agreement is terminated for any reason:

(a) All rights and licenses of Sublicensees shall continue in force provided that the Sublicensee is in good standing and agrees in writing to assume all of the obligations of Licensee, provided however if there is more than one Sublicense that survives the termination of this Agreement, the patent cost reimbursement obligations may be shared among the Sublicenses in proportions agreed by Licensor, and such Sublicensee provides Licensor with written notice thereof within 30 days after termination of the Agreement, then such Sublicense Agreement shall survive; and

(b) Licensee shall cease making, having made, distributing, having distributed, using, selling, offering to sell, leasing, loaning and importing any Licensed Products and performing Licensed Services by the effective date of termination; and

(c) Licensee shall tender payment of all accrued royalties and other payments due to Licensor as of the effective date of termination; and

(d) Nothing in the Agreement will be construed to release either Party from any obligation that matured prior to the effective date of termination; and

(e) The provisions of Sections 8 (Confidentiality), 9 (Infringement and Litigation), 11 (Representations and Disclaimers), 12 (Limit of Liability), 13 (Indemnification), 14 (Insurance), 17 (Use of Name), 18 (Notices), and 19 (General Provisions) will survive any termination or expiration of the Agreement. In addition, the provisions of Sections 3 (Compensation), 4.1 (Quarterly Payment and Milestone Reports), 5 (Payment, Records and Audits), 6.1 (Patent Expenses) of the Patent License Agreement shall survive with respect to all activities and payment obligations accruing prior to the termination or expiration of the Agreement.

8. Confidentiality

8.1 Definition

"**Confidential Information**" means all information that is of a confidential and proprietary nature to Licensor or Licensee and provided by one Party to the other Party under the Agreement. Licensor's Confidential Information includes unpublished information related to novel drug formulations, formulation technologies including thin film freezing technology and its applications, including information related to subject of patent filings and applications listed in Exhibit B, and also data, Know-How, and information related to thin film freezing technology and its applications that is not described in the patents and patent applications in Exhibit B or that are the subject of sponsored research, feasibility studies, or technology validations between the Parties.

8.2 Protection and Marking

Licensor and Licensee each agree that all Confidential Information disclosed in tangible form, and marked "confidential" and forwarded to one by the other, or if disclosed orally, is designated as confidential at the time of disclosure: (i) is to be held in strict confidence by the receiving Party, (ii) is to be used by and under authority of the receiving Party only as authorized in the Agreement, and (iii) shall not be disclosed by the receiving Party, its agents or employees without the prior written consent of the disclosing Party or as authorized in the Agreement. Licensee has the right to use and disclose Confidential Information of Licensor reasonably in connection with the exercise of its rights under the Agreement, including without limitation disclosing to Affiliates, Sublicensees, potential investors, acquirers, and others on a need to know basis, if such Confidential Information is provided under conditions which reasonably protect the confidentiality thereof. Each Party's obligation of confidence hereunder includes, without limitation, using at least the same degree of care with the disclosing Party's Confidential Information as it uses to protect its own Confidential Information, but always at least a reasonable degree of care.

8.3 Confidentiality of Terms of Agreement

Each Party agrees not to disclose to any third party the terms of the Agreement without the prior written consent of the other Party hereto, except each Party may disclose the terms of the Agreement: (a) to advisors, actual or potential Sublicensees, acquirers or investors, and others on a need to know basis, in each case, under appropriate confidentiality obligations substantially similar to those of this Section 8; and (b) to the extent necessary to comply with applicable laws and court orders (including, without limitation, The Texas Public Information Act, as may be amended from time to time, other open records laws, decisions and rulings, and securities laws, regulations and guidance). Notwithstanding the foregoing, the existence of the Agreement shall not be considered Confidential Information.

8.4 Disclosure Required by Court Order or Law

If the receiving Party is required to disclose Confidential Information of another Party hereto, or any terms of the Agreement, pursuant to the order or requirement of a court, administrative agency, or other governmental body or applicable law, the receiving Party may disclose such Confidential Information or terms to the extent required, provided that the receiving Party shall use reasonable efforts to provide the disclosing Party with reasonable advance notice thereof to enable the disclosing Party to seek a protective order and otherwise seek to prevent such disclosure. To the extent that Confidential Information so disclosed does not become part of the public domain by virtue of such disclosure, it shall remain Confidential Information protected pursuant to Section 8.

8.5 Copies

Each Party agrees not to copy or record any of the Confidential Information of the other Party, except as reasonably necessary to exercise its rights or perform its obligations under the Agreement, and for archival and legal purposes.

8.6 Continuing Obligations

Subject to the exclusions listed in Section 8.7, the Parties' confidentiality obligations under the Agreement will survive termination of the Agreement and will continue for a period of five years thereafter.

8.7 Exclusions

Information shall not be considered Confidential Information of a disclosing Party under the Agreement to the extent that the receiving Party can establish by competent written proof that such information:

(a) Was in the public domain at the time of disclosure; or

(b) Later became part of the public domain through no act or omission of the recipient Party, its employees, agents, successors or assigns in breach of the Agreement; or

(c) Was lawfully disclosed to the recipient Party by a third party having the right to disclose it not under an obligation of confidentiality; or

(d) Was already known by the recipient Party at the time of disclosure; or

(e) Was independently developed by the recipient Party without use of the disclosing Party's Confidential Information.

8.8 Copyright Notice

The placement of a copyright notice on any Confidential Information will not be construed to mean that such information has been published and will not release the other Party from its obligation of confidentiality hereunder.

9. Infringement and Litigation

9.1 Notification

If either Licensee or Licensor's designated office for technology commercialization becomes aware of any infringement or potential infringement of Patent Rights in the Field in the Territory, such Party shall give prompt written notice to the other Party of such infringement.

9.2 Enforcement Against Infringer

Licensee shall have the right, but no obligation, to enforce the Patent Rights against any infringement by a third party in all fields licensed exclusively to Licensee. Licensee shall confer with Licensor and give due consideration to Licensor's input concerning any such enforcement action. If an enforcement action results in a sublicense to the alleged infringer, any consideration received by Licensee shall be shared with Licensor according to the terms of this Agreement (e.g., non-royalty sublicensing consideration and/or royalties on sales going forward). If an enforcement action results in Licensee obtaining an award of damages for infringement, such damages shall be treated as non-royalty sublicensing consideration for purposes of sharing such damages with Licensor. If an enforcement action is commenced, both Parties agree to cooperate fully with each other and to permit reasonable access to all relevant personnel, records, papers, information, samples, specimens, etc., relevant to the action.

9.3 Cooperation between Licensor and Licensee

In any infringement suit or dispute, the Parties agree to cooperate fully with each other. At the request of the Party bringing suit, the other Party will permit reasonable access after reasonable advance notice to all relevant personnel, records, papers, information, samples, specimens, etc., during regular business hours.

If it is necessary to name Licensor as a party in such action, then Licensee must first obtain Licensor's prior written permission, which permission shall not be unreasonably withheld, provided that Licensor shall have reasonable prior input on choice of counsel on any matter where such counsel represents Licensor, and Licensee and such counsel agree to follow all required procedures of the Texas Attorney General regarding retention of outside counsel for state entities.

10. Export Compliance

Licensee understands that the Arms Export Control Act (AECA), including its implementing International Traffic In Arms Regulations (ITAR), and the Export Administration Act (EAA), including its Export Administration Regulations (EAR), are some (but not all) of the laws and regulations that comprise the U.S. export laws and regulations. Licensee further understands that the U.S. export laws and regulations include (but are not limited to): (a) ITAR and EAR product/service/data-specific requirements; (b) ITAR and EAR ultimate destination-specific requirements; (c) ITAR and EAR end user-specific requirements; (d) Foreign Corrupt Practices Act; and (e) anti-boycott laws and regulations. Licensee will comply with all then-current applicable export laws and regulations of the U.S. Government (and other applicable U.S. laws and regulations) pertaining to the Licensed Products and Licensed Services (including any associated products, items, articles, computer software, media, services, technical data, and other information). Licensee certifies that it will not, directly or indirectly, export (including any deemed export), nor re-export (including any deemed re-export) the Licensed Products and Licensed Services (including any associated products, items, articles, computer software, media, services, technical data, and other information) in violation of applicable U.S. laws and regulations. Licensee will include a provision in its agreements, substantially similar to this Section 10, with its Sublicensees, third party wholesalers and distributors, and physicians, hospitals or other healthcare providers who purchase a Licensed Product, requiring that these parties comply with all then-current applicable U.S. export laws and regulations and other applicable U.S. laws and regulations.

11. Representations and Disclaimers

11.1 Licensor Representations

Except for the rights, if any, of the Government as set forth in Section 11.2, Licensor represents and warrants to Licensee that to the knowledge of Licensor's designated office for technology commercialization (i) Licensor is the owner or agent of the entire right, title, and interest in and to Patent Rights and TFF Technology (other than the right, title and interest of any joint owner identified in Section 1 of the Patent License Agreement), (ii) Licensor has the right to grant licenses hereunder, and (iii) Licensor has not knowingly granted and will not knowingly grant licenses or other rights under the Patent Rights that are in conflict with the terms and conditions in the Agreement.

11.2 Government Rights

Licensee understands that Patent Rights may have been developed under a funding agreement with Government and, if so, that Government may have certain rights relative thereto. The Agreement is made subject to the Government's rights under any such agreement and under any applicable Government law or regulation. To the extent that there is a conflict between any such agreement, such applicable law or regulation and the Agreement, the terms of such Government agreement, and applicable law or regulation, shall prevail. Licensee agrees that, to the extent required by U.S. laws and regulations, Licensed Products used or Sold in the U.S. will be manufactured substantially in the U.S., unless a written waiver is obtained in advance from the U.S. Government.

11.3 Licensor Disclaimers

EXCEPT AS SPECIFICALLY SET FORTH IN SECTION 11.1, LICENSEE UNDERSTANDS AND AGREES THAT LICENSOR MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, AS TO THE LICENSED PRODUCTS OR LICENSED SERVICES, OR AS TO THE OPERABILITY OR FITNESS FOR ANY USE OR PARTICULAR PURPOSE, MERCHANTABILITY, SAFETY, EFFICACY, APPROVABILITY BY REGULATORY AUTHORITIES, TIME AND COST OF DEVELOPMENT, PATENTABILITY, AND/OR BREADTH OF PATENT RIGHTS. LICENSOR MAKES NO REPRESENTATION AS TO WHETHER ANY PATENT WITHIN PATENT RIGHTS IS VALID, OR AS TO WHETHER THERE ARE ANY PATENTS NOW HELD, OR WHICH WILL BE HELD, BY OTHERS OR BY LICENSOR THAT MIGHT BE REQUIRED FOR USE OF PATENT RIGHTS IN FIELD. NOTHING IN THE AGREEMENT WILL BE CONSTRUED AS CONFERRING BY IMPLICATION, ESTOPPEL OR OTHERWISE ANY LICENSE OR RIGHTS TO ANY PATENTS OR TECHNOLOGY OF LICENSOR OTHER THAN THE PATENT RIGHTS, WHETHER SUCH PATENTS ARE DOMINANT OR SUBORDINATE TO THE PATENT RIGHTS.

11.4 Licensee Representation

By execution of the Agreement, Licensee represents, acknowledges, covenants and agrees (a) that Licensee has not been induced in any way by Licensor or its employees to enter into the Agreement, and (b) that Licensee has been given an opportunity to conduct sufficient due diligence with respect to all items and issues pertaining to this Section 11 (Representations and Disclaimers) and all other matters pertaining to the Agreement; and (c) that Licensee has adequate knowledge and expertise, or has utilized knowledgeable and expert consultants, to adequately conduct the due diligence, and (c) that Licensee accepts all risks inherent herein. Licensee represents that it is a duly organized, validly existing entity of the form indicated in Section 1 of the Patent License Agreement, and is in good standing under the laws of its jurisdiction of organization as indicated in Section 1 of the Patent License Agreement, and has all necessary corporate or other appropriate power and authority to execute, deliver and perform its obligations hereunder.

12. Limit of Liability

IN NO EVENT SHALL LICENSOR, THE UNIVERSITY SYSTEM IT GOVERNS, ITS MEMBER INSTITUTIONS, INVENTORS, REGENTS, OFFICERS, EMPLOYEES, STUDENTS, AGENTS OR AFFILIATED ENTERPRISES, BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, INCIDENTAL, EXEMPLARY, OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER ANY SUCH PARTY KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES.

OTHER THAN FOR ANY CLAIMS AGAINST LICENSEE FOR MISUSE OR MISAPPROPRIATION OR INFRINGEMENT OF LICENSOR'S INTELLECTUAL PROPERTY RIGHTS, LICENSEE WILL NOT BE LIABLE TO LICENSOR FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER LICENSEE KNOWS OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES.

13. Indemnification

13.1 Indemnification Obligation

Subject to Section 13.2, Licensee agrees to hold harmless, defend and indemnify Licensor, the university system it governs, its member institutions, its Regents, officers, employees, students and agents ("Indemnified Parties") from and against any liabilities, damages, causes of action, suits, judgments, liens, penalties, fines, losses, costs and expenses (including, without limitation, reasonable attorneys' fees and other expenses of litigation) (collectively "Liabilities") resulting from claims or demands brought by third parties against an Indemnified Party on account of any injury or death of persons, damage to property, or any other damage or loss arising out of or in connection with the Agreement or the exercise or practice by or under authority of Licensee, its Affiliates or their Sublicensees, or third party wholesalers or distributors, or physicians, hospitals or other healthcare providers who purchase a Licensed Product, of the rights granted hereunder.

13.2 Conditions of Indemnification

Licensee shall have no responsibility or obligation under Section 13.1 for any Liabilities to the extent caused by the gross negligence or willful misconduct by Licensor. Obligations to indemnify, and hold harmless under Section 13.1 are subject to: (a) to the extent authorized by the Texas Constitution and the laws of the State of Texas, and subject to the statutory duties of the Texas Attorney General, the Indemnified Party giving Licensee control of the defense and settlement of the claim and demand; and (b) to the extent authorized by the Texas Constitution and the laws of the State of Texas and subject to statutory duties of the Texas Attorney General, the Indemnified Party providing assistance reasonably requested by Licensee, at Licensee's expense.

14. Insurance

14.1 Insurance Requirements

Prior to any Licensed Product being used or Sold (including for the purpose of obtaining regulatory approvals), and prior to any Licensed Service being performed by Licensee, an Affiliate, or by a Sublicensee, and for a period of five years after the Agreement expires or is terminated, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in commercially reasonable and appropriate amounts for the Licensed Product being used or Sold or the Licensed Service being performed. Licensee shall use commercially reasonable efforts to have Licensor, the university system it governs, its member institutions, Regents, officers, employees, students and agents named as additional insureds. Such commercial general liability insurance shall provide, without limitation: (i) product liability coverage; (ii) broad form contractual liability coverage for Licensee's indemnification under the Agreement; and (iii) coverage for litigation costs.

14.2 Evidence of Insurance and Notice of Changes

Upon request by Licensor, Licensee shall provide Licensor with written evidence of such insurance. Additionally, Licensee shall provide Licensor with written notice of at least 60 days prior to Licensee cancelling, not renewing, or materially changing such insurance.

15. Assignment

The Agreement may not be assigned by Licensee without the prior written consent of Licensor, which consent will not be unreasonably withheld; except, however, that Licensee shall be permitted to assign this Agreement without Licensee's consent to (i) any of its Affiliates or ii) a successor-in-interest whether by way of stock sale, asset sale, merger, or otherwise. For any permitted assignment to be effective, (a) the Licensee must be in good standing under this Agreement, (b) the assignee must assume in writing all of Licensee's interests, rights, duties and obligations under the Agreement and agree to comply with all terms and conditions of the Agreement as if the assignee were an original Party to the Agreement (c) provide written notice to the Licensor of such assignment no less than 15 days after completion of such assignment. Any such assignment must be of all rights and obligations of Licensee, such that there is only one existing Licensee at any one time.

16. Governmental Markings

16.1 Patent Markings

Licensee agrees that all Licensed Products Sold by Licensee, Affiliates, or Sublicensees will be legibly marked with the number of any applicable patent(s) licensed hereunder as part of the Patent Rights in accordance with each country's patent marking laws, including Title 35, U.S. Code, or if such marking is not practicable, shall so mark the accompanying outer box or product insert for Licensed Products accordingly.

16.2 Governmental Approvals and Marketing of Licensed Products and or Licensed Services

Licensee will be responsible for obtaining all necessary governmental approvals for the development, production, distribution, Sale, and use of any Licensed Product or performance of any Licensed Service, at Licensee's expense, including, without limitation, any safety studies. Licensee will have sole responsibility for any warning labels, packaging and instructions as to the use and the quality control for any Licensed Product or Licensed Service.

16.3 Foreign Registration and Laws

Licensee agrees to register the Agreement with any foreign governmental agency that requires such registration; and Licensee will pay all costs and legal fees in connection with such registration. Licensee is responsible for compliance with all foreign laws affecting the Agreement or the Sale of Licensed Products and Licensed Services to the extent there is no conflict with United States law, in which case United States law will control.

17. Use of Name

Licensee will not use the name, trademarks or other marks of Licensor (or the name of the university system it governs, its member institutions, any of its Regents or employees) without the advance written consent of Licensor. Licensor may use Licensee's name and logo for annual reports, brochures, website, and internal reports without prior consent.

18. Notices

Any notice or other communication of the Parties required or permitted to be given or made under the Agreement will be in writing and will be deemed effective when sent in a manner that provides confirmation or acknowledgement of delivery and received at the address set forth in Section 18 of the Patent License Agreement (or as changed by written notice pursuant to this Section 18). Notices required under the Agreement may be delivered via E-mail provided such notice is confirmed in writing as indicated.

Notices shall be provided to each Party as specified in the "Contact for Notice" address set forth in Section 18 of the Patent License Agreement. Each Party shall update the other Party in writing with any changes in such contact information.

19. General Provisions

19.1 Binding Effect

The Agreement is binding upon and inures to the benefit of the Parties hereto, their respective executors, administrators, heirs, permitted assigns, and permitted successors in interest.

19.2 Construction of Agreement

Headings are included for convenience only and will not be used to construe the Agreement. The Parties acknowledge and agree that both Parties substantially participated in negotiating the provisions of the Agreement; therefore, both Parties agree that any ambiguity in the Agreement shall not be construed more favorably toward one Party than the other Party, regardless of which Party primarily drafted the Agreement.

19.3 Intentionally left blank

19.4 Compliance with Laws

Licensee will comply with all applicable federal, state and local laws and regulations, including, without limitation, all export laws and regulations.

19.5 Governing Law

The Agreement will be construed and enforced in accordance with laws of the U.S. and the State of Texas, without regard to choice of law and conflicts of law principles.

19.6 Modification

Any modification of the Agreement will be effective only if it is in writing and signed by duly authorized representatives of both Parties. No modification will be made by email communications.

19.7 Severability

If any provision hereof is held to be invalid, illegal or unenforceable in any jurisdiction, the Parties hereto shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties, and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such other provisions in any other jurisdiction, so long as the essential essence of the Agreement remains enforceable.

19.8 Third Party Beneficiaries

Nothing in the Agreement, express or implied, is intended to confer any benefits, rights or remedies on any entity, other than the Parties and their permitted successors and assigns. However, if there is a joint owner of any Patent Rights identified in Section 1 of the Patent License Agreement (other than Licensee), then Licensee hereby agrees that the following provisions of these Terms and Conditions extend to the benefit of the co-owner identified therein (excluding the Licensee to the extent it is a co-owner) as if such co-owner was identified in each reference to the Licensor: the retained rights under clause (b) of Section 2.1; Section 11.3 (Licensor Disclaimers); Section 12 (Limitation of Liability); Section 13 (Indemnification); Section 14.1 (Insurance Requirements); Section 17 (Use of Name); and Section 19.10 (Sovereign Immunity, if applicable).

19.9 Waiver

Neither Party will be deemed to have waived any of its rights under the Agreement unless the waiver is in writing and signed by such Party. No delay or omission of a Party in exercising or enforcing a right or remedy under the Agreement shall operate as a waiver thereof.

19.10 Sovereign Immunity

Nothing in the Agreement shall be deemed or treated as any waiver of Licensor’s sovereign immunity.

19.11 Entire Agreement

The Agreement constitutes the entire Agreement between the Parties regarding the subject matter hereof, and supersedes all prior written or verbal agreements, representations and understandings relative to such matters.

19.12 Claims Against Licensor for Breach of Agreement

Licensee acknowledges that any claim for breach of the Agreement asserted by Licensee against Licensor shall be subject to Chapter 2260 of the Texas Government Code and that the process provided therein shall be Licensee’s sole and exclusive process for seeking a remedy for any and all alleged breaches of the Agreement by Licensor or the State of Texas.

-- END OF EXHIBIT A --

EXHIBIT B

Patent Rights

UT Tech ID	App. No./ Date of Filing	Title	Inventor(s)	Jointly Owned? (Y/N; if Y, with whom?)	Prosecution Counsel
7861 WIL	63/254,487 filed on 10/11/2021	DRY FORMULATIONS OF ANTI-SARS-COV-2 VIRUS ANTIBODIES AND COMPOSITIONS AND METHODS OF USE THEREOF	Robert O. Williams III (UT), Zhengrong Cui (UT), Haiyue Xu (UT), Christopher Emig (Augmenta), Steven J. Henry (Augmenta), Adela A. Vitug (Augmenta), Dale Christensen (TFF)	Y, TFF Pharmaceuticals and Augmenta Bioworks, Inc.	Cooley LLP (TFF Pharma leading prosecution)
7822 CUI	63/232,099 filed on 8/11/2021	DRY LIPOSOME FORMULATIONS AND RELATED METHODS THEREOF	Robert O. Williams III, Khaled AboulFotouh, Zhengrong Cui	N	Parker Highlander PLLC
7779 CUI	63/232,091 filed on 8/11/2021	DRY POWDER COMPOSITIONS OF OIL-IN-WATER (O/W) EMULSION ADJUVANTED VACCINES	Robert O. Williams III, Chaeho Moon, Khaled AboulFotouh, Haiyue Xu, Zhengrong Cui	N	Parker Highlander PLLC
7752 WIL	63/239,333 filed on 8/31/2021	Delayed Release Niclosamide Formation	Robert O. Williams III (UT), Zachary N. Warnken, Miguel O. Jara John Koleng (TFF),	Y, TFF Pharmaceuticals	Parker Highlander PLLC
7714 WIL	63/158,280 filed on 3/8/2021	Dry Powder Formulations of Nucleic Acid Lipid Nanoparticles	Robert O. Williams III, Chaeho Moon, Sawittree Sahakijpijarn, Haiyue Xu, Zhengrong Cui	N	Parker Highlander PLLC
7715 CUI	63/232,076 filed on 8/11/2021	DRY LIPOSOME ADJUVANT-CONTAINING VACCINES AND RELATED METHODS	Robert O. Williams III, Zhengrong Cui Haiyue Xu, Khaled AboulFotouh	N	Parker Highlander PLLC
7626 WIL	PCT/US2021/042010 filed on 7/16/2021, claiming priority to 63/053,339 Filed on 7/17/2020	Compositions for delivery of Remdesivir by inhalation	Robert O. Williams III, Chaeho Moon, Sawittree Sahakijpijarn, John Koleng (TFF), Dale Christensen (TFF), Glenn Mattes (TFF)	Y, TFF Pharmaceuticals	Parker Highlander PLLC

UT Tech ID	App. No./ Date of Filing	Title	Inventor(s)	Jointly Owned? (Y/N; if Y, with whom?)	Prosecution Counsel
7625 WIL	63/162,835 filed on 3/18/21	Compositions for delivery of drug combinations to treat lung disease	Robert O. Williams III, Jay I. Peters (UTHSC-SA), Tuangrat Praphawatvet, Sawittree Sahakijpijarn, Chaeho Moon	Y, University of Texas Health Science Center at San Antonio	Parker Highlander PLLC
7574 WIL	PCT/US2021/025455 filed on 4/01/2021, US 17/220,833 filed on 4/01/2021, claiming priority to 63/003,793 filed on 4/01/2020	Pharmaceutical Compositions of Niclosamide	Robert O. Williams III, Hugh D. Smyth, Zachary N. Warnken, Miguel O. Jara Gonzalez, Hyo-Jong Seo, Ashlee D. Brunaugh, Matthew Herpin	N	Parker Highlander PLLC
7597 WIL	63/160,588 filed on 3/12/2021	Methods to Prepare Dry Powder using Suspension-based Thin Film Freezing	Robert O. Williams III, Sawittree Sahakijpijarn, Chaeho Moon, John J. Koleng (TFF)	Y, TFF Pharmaceuticals	Parker Highlander PLLC
7572 WIL	PCT/US2021/028140 filed on 4/20/2021, US 17/235,771 filed on 4/20/2021, Claiming priority to 63/012,792 filed on 4/20/20	Biologically Active Dry Powder Compositions And Method Of Their Manufacture And Use	Hugh D. Smyth, Hairui Zhang, Zhengrong Cui, Jieliang Wang, Haiyue Xu, Yajie Zhang. Debadyuti Ghosh, Jasmim Leal, Melissa Soto, Robert O. Williams III, Chaeho Moon, Sawittree Sahakijpijarn	N	Parker Highlander PLLC
7488 WIL	PCT/US2020/051388 filed on 9/18/2020 claiming priority to 62/902,095 filed on 9/18/2019	Compositions for delivery of cannabinoids by inhalation	Robert O. Williams III, Chaeho Moon, John J. Koleng (TFF)	Y, TFF Pharmaceuticals	Parker Highlander PLLC

UT Tech ID	App. No./ Date of Filing	Title	Inventor(s)	Jointly Owned? (Y/N; if Y, with whom?)	Prosecution Counsel
7314 WIL	China (PRC) 201980055623.X filed on 7/24/2019, Mexico MX/a/2021/000796 filed on 7/24/2019, Australia 2019311086 filed on 7/24/2019, Brazil BR1120210012907 filed on 7/24/2019, Canada 3,106,618 filed on 7/24/2019, India 2021170031365 filed on 7/24/2019, Europe 19840589.6 filed on 7/24/2019, Israel 280342 filed on 7/24/2019, US 17/262,313 filed on 7/24/2019, Japan 2021-503813 filed on 7/24/2019, South Korea 10-2021-7005060 filed on 7/24/2019, Eurasia 202190331 filed on 7/24/2019, PCT/US2019/043202 filed on 7/24/2019, Claiming priority to 62/702,674 filed on 7/24/2018	Compositions of surface-modified therapeutically active particles by ultra-rapid freezing	Robert O. Williams III, Chaeho Moon, Alan B. Watts, John J. Koleng	N	Parker Highlander PLLC

UT Tech ID	App. No./ Date of Filing	Title	Inventor(s)	Jointly Owned? (Y/N; if Y, with whom?)	Prosecution Counsel
7149 CUI	Canada 3,083,953 filed on 12/11/2018, US 16/771,648 filed on 12/11/2018, PCT/US2018/064837 filed on 12/11/2018, Claiming priority to 62/597,037 filed on 12/11/2017	Dry Adjuvanted Immune Stimulating Compositions and Use Thereof for Mucosal Administration	Zhengrong Cui, Sachin G. Thakkar	N	Parker Highlander PLLC
6677 WIL	China (PRC) 201580080517.9 filed on 09/02/2015, PCT/US2015/048093 filed on 09/02/2015, Australia 2015393953 filed on 09/02/2015, Canada 2,983,427 filed on 09/02/2015, US 15/570,828 filed on 09/02/2015, Brazil BR 112017023351-7 filed on 09/02/2015, Japan 2017-557057 filed on 09/02/2015, Japan 2021-34347 filed on 09/02/2015, India 201717040247 filed on 09/02/2015, Europe 15766292.5, Patent No 3288541, Registered in United Kingdom, Ireland France Patent No EP3288541, Germany Patent No 602015058428.7, Luxembourg Switzerland Monaco filed on 09/02/2015, South Korea 10-2017-7034565 filed on 09/02/2015, claiming priority to 62/156,052 filed on 05/01/2015	Multidrug Brittle Matrix Compositions	Robert O. Williams III, Alan B. Watts, Jay I. Peters (UTHSC-SA), Simone Carvalho	Y, University of Texas Health Science Center at San Antonio	Parker Highlander PLLC

UT Tech ID	App. No./ Date of Filing	Title	Inventor(s)	Jointly Owned? (Y/N; if Y, with whom?)	Prosecution Counsel
6272 CUI	US 16/156,511 filed on 10/10/2018, divisional of 14/941,323 filed on 11/13/2016, PCT/US2014/038475 filed on 5/16/2014, Claiming priority to 61/824,181 filed on 5/16/2013	Dry Solid Aluminum Adjuvant-Containing Vaccines and Related Methods Thereof	Zhengrong Cui, Robert O. Williams III, Xinran Li	N	Parker Highlander PLLC
5612 DOW	US 14/861,046 Filed on 9/22/2015 divisional of US 10/639,361, Patent No 9,175,906 filed on 8/12/2003, PCT/US2003/025338 filed on 8/12/2003, Singapore 200504247-8, Patent No 112782 filed on 8/12/2003, Japan 2004-566896, Patent No 4933732 filed on 8/12/2003	Drug Particles From Freezing onto a Surface	James E. Hitt (DOW), Brian D. Scherzer (DOW), Jonathan C. Evans (DOW)	N	Parker Highlander PLLC
5408 JOH	US 16/839,957 filed on 4/3/2020, Continuation of 16/555,165, Patent No 10,660,850 filed on 8/29/2019, Divisional of 16/115,888, Patent No 10,434,062 filed on 8/29/2018, CIP of 12/778,795, Patent No 10,092,512 filed on 5/12/2010	Compositions and Methods of Making Brittle-Matrix Particles Through Blister Pack Freezing	Keith P. Johnston, Jasmine Tam (Rowe), Alan B. Watts,. Robert O. Williams III, Joshua D. Engstrom.	N	Parker Highlander PLLC

UT Tech ID	App. No./ Date of Filing	Title	Inventor(s)	Jointly Owned? (Y/N; if Y, with whom?)	Prosecution Counsel
5312 JOH	US 12/371,573 filed on 2/13/2009, Australia Patent No 2009214443 filed on 2/13/2009, Canada Patent No 2,723,314 filed on 2/13/2009, Europe 09709833.9, Patent No 2252275, Registered in Belgium, Sweden Patent No 09709833.9, Norway, Netherlands, Switzerland, Denmark, United Kingdom, Ireland, Monaco, Finland, Luxembourg, Germany Patent No 602009049607.7, France, filed on 2/13/2009, Claiming priority to US 61/028,218 filed on 2/13/2008	Templated Open Flocs of Anisotropic Particles for Enhanced Pulmonary Delivery	Joshua D. Engstrom,. Keith P. Johnston, asmine Tam (Rowe),	N	Parker Highlander PLLC

UT Tech ID	App. No./ Date of Filing	Title	Inventor(s)	Jointly Owned? (Y/N; if Y, with whom?)	Prosecution Counsel
5254 JOH	US 17/154,610 filed on 1/21/2021, Continuation of 16/410,189, Patent No 10,898,437 filed on 5/13/2019, Continuation of 15/479,137, Patent No 10,285,945 filed on 4/4/2017, Continuation of 14/603,211, Patent No 9,622,974, filed on 1/22/2015, Divisional of 12/665,386, Patent No 8,968,786, filed on 6/20/2008 Canada 2,691,531, Patent No 2,691,531 filed on 12/22/2009, Japan 2010-513468, Patent No 5658031, filed on 6/20/2008, PCT/US2008/067766 filed on 6/20/2008, Europe 08771657.7, Patent No 2170283, Registered in France, Germany Patent No 60 2008 058 694.4, Switzerland, United Kingdom, Denmark, Finland, Hungary, Iceland, Netherlands, Norway, Sweden, Spain, Belgium, Ireland, Italy Patent No 502019000027264, Claiming priority to 60/945,737 filed on 6/22/2007	Formation of Stable Submicron Protein Particles by Thin Film Freezing	Joshua D. Engstrom,. Keith P. Johnston,	N	Parker Highlander PLLC

UT Tech ID	App. No./ Date of Filing	Title	Inventor(s)	Jointly Owned? (Y/N; if Y, with whom?)	Prosecution Counsel
5175 WIL	US 16/294,885, filed on 3/06/2019, Continuation of 14/621,337, Patent No 10,231,955 filed on 2/12/2015, Continuation of 12/522,774, Patent No 9,044,391, filed on 1/10/2008, Canada 3,027,598, Patent No 3,027,598, filed on 12/14/2018, Divisional of Canada 2,678,455, Patent No 2,678,455, filed on 1/10/2008, PCT/US2008/050795 filed on 1/10/2008, Europe 08780367.2, Patent No 2124898 filed on 1/10/2008, United Kingdom 2124898 filed on 8/06/2009, Spain 08780367.2, Patent No 2124898 filed on 8/06/2009, France 2124898, Patent No 2124898 filed on 8/06/2009 Germany 08780367.2, Patent No 602008026819.5 filed on 8/06/2009 Claiming priority to 60/884,383 filed on 1/10/2007	Enhanced Delivery of Immunosuppressive Drug Compositions for Pulmonary Delivery	Jay I. Peters, Prapasri Sinswat, Robert O. Williams III, Jason T. McConville, Robert L. Talbert Jr., Keith P. Johnston, Alan B. Watts, True L. Rogers (DOW)	N	Parker Highlander PLLC
2802 WIL	14/713,156, Patent No 9,724,344 filed on 5/15/2015, Continuation of 11/660,012, Patent No 9,061,027 filed on 8/15/2007, PCT/US2005/030543 filed on 8/26/2005 Claiming priority to 60/605,179 filed on 8/27/2004	Enhanced Delivery of Drug Compositions to Treat Life Threatening Infections	Nicholas S. Beck (DOW) David S. Burgess, Ian B. Gillespie (DOW), Paula C. Garcia (DOW), David A. Hayes (DOW), Keith P. Johnston, James E. Hitt (DOW), Jay I. Peters (UTHSC-SA), True L. Rogers, Jason T. McConville, Brian D. Scherzer (DOW), Robert L. Talbert Jr., Christopher J. Tucker (DOW), Robert O. Williams III, Timothy J. Young	Y, University of Texas Health Science Center at San Antonio. .	Parker Highlander PLLC

EXHIBIT C

Niclosamide Diligence Milestones

Licensee by itself or through its Affiliates and Sublicensees will use diligent efforts to make commercially available products or services that practice an issued or pending claim of any patent or application listed under or claiming priority from an application listed under UT Tech ID 7574 WIL in the Patent Rights in Exhibit B, for example, oral or inhaled formulations of niclosamide ("**Niclosamide Products**"). Without limiting the foregoing, Licensee will (a) maintain a reasonably funded, ongoing and active research, development, manufacturing, regulatory, marketing or sales program required to make Niclosamide Products commercially available, and (b) by itself or through its Affiliates and Sublicensees fulfill the Niclosamide Milestone Events specified in this Exhibit C and (c) use diligent and commercially reasonable efforts to perform and complete the plans described in the annual report submitted pursuant to Section 4.2 (Annual Written Progress Report). If the obligations under this Exhibit C are not fulfilled, Licensor may treat such failure as a breach in accordance with Section 7.3(b), provided however if the breach is a result of not meeting the Niclosamide Milestone Events specified in this Exhibit C, Licensor will work in good faith with Licensee to cure such breach by amending the PLA to change the Field of the exclusive license to Patent Rights based on UT Tech ID 7574 WIL from "All fields" to "dry powders manufactured by thin film freezing or ultra-rapid freezing technology."

With regard to the Niclosamide Milestone Events specified in this Exhibit C, Licensee may at its election, extend the target date for fulfillment of such milestone events by twelve (12) months upon written notice to Licensor and payment to Licensor of an amount equal to $10,000. Licensee may invoke this clause only one time.

If Licensee sublicenses Patent Rights for the development of Niclosamide Products, and Sublicensee develops an alternate development plan within 24 months of Amendment Effective Date, Licensor will renegotiate Niclosamide Milestone Events in good faith according to Sublicensee's reasonable timeline.

Niclosamide Diligence Milestones and deadlines	**Niclosamide Milestone Events**	**Deadlines**
	Manufacture dosage form under GMP or GLP conditions for a Niclosamide Product that is intended for oral administration.	July 1, 2021
	Test a Niclosamide Product in humans that is administered orally.	July 1, 2022
	IND submission for a Niclosamide Product that is intended for oral administration.	July 1, 2023
	Initiate appropriate clinical study for an orally available Niclosamide Product.	July 1, 2024
	Receive Regulatory Approval for a Niclosamide Product for oral administration.	July 1, 2027
	First sale of orally available Niclosamide Product.	July 1, 2028

If Licensor or a third party discovers that the Niclosamide Products are useful for an application for which Products have not been developed or are not currently under development by Licensee by itself or through its Affiliates and Sublicensees, then Licensor shall give written notice to the Licensee, except for information that is subject to restrictions of confidentiality with third parties.

Within ninety (90) days following Licensee's receipt of Licensor's notification, Licensee shall give Licensor written notice stating whether Licensee elects to develop Niclosamide Products for the application. If Licensee elects to develop and commercialize the proposed Niclosamide Products for the new application, Licensee shall provide Licensor with a commercial development plan for the new application, including proposed commercial milestones. Licensor and Licensee shall negotiate in good faith new diligence milestones for such application, which shall be added to this Agreement by amendment.

If Licensee elects not to develop and commercialize the proposed Niclosamide Products for use in the new application, Licensor may seek third parties to develop and commercialize the proposed Niclosamide Products for the new application. If Licensor identifies a third party, it shall refer such third party to Licensee. If the third party requests a sublicense under this Agreement, then Licensee shall report the request to Licensor within thirty (30) days from the date of such written request. If Licensee does not grant a sublicense to such third party within ninety (90) days of its request, then Licensee shall submit to Licensor a report specifying the license terms proposed by the third party and written justification for the Licensee's refusal to grant the proposed sublicense. If Licensor, at is sole discretion, determines that the terms of the sublicense proposed by the third party are reasonable under the totality of the circumstances, taking into account the Niclosamide Products in development by Licensee or through its Affiliates and Sublicensees, then Licensor shall have the right to grant such third party a non-exclusive license to use, sell, offer for sale, and import Niclosamide Products for such new application in the Licensed Field on substantially the same terms as proposed to Licensee by the third party, providing royalty rates are at least equal to those paid or required to be paid by Licensee under this Agreement.

Exhibit 31.1

CERTIFICATIONS

I, Glenn Mattes, certify that:

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

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

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

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

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

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

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

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

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

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

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

TFF PHARMACEUTICALS, INC.

Date: May 11, 2022

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

Exhibit 31.2

CERTIFICATIONS

I, Kirk Coleman, certify that:

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

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

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

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

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

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

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

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

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

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

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

TFF PHARMACEUTICALS, INC.

Date: May 11, 2022

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

Exhibit 32.1

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

In connection with the Quarterly Report of TFF Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Glenn Mattes, the Chief Executive Officer, and Kirk Coleman, the Chief Financial Officer, of the Company, respectively, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

By: */s/ Glenn Mattes* Dated: May 11, 2022
Glenn Mattes,
Title: President and Chief Executive Officer

By: */s/ Kirk Coleman* Dated: May 11, 2022
Kirk Coleman,
Title: Chief Financial Officer

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