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

FORM 10-Q

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

For the Quarterly Period Ended September 30, 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. See the definitions of "large accelerated filer,"

"accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b–2 of the Exchange Act

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

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

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

The number of shares of the registrant's common stock outstanding as of November 7, 2022 was 25,518,084.

TFF PHARMACEUTICALS, INC.

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CAUTIONARY NOTICE

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.

These and other factors that may affect our financial results are discussed more fully in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in this report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for us to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in our forward-looking statements. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We caution readers not to place undue reliance on any forward-looking statements. We do not undertake, and specifically disclaim any obligation, to update or revise such statements to reflect new circumstances or unanticipated events as they occur, and we urge readers to review and consider disclosures we make in this and other reports that discuss factors germane to our business. See in particular our reports on Forms 10-K, 10-Q, and 8-K subsequently filed from time to time with the Securities and Exchange Commission.

RISK FACTOR SUMMARY

Our business is subject to numerous risks and uncertainties, including those described in Item 1A Risk Factors in this Quarterly Report on Form 10-Q. These risks include, but are not limited to the following:

We are a clinical-stage biopharmaceutical company with limited operating history.

We have a history of significant operating losses and anticipate continued operating losses for the foreseeable future.

We expect we will need additional financing to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all.

Our business model is entirely dependent on certain patent rights licensed to us from the University of Texas at Austin, and the loss of those license rights would, in all likelihood, cause our business, as presently contemplated, to fail.

Our business model includes the licensing of our TFF Platform to other pharmaceutical companies, however technology licensing in the pharmaceutical industry is a lengthy process and subject to several risks and factors outside of our control, and we cannot forecast our ability to successfully license our technology or the length of time it takes to establish a new licensing relationship.

Our business may be adversely affected by the recent COVID-19 outbreak.

We currently have no sales and marketing organization. If we are unable to establish satisfactory sales and marketing capabilities or secure a third-party sales and marketing relationship, we may not be able to successfully commercialize any of our product candidates.

We will be completely dependent on third parties to manufacture our product candidates, and the c commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

Our business operations could suffer in the event of information technology systems' failures or security breaches.

Sales of counterfeit versions of our product candidates, as well as unauthorized sales of our product candidates, may have adverse effects on our revenues, business, results of operations and damage our brand and reputation.

Our success is entirely dependent on our ability to obtain the marketing approval for our product candidates by the FDA and the regulatory authorities in foreign jurisdictions in which we intend to market our product candidates, of which there can be no assurance.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome.

Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited.

Even if we obtain marketing approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Even though we may apply for orphan drug designation for a product candidate, we may not be able to obtain orphan drug marketing exclusivity.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of any of our product candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues.

Any product candidates we develop that incorporate CBD will be subject to U.S. controlled substance laws and regulations and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition.

The passage of the 2018 Farm Bill will impact our development of a dry powder version of CBD.

We are dependent on rights to certain technologies licensed to us. We do not have complete control over these technologies and any loss of our rights to them could prevent us from selling our product candidates.

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

The market price of our shares may be subject to fluctuation and volatility. You could lose all or part of your investment.

If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

Future capital raises may dilute your ownership and/or have other adverse effects on our operations.

We are an "emerging growth company" under the JOBS Act of 2012 and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.

We have not paid dividends in the past and have no immediate plans to pay dividends.

We may be at an increased risk of securities class action litigation.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.

Our certificate of incorporation and amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

TFF PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,147,090	$ 33,794,672
Receivable due from collaboration agreement	1,812,975	1,628,703
Research and development tax incentive receivable	949,168	966,646
Prepaid assets and other current assets	1,069,761	2,447,930
Total current assets	16,978,994	38,837,951
Operating lease right-of-use asset, net	214,264	-
Property and equipment, net	3,026,466	1,859,860
Other assets	7,688	-
Total assets	$ 20,227,412	$ 40,697,811
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,634,024	$ 1,493,842
Accrued compensation	-	416,910
Deferred research grant revenue	362,710	50,000
Current portion of operating lease liability	79,838	-
Total current liabilities	2,076,572	1,960,752
Operating lease liability, net of current portion	128,314	-
Total liabilities	2,204,886	1,960,752
Commitments and contingencies (see Note 4)		
Stockholders' equity:		
Common stock; $0.001 par value, 45,000,000 shares authorized; 25,518,084 and 25,371,781 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	25,518	25,372
Additional paid-in capital	107,922,543	104,078,968
Accumulated other comprehensive loss	(210,347)	(48,921)
Accumulated deficit	(89,715,188)	(65,318,360)
Total stockholders' equity	18,022,526	38,737,059
Total liabilities and stockholders' equity	$ 20,227,412	$ 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Grant revenue	$ 87,586	$ 50,000	$ 183,025	$ 76,165
Operating expenses:				
Research and development	4,025,940	6,339,993	14,360,293	14,380,415
General and administrative	3,342,266	2,387,585	10,238,744	7,386,007
Total operating expenses	7,368,206	8,727,578	24,599,037	21,766,422
Loss from operations	(7,280,620)	(8,677,578)	(24,416,012)	(21,690,257)
Other income (expense):				
Other income	-	(13,129)	-	659,695
Interest income	6,119	12,051	19,184	41,619
Total other income (expense), net	6,119	(1,078)	19,184	701,314
Net loss	$ (7,274,501)	$ (8,678,656)	$(24,396,828)	$(20,988,943)
Net loss per share, basic and diluted	$ (0.29)	$ (0.34)	$ (0.96)	$ (0.85)
Weighted average common shares outstanding, basic and diluted	25,451,691	25,371,781	25,399,352	24,635,350

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Net loss	$ (7,274,501)	$ (8,678,656)	$(24,396,828)	$(20,988,943)
Other comprehensive loss:				
Foreign currency translation adjustments	(103,226)	(53,498)	(161,426)	(118,790)
Comprehensive loss	$ (7,377,727)	$ (8,732,154)	$(24,558,254)	$(21,107,733)

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

TFF PHARMACEUTICALS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2022 AND 2021

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

compensation	-	-	1,177,702	-	-	1,177,702
Foreign currency translation adjustment	-	-	-	47,234	-	47,234
Net loss	-	-	-	-	(8,376,002)	(8,376,002)
Balance, March 31, 2022	25,371,781	25,372	105,256,670	(1,687)	(73,694,362)	31,585,993
Issuance of common stock for stock option exercises	2,037	2	10,183	-	-	10,185
Stock-based compensation	-	-	1,195,081	-	-	1,195,081
Foreign currency translation adjustment	-	-	-	(105,434)	-	(105,434)
Net loss	-	-	-	-	(8,746,325)	(8,746,325)
Balance, June 30, 2022	25,373,818	25,374	106,461,934	(107,121)	(82,440,687)	23,939,500
Sale of common stock, net of offering costs	104,011	104	404,451	-	-	404,555
Issuance of common stock for stock option exercises	40,255	40	100,597	-	-	100,637
Stock-based compensation	-	-	955,561	-	-	955,561
Foreign currency translation adjustment	-	-	-	(103,226)	-	(103,226)
Net loss	-	-	-	-	(7,274,501)	(7,274,501)
Balance, September 30, 2022	25,518,084	$ 25,518	$ 107,922,543	$ (210,347)	$ (89,715,188)	$ 18,022,526
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					)	)

Balance, March 31, 2021	- 25,364,281	- 25,364	- 101,535,068	- (89,496)	(7,654,575) (41,934,223)	(7,654,575) 59,536,713
Additional offering costs related to the sale of common stock	-	-	(8,545)	-	-	(8,545)
Issuance of common stock for stock option exercises	7,500	8	34,492	-	-	34,500
Stock-based compensation	-	-	740,535	-	-	740,535
Foreign currency translation adjustment	-	-	-	(27,334)	-	(27,334)
Net loss	-	-	-	-	(4,655,712)	(4,655,712)
Balance, June 30, 2021	25,371,781	25,372	102,301,550	(116,830)	(46,589,935)	55,620,157
Stock-based compensation	-	-	856,594	-	-	856,594
Foreign currency translation adjustment	-	-	-	(53,498)	-	(53,498)
Net loss	-	-	-	-	(8,678,656)	(8,678,656)
Balance, September 30, 2021	25,371,781	$ 25,372	$ 103,158,144	$ (170,328)	$ (55,268,591)	$ 47,744,597

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

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

	For The Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$(24,396,828)	$(20,988,943)
Adjustment to reconcile net loss to net cash used in operating activities:		
Stock based compensation	3,328,344	2,627,544
Depreciation and amortization	267,311	34,426
Changes in operating assets and liabilities:		
Receivable due from collaboration agreement	(184,272)	(831,061)
Research and development tax incentive receivable	(103,307)	(1,168,553)
Prepaid assets and other assets	1,433,966	1,407,862
Accounts payable	148,657	269,433
Accrued compensation	(416,910)	-
Deferred revenue	312,710	(24,315)

Operating lease obligation	(29,869)	-
Net cash used in operating activities	(19,640,198)	(18,673,607)
Cash flows from investing activities:		
Purchases of property and equipment	(1,410,159)	(741,853)
Net cash used in investing activities	(1,410,159)	(741,853)
Cash flows from financing activities:		
Net proceeds from issuance of common stock	404,555	28,015,019
Proceeds from issuance of common stock for stock option exercises	10,185	689,753
Proceeds from issuance of common stock for warrant exercises	-	180,212
Net cash provided by financing activities	414,740	28,884,984
Effect of exchange rate changes on cash and cash equivalents	(11,965)	(54,586)
Net change in cash and cash equivalents	(20,647,582)	9,414,938
Cash and cash equivalents at beginning of period	33,794,672	35,300,805
Cash and cash equivalents at end of period	$ 13,147,090	$ 44,715,743
Supplemental disclosure of non-cash investing and financing activities:		
Receivable for option exercise	$ 100,637	$ -
Cashless exercise of warrants	$ -	$ 416
ROU asset obtained under for new operating lease	$ 238,021	$ -

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

TFF PHARMACEUTICALS, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
For The Three and Nine Months Ended September 30, 2022 and 2021

NOTE 1 - ORGANIZATION AND DESCRIPTION OF BUSINESS

TFF Pharmaceuticals, Inc. (the "Company") was incorporated in the State of Delaware on January 24, 2018. The Company's initial focus is on the development of inhaled dry powder drugs to enhance the treatment of pulmonary diseases and conditions. In December 2019, the Company established a wholly owned Australian subsidiary, TFF Pharmaceuticals Australia Pty Ltd ("TFF Australia"), in order to conduct clinical research. TFF Pharmaceuticals, Inc., along with TFF Australia, are collectively referred to as the "Company". The Company is in the development stage and is devoting substantially all of its efforts toward technology research and development and the human clinical trials of its initial product candidates.

NOTE 2 – LIQUIDITY AND MANAGEMENT'S PLANS

For the three and nine months ended September 30, 2022, the Company reported a net loss of $7.3 million and $24.4 million, respectively, and negative cash flow from operations for the nine months ended September 30, 2022

of $19.6 million. The Company had an accumulated deficit of $89.7 million and cash and cash equivalents of $13.1 million as of September 30, 2022. The Company has not generated revenues from commercial operations since inception and expects to continue incurring losses for the foreseeable future and needs to raise additional capital to continue the pursuit of its product development. On June 10, 2022, the Company entered into an Open Market Sale Agreement with Jefferies LLC, as agent, under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to $35.0 million in an "at-the-market" ("ATM") offering, to or through the agent. Through September 30, 2022, the Company sold 104,011 shares of its common stock at average price of $5.96 per share resulting in net proceeds of approximately $405,000, after deducting sales agent commissions and offering expenses.

NOTE 2 – LIQUIDITY AND MANAGEMENT'S PLANS (continued)

The Company expects to further increase its research and development activities, which will increase the amount of cash utilized subsequent to September 30, 2022. Specifically, the Company expects increased spending on research and development activities and higher payroll expenses as it hires additional 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 its presently planned level of operations. The Company plans to seek additional funding through various financing sources, including the sale of its equity and/or debt securities, and/or licensing fees for its technology and co-development and joint ventures with industry partners. The Company believes that its current cash and cash equivalents, and its access to capital through the sale of its equity securities, including the ATM offering, are sufficient to fund its present plan of operations for the next 12 months from the date of filing of these condensed consolidated financial statements. In addition, the Company will consider alternatives to its current business plan that may enable it to achieve its product development goals with a smaller amount of capital.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial statements and with Form 10-Q and Article 10 of Regulation S-X of the United States Securities and Exchange Commission ("SEC"). Accordingly, they do not contain all information and footnotes required by GAAP for annual financial statements. In the opinion of the Company's management, the accompanying unaudited condensed consolidated financial statements contain all the adjustments necessary (consisting only of normal recurring accruals) to present the financial position of the Company as of September 30, 2022 and the results of operations, changes in stockholders' equity and cash flows for the periods presented. The results of operations for the three and nine months ended September 30, 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.

Reclassification

Certain prior period amounts have been reclassified to conform to the current period classification. Amounts received from the United States Internal Revenue Service ("IRS") for payroll tax credits have been reclassified from other income to operating expenses in the condensed consolidated statements of operations to net the amounts

with the related expense that was incurred with no changes in the previously reported net losses.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, continued

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.

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. At times, the Company's cash balances may be uninsured for deposit accounts that exceed insured limits. The Company has not experienced any losses on such accounts. 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 September 30, 2022 and December 31, 2021, the Company had cash in Australia of AUD$59,664 (US$38,376) and AUD$831,984 (US$604,944), respectively.

Leases

At the inception of an arrangement, the Company determines whether an arrangement is or contains a lease based on the facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Leases with a term greater than one year are recognized on the condensed consolidated balance sheets as operating lease right-of-use assets and current and long-term operating lease liabilities, as applicable. The Company has elected not to recognize on the condensed consolidated balance sheets leases with terms of 12 months or less. The Company typically only includes the initial lease term in its assessment of a lease arrangement. Options to extend a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued rent. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

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 September 30, 2022 and 2021, the Company rendered the related services and recognized revenue and research and development expenses of $87,586 and $50,000, respectively. During the nine months ended September 30, 2022 and 2021, the Company rendered the related services and recognized revenue and research and development expenses of $183,025 and $76,165, respectively. As of September 30, 2022 and December 31, 2021, the Company had receivables due related to Feasibility Agreements of $232,296 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 $362,710 and $50,000, respectively.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, continued

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.

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 September 30, 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 periods ended September 30, 2022 and 2021. In addition, the Company is also eligible to receive amounts from the 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 $949,168 and $966,646 as of September 30, 2022 and December 31, 2021, respectively, in the condensed consolidated balance sheets. The Company recorded other income (expense) of $(13,129) and $659,695, in the condensed consolidated statements of operations for the three and nine months ended September 30, 2021, respectively, related to refundable research and development incentive program payments for expenditures incurred during 2020. The Company recorded a reduction to research and development expenses of $25,544 and $103,307 during the three and nine months ended September 30, 2022, respectively, and $219,520 and $735,927 during the three and nine months ended September 30, 2021, respectively.

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.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES, continued

For the nine months ended September 30, 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:

	Nine Months Ended September 30,	
	2022	2021
Stock Options	2,866,439	2,723,339
Warrants	414,233	389,233
	3,280,672	3,112,572

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.

Risks and Uncertainties

In December 2019, COVID-19, a novel strain of coronavirus, was first identified in China. In March 2020, the World Health Organization categorized COVID-19 as a pandemic, and the virus has spread to over 100 countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world.

Potential impacts to the Company's business include, but are not limited to, temporary closures of facilities of its vendors, disruptions or restrictions on its employees' ability to travel, disruptions to or delays in ongoing laboratory experiments, preclinical studies, clinical trials, third-party manufacturing supply and other operations, the supply of comparator products, the potential diversion of healthcare resources and staff away from the conduct of clinical trials to focus on pandemic concerns, interruptions or delays in the operations of the U.S. Food and Drug Administration or other regulatory authorities, and the Company's ability to raise capital and conduct business development activities.

The Company has experienced COVID-19 related delays in its Phase 2 clinical trials for TFF Voriconazole Inhalation Powder ("TFF Vori") and TFF Tacrolimus Inhalation Powder ("TFF Tac-Lac"). While the Company believes it will be able to effectively manage the delays, 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.

Recent Accounting Standards

There have been no recent accounting pronouncements, changes in accounting pronouncements or recently adopted accounting guidance during the nine months ended September 30, 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, 2023, as amended. The lease has an additional one-year option for renewal, and the base rent is $36,000 per year through October 31, 2022 and increases to

$37,080 per year through October 31, 2023. 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. In May 2022, the Company entered into a lease agreement for lab space in Austin, Texas. The lease commenced on June 1, 2022 and expires on May 31, 2025. The lease has an additional three-year option for renewal, which the Company has determined it is not reasonably certain to exercise.

NOTE 4 - COMMITMENTS AND CONTINGENCIES, continued

Supplemental balance sheet information related to leases was as follows:

	September 30, 2022
Operating leases:	
Operating lease right-of-use assets	$ 214,264
Operating lease liability – current portion	$ 79,838
Operating lease liability – long-term portion	128,314
Total operating lease liabilities	$ 208,152

Supplemental lease expense related to leases was as follows:

Lease	Statement of Operations Classification	For The Three Months Ended September 30, 2022	For The Three Months Ended September 30, 2021	For The Nine Months Ended September 30, 2022	For The Nine Months Ended September 30, 2021
Operating lease cost	Research and development	$ 22,275	$ -	$ 29,700	$ -
Short-term lease cost	Research and development	6,244	11,000	18,733	27,000
Short-term lease cost	General and administrative	21,000	9,000	62,659	27,000
Total lease expense		$ 49,519	$ 20,000	$ 111,092	$ 54,000

Other information related to operating leases:

	September 30, 2022
Weighted-average remaining lease term	2.7 years
Weighted-average discount rate	8%

Supplemental cash flow information related to operating leases was as follows:

	For The Nine Months Ended September 30, 2022	For The Nine Months Ended September 30, 2021

Cash paid for operating lease liabilities	$ 29,869	$ -

Approximate future minimum lease payments under non-cancellable leases (including short-term leases) are as follows:

Fiscal Year Ending December 31,	
2022 (Remaining)	$ 24,000
2023	119,000
2024	91,000
2025	38,000
Total minimum lease payments	272,000
Less: Imputed interest	(23,000)
Total	$ 249,000

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, and in March 2022 the Company and UT entered into an amended and restated patent license agreement for purposes of further strengthening the Company's license rights, including the Company's exclusive right to license all future UT patents relating to the TFF technology and all know-how held by UT relating to the TFF technology . 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 $0 as of both September 30, 2022 and December 31, 2021. During the three and nine months ended September 30, 2022, the Company recorded research and development costs of approximately $41,000 and $2,358,000, respectively, pertaining to this agreement. During the three and nine months ended September 30, 2021, the Company recorded research and development costs of approximately $0 and $2,380,000, 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, TFF Vori. The accounts payable due in connection with this agreement was approximately $0 and $21,000 as of September 30, 2022 and December 31, 2021, respectively. During the three and nine months ended September 30, 2022, the Company recorded research and development costs of approximately $209,000 and $835,000, respectively, pertaining to this agreement. During the three and nine months ended September 30, 2021, the Company recorded research and development costs of approximately $639,000 and $1,436,000, respectively, pertaining to this agreement.

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$38,000 (US$24,000) and AUD$138,000 (US$100,000) as of September 30, 2022 and December 31, 2021, respectively. During the three and nine months ended September 30, 2022, the Company recorded research and development costs of approximately AUD$87,000 (US$59,000) and AUD$550,000 (US$388,000), respectively, pertaining to this agreement. During the three and nine months ended September 30, 2021, the Company recorded research and development costs of approximately AUD$547,000 (US$402,000) and AUD$1,468,000 (US$1,113,000), 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, TFF Tac-Lac. The accounts payable due in connection with this agreement was approximately $0 and AUD$161,000 (US$117,000) as of September 30, 2022 and December 31, 2021, respectively. During the three and nine months ended September 30, 2022, the Company did not record any research and development costs pertaining to this agreement. During the three and nine months ended September 30, 2021, the Company recorded research and development costs of approximately AUD$119,000 (US$87,000) and AUD$565,000 (US$429,000), 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.

NOTE 5 - LICENSE AND AGREEMENTS, continued

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, TFF Vori. The accounts payable due in connection with this agreement was approximately $133,000 and $313,000 as of September 30, 2022 and December 31, 2021, respectively. During the three and nine months ended September 30, 2022, the Company recorded research and development costs of approximately $643,000 and $1,223,000, respectively, pertaining to this agreement. During the three and nine months ended September 30, 2021, the Company recorded research and development costs of approximately $735,000 and $1,036,000, 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, which was replaced by a Master Services Agreement entered into in May 2022, for one of the Company's drug product candidates, TFF Vori. The accounts payable due in connection with this agreement was approximately $363,000 as of September 30, 2022. During the three and nine months ended September 30, 2022, the Company recorded research and development costs of approximately $800,000 and $2,099,000, respectively, 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 and nine months ended September 30, 2022, the Company recorded research and development expenses of $0 and $184,273, respectively. During the three and nine months ended September 30, 2021, the Company recorded research and development expenses of $341,840 and $828,511, respectively. The Company has recorded a receivable of $1,812,975 and $1,628,703 for reimbursement due from Augmenta as of September 30, 2022 and December 31, 2021, respectively.

NOTE 6 - STOCKHOLDERS' EQUITY

Common Stock

Stock Option Exercises

During the nine months ended September 30, 2022, 42,292 shares of common stock were issued in connection with the exercise of stock options for total proceeds of $110,822, including $100,637 that was included in prepaid assets and other current assets as of September 30, 2022 and was received in October 2022.

At-Market-Offering

On June 10, 2022, the Company entered into an Open Market Sale Agreement with Jefferies LLC, as agent, under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to $35.0 million in an ATM offering, to or through the agent. Through September 30, 2022, the Company sold 104,011 shares of its common stock at average price of $5.96 per share resulting in net proceeds of approximately $405,000, after deducting offering expenses.

NOTE 7 - STOCK-BASED COMPENSATION

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

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 and nine months ended September 30, 2022 and 2021 for stock options and warrants:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 228,170	$ 137,549	$ 676,053	$ 274,285
General and administrative	727,391	719,045	2,652,291	2,353,259
	$ 955,561	$ 856,594	$ 3,328,344	$ 2,627,544

As of September 30, 2022, there was approximately $6,708,000 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 1.9 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 assumptions:

	Nine Months September 30, 2022
Weighted average exercise price	$ 7.06
Weighted average grant date fair value	$ 5.34
Assumptions	
Expected volatility	90%-97%
Weighted average expected term (in years)	6.3-10.0
Risk-free interest rate	2.41%-2.84%
Expected dividend yield	0.00%

NOTE 7 - STOCK BASED COMPENSATION, continued

The risk-free interest rate was obtained from U.S. Treasury rates for the applicable periods. The Company's expected volatility was based upon the historical volatility for industry peers and used an average of those volatilities. The expected life of the Company's options was determined using the simplified method as a result of limited historical data regarding the Company's activity 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

The following table summarizes stock option activity during the nine months ended September 30, 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	135,000	7.06	—	—
Exercised	(42,292)	2.62	—	—
Cancelled	(120,108)	7.44	—	—

Outstanding at September 30, 2022	2,866,439	$ 6.53	7.41	$ 1,186,091
Exercisable at September 30, 2022	1,770,913	$ 5.37	6.88	$ 1,138,945

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. The intrinsic value of the options exercised during 2022 was approximately $76,000.

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 nine months ended September 30, 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.

Warrants

On June 7, 2022, the Company issued a five-year warrant to purchase 25,000 shares of common stock at $5.70 per share to a consultant. The fair value of the warrant on the grant date was estimated using the Black-Scholes-Merton option pricing model with a common stock value of $5.74 per share, a contractual life of 5.0 years, a dividend yield of 0%, volatility of 96.87% and an assumed risk-free interest rate of 2.99%. The warrant is immediately exercisable. The fair value of the warrant was determined to be approximately $107,000 and was recorded in general and administrative expenses in the condensed consolidated statements of operations during the period ended September 30, 2022.

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

NOTE 8 - SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to September 30, 2022 through the filing date of this Quarterly Report. Based on its evaluation, nothing other than the events included in the notes to the condensed consolidated financial statements 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 a Phase 1b clinical trial of TFF Vori in asthma patients in the first quarter of 2022. A Phase 2 clinical trial of TFF Vori in patients with invasive pulmonary aspergillosis was initiated in 2022, and we anticipate reporting individual patient data in the first quarter of 2023. We have reported the positive efficacy and safety data of two patients who have been dosed with Voriconazole Inhalation Powder in a compassionate use study. In September 2021, we completed Phase 1 human clinical trials of our TFF Tac-Lac product in Australia. A Phase 2 clinical trial of TFF Tac-Lac in lung transplant patients was initiated in 2022 and we anticipate reporting individual patient data in the first half of 2023. 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 and our partner, Union Therapeutics, have not further progressed TFF Niclosamide pending the parties' further review of the Phase 1 results, animal data, and anti-viral market opportunities. 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 a collaboration agreement with UNION therapeutics A/S to develop a dry powder formulation of niclosamide. 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 the 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. A Phase 2 clinical trial of TFF Vori in patients with invasive pulmonary aspergillosis was initiated in 2022, and we anticipate reporting individual patient data in the first quarter of 2023. 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 toxicity 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. A Phase 2 clinical trial of TFF Tac-Lac in lung transplant patients was initiated in

2022, and we anticipate reporting individual patient data in the first half of 2023.

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 the first quarter of 2022, we completed the database lock for the Phase 1 trial of TFF Niclosamide. We and our partner, Union Therapeutics, have not further progressed TFF Niclosamide pending the parties' further review of the Phase 1 results, animal data, and anti-viral market opportunities. We have conducted independent market research to assess the additional therapeutic and market opportunities for TFF Niclosamide in other serious viral infections.

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. Through a 3-way CRADA between TFF, USAMRIID, and Geneva Foundation, USAMRIID will assess the immunogenicity and protective efficacy against SARS-CoV-2 induced by the TFF dry powder formulations when administered mucosally (directly to the site of infection), as compared to the traditional routes of administration (intramuscularly). 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.

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 agreed to collaborate on the joint development of novel commercial products incorporating Augmenta's human-derived monoclonal antibodies ("mAbs") for potential COVID-19 therapeutics. Both companies collaborated to conduct pre-clinical evaluations and successfully formulated the active pharmaceutical ingredient. Based on the pre-clinical results in the Omicron COVID-19 variant, we have suspended further development at this time.

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.

On June 10, 2022, we entered into an Open Market Sale Agreement with Jefferies LLC, as agent, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $35.0 million in an "at-the-market" or ATM offering, to or through the agent. Through September 30, 2022, the Company sold 104,011 shares of its common stock at average price of $5.96 per share resulting in net proceeds of approximately $405,000, after deducting offering expenses.

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 September 30, 2022 and 2021 together with the percentage change for those items.

	Three Months Ended September 30,			
	2022	2021	Increase (Decrease)	Change
Grant revenue	$ 87,586	$ 50,000	$ 37,586	75%
Research and development expense	$ 4,025,940	$ 6,339,993	$ (2,314,053)	(36)%
General and administrative expense	3,342,266	2,387,585	954,681	40%
Total operating expense	$ 7,368,206	$ 8,727,578	$ (1,359,372)	(16)%

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 September 30, 2022 and 2021, we recognized $87,586 and $50,000, respectively, of grant revenue.

During the three months ended September 30, 2022 and 2021, we incurred $4.0 million and $6.3 million of research and development expenses and $3.3 million and $2.4 million of general and administrative expenses, respectively.

The change in research and development expenses during 2022 was mainly due to increased clinical expenses of approximately $210,000 related to Niclosamide, TFF Vori and TFF Tac-Lac, increased stock-based

compensation of approximately $91,000, and increased lab expenses of approximately $122,000, offset by a decrease in manufacturing costs of approximately $1.7 million (which includes a decrease of approximately $342,000 in manufacturing expense related to the Augmenta monoclonal antibody), a decrease in preclinical expenses of approximately $1.0 million and a decrease in payroll and related expense of approximately $84,000. 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 $544,000, and consulting and business development expenses of approximately $288,000, along with other general increases. 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 September 30, 2022 and 2021 together with the percentage change for those items.

	Three Months Ended September 30,			
	2022	2021	Increase (Decrease)	Change
Other income (expense)	$ -	$ (13,129)	$ 13,129	100%
Interest income	$ 6,119	$ 12,051	$ (5,932)	(49)%

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 $7.3 million and $8.7 million for the three months ended September 30, 2022 and 2021, respectively.

The following table summarizes our results of operations with respect to the items set forth below for the nine months ended September 30, 2022 and 2021 together with the percentage change for those items.

	Nine Months Ended September 30,			
	2022	2021	Increase (Decrease)	Change
Grant revenue	$ 183,025	$ 76,165	$ 106,860	140%
Research and development expense	$14,360,293	$14,380,415	$ (20,122)	0%
General and administrative expense	10,238,744	7,386,007	2,852,737	39%
Total operating expense	$24,599,037	$21,766,422	$ 2,832,615	13%

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 nine months ended September 30, 2022 and 2021, we recognized $183,025 and $76,165, respectively, of grant revenue.

During the nine months ended September 30, 2022 and 2021, we incurred $14.4 million and $14.4 million of research and development expenses and $10.2 million and $7.4 million of general and administrative expenses,

respectively.

The change in research and development expenses during 2022 was mainly due to increased clinical expenses of approximately $3.2 million related to Niclosamide, TFF Vori and TFF Tac-Lac, payroll and related expense of approximately $497,000, stock-based compensation of approximately $402,000, depreciation expense of approximately $209,000, and increased lab expenses of approximately $356,000, offset by a decrease in preclinical expenses of approximately $3.0 million and manufacturing costs of approximately $1.5 million (which includes a decrease of approximately $644,000 in manufacturing expense related to the Augmenta monoclonal antibody),. 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 $1.5 million, payroll and related expenses of approximately $221,000, consulting and business development expenses of approximately $424,000 and stock-based compensation expense of approximately $299,000, along with other general increases. 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 nine months ended September 30, 2022 and 2021 together with the percentage change for those items.

	Nine Months Ended September 30,			
	2022	2021	Increase (Decrease)	Change
Other income	$ -	$ 659,695	$ (659,695)	(100)%
Interest income	$ 19,184	$ 41,619	$ (22,435)	(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 $24.4 million and $21.0 million for the nine months ended September 30, 2022 and 2021, respectively.

Financial Condition

As of September 30, 2022, we had total assets of approximately $20.2 million and working capital of approximately $14.9 million. As of September 30, 2022, our liquidity included approximately $13.1 million of cash and cash equivalents. On June 10, 2022, we entered into an Open Market Sale Agreement with Jefferies LLC, as agent, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $35.0 million in an “at-the-market” or ATM offering, to or through the agent. As of the date of this report, we will need additional capital to fund our operations through to the marketing approval for TFF Vori and TFF Tac-Lac, assuming such approval can be obtained at all, and to engage in the substantial development of any other of our drug candidates, such as formulation, early-stage animal testing and formal toxicology studies. We intend to seek additional funding through various financing sources, including the sale of our equity and/or debt securities, and/or licensing fees for our technology and co-development and joint ventures with industry partners. We believe that our current cash and cash equivalents, and our access to capital through the sale of our equity securities, including the ATM offering, are sufficient to fund our present plan of

operations for the next 12 months from the date of filing of these condensed consolidated financial statements. In addition, we will consider alternatives to our current business plan that may enable us to achieve our product development goals with a smaller amount of capital. However, there can be no guarantees that such funds, including any potential funds through the sale of our equity securities, including our ATM offering, 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 nine months ended September 30, 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 September 30, 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 September 30, 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

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

Risks Related to Our Business

We are a clinical-stage biopharmaceutical company with limited operating history. We are a biopharmaceutical company, newly-formed in January 2018, and have limited operating history. We have not commenced revenue-producing operations. In 2021, we completed Phase I human clinical trials for our TFF Voriconazole Inhalation Powder, or TFF Vori, and TFF Tacrolimus Inhalation Powder, or TFF Tac-Lac, product candidates, and in 2022 we initiated Phase 2 clinical trials for TFF Vori and TFF Tac-Lac. In addition, in November 2021 we commenced dosing in a Phase 1 human clinical trial of the TFF Niclosamide product in Canada, and in the first quarter of 2022, we completed the database lock for the Phase 1 trial of TFF Niclosamide. However, to date, our operations have otherwise consisted of preliminary research and development, drug formulation and characterization and testing of our initial product candidates. Our limited operating history makes it difficult for potential investors to evaluate our technology or prospective operations. As a development stage biopharmaceutical company, we are subject to all the risks inherent in the organization, financing, expenditures, complications and delays involved with a new business. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical-stage biopharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we may be unable to:

successfully implement or execute our business plan, or ensure that our business plan is sound;

successfully complete pre-clinical and clinical trials and obtain regulatory approval for the marketing of our product candidates;

successfully demonstrate a favorable differentiation between our dry powder candidates and the current products on the market;

our ability to commercially license our TFF platform to other pharmaceuticals companies

successfully contract for the manufacture of our clinical drug products and establish a commercial drug supply;

secure market exclusivity and/or adequate intellectual property protection for our product candidates;

attract and retain an experienced management and advisory team; and

raise sufficient funds in the capital markets to effectuate our business plan, including product and clinical development, regulatory approval and commercialization for our product candidates.

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

We have a history of significant operating losses and anticipate continued operating losses for the foreseeable future. For the fiscal years ended December 31, 2021 and 2020, we incurred a net loss of $31.0 million and $18.6 million, respectively, and for the nine months ended September 30, 2022 and 2021 we incurred a net loss of $24.4 million and $21.0 million, respectively. As of September 30, 2022, we had an accumulated deficit of $89.7 million. We expect to continue to incur substantial expenses without any corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize at least one of our product candidates or enter into one or more commercial license agreements for our TFF platform. However, there can be no assurance we will be able to obtain regulatory approval for any of our product candidates or enter into a commercial license. Even if we are able to obtain regulatory approval and subsequently commercialize our product candidates or successfully license our TFF platform, there can be no assurance that we will generate significant revenues or ever achieve profitability.

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

We will need additional financing to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all. As of September 30, 2022, we had total assets of approximately $20.2 million and working capital of approximately $14.9 million. As of September 30, 2022, our liquidity included approximately $13.1 million of cash and cash equivalents. We plan to seek additional funding through various financing sources, including the sale of our equity and/or debt securities, and/or licensing fees for our technology and co-development and joint ventures with industry partners. We believe that our current cash and cash equivalents, and our access to capital through the sale of our equity securities, including the current at-the-market, or ATM, offering, are sufficient to fund our present plan of operations for the next 12 months from the date this report. In addition, we will consider alternatives to our current business plan that may enable us to achieve our product development goals with a smaller amount of capital. However, there can be no guarantees that such funds will be available on commercially reasonable terms, if at all. If such financing is not available on satisfactory terms, we may be unable to further pursue our business plan and we may be unable to continue operations, in which case you may lose your entire investment.

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

Our business model includes the licensing of our TFF Platform to other pharmaceutical companies, however technology licensing in the pharmaceutical industry is a lengthy process and subject to several risks and factors outside of our control, and we cannot forecast our ability to successfully license our technology or the length of time it takes to establish a new licensing relationship. Our business model includes 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 feasibility studies of new chemical entities with multiple U.S. and international pharmaceutical companies. Our involvement with these pharmaceuticals companies typically begins with our formulation of dry powder versions of one or more proprietary drugs owned by the pharmaceutical company, followed by a period of feasibility testing and evaluation of the dry powder formulations by our potential licensee. Assuming the feasibility study is successful, and our dry powder formulation appears to provide the expected benefits, our ability to convert the successful test into a commercial license of our TFF platform is dependent on a number of risks and factors, many of which are outside our control, including:

the rate of adoption and incorporation of new technologies, including our TFF platform, by members of the pharmaceutical industry generally;

our potential licensee's internal evaluation of the economic benefits of marketing a dry powder version of a drug that may be currently marketed by the potential licensee, regardless of the benefits or advantages of the dry powder version;

our potential licensee's internal budgetary and product development issues, including their ability to commit the capital and human resources towards the development and of the dry powder product candidate;

our potential licensee's willingness to accept our requirements for upfront fees and ongoing royalties; and

the other risks relating to the adoption of our TFF platform discussed throughout this "Risk Factor" section

For example, in November 2021, we commenced dosing of TFF Niclosamide in a Phase 1 human clinical trial in Canada. Dosing was completed for the Phase 1 trial in January 2022. We and our partner, Union Therapeutics, have not further progressed TFF Niclosamide pending the parties' further review of the Phase 1 results, animal data, and anti-viral market opportunities.

In addition, we believe that in many cases our potential licensee engages with us in the early-stage feasibility testing as part of their evaluation of multiple drug and drug delivery options and prior to making any decision or commitment to the development of a dry powder version of their proprietary drug product. Consequently, even if our TFF platform is successful in early feasibility studies, our potential licensee may decide, for reasons unrelated to the performance of our TFF platform, not to enter into a license agreement with us. Therefore, we are unable to predict the degree to which our proposed licensing model will be successful.

Our business may be adversely affected by the recent COVID-19 outbreak. In December 2019, COVID-19, a novel strain of coronavirus, was first identified in China. In March 2020, the World Health Organization categorized COVID-19 as a pandemic, and the virus has spread to over 100 countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. Potential impacts to our business include, but are not limited to, temporary closures of facilities of its vendors, disruptions or restrictions on its employees' ability to

travel, disruptions to or delays in ongoing laboratory experiments, preclinical studies, clinical trials, third-party manufacturing supply and other operations, the supply of comparator products, the potential diversion of healthcare resources and staff away from the conduct of clinical trials to focus on pandemic concerns, interruptions or delays in the operations of the U.S. Food and Drug Administration, or FDA. or other regulatory authorities, and our ability to raise capital and conduct business development activities.

We have experienced COVID-19 related delays in our Phase 2 clinical trials for TFF Vori and TFF Tac-Lac. While we believe we will be able to effectively manage the delays, there can be no assurance that our 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.

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

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

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

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

the need arise.

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

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

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

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in development delays and lost sales. Additionally, we will rely on third parties to supply the raw materials needed to manufacture our product candidates. Any such reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery

schedules, reliability and quality. Any unanticipated disruption to the operation of one of our contract manufacturers caused by problems with suppliers could delay shipment of any of our product candidates, increase our cost of goods sold and result in lost sales.

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

decreased demand for any of our product candidates or any future products that we may develop;

injury to our reputation;

failure to obtain regulatory approval for our product candidates;

withdrawal of participants in our clinical trials;

costs associated with our defense of the related litigation;

a diversion of our management's time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

the inability to commercialize some or all of our product candidates; and

a decline in the value of our stock.

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

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

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

Risks Related to Product Regulation

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

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

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

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

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

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

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Our business model depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. In 2021, we completed Phase I human clinical trials for our TFF Vori and TFF Tac-Lac product candidates, and in November 2021 we commenced dosing in a Phase 1 human clinical trial of the TFF Niclosamide product in Canada. However, as of the date of this report, we have not otherwise progressed any of our product candidates beyond performance characterization and animal testing. We may not be successful in obtaining approval from the FDA or comparable foreign regulatory authorities to start clinical trials for any other of our product candidates. If we do not obtain such approvals as presently planned, the time in which we expect to commence clinical programs for any product candidate will be extended and such extension will increase our expenses, delay our potential receipt of any revenues, and increase our need for additional capital. Moreover, there is no guarantee that we will receive approval to commence human clinical trials or, if we do receive approval, that our clinical trials will be successful or that we will continue clinical development in support of an approval from the FDA or comparable foreign regulatory authorities for any indication. We note that most product candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. Therefore, our business currently depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur.

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

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies;
- efficacy of our product candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates in applicable therapeutic and vaccine guidelines;

the effectiveness of our own or any future collaborators' sales and marketing strategies;

limitations or warnings contained in approved labeling from regulatory authorities;

our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and

the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

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

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

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

The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further

requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

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

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

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

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

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

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

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

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

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

applications.

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

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

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

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

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

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

the FDA or a comparable foreign regulatory authority failing to grant permission to proceed and placing the clinical study on hold;

subjects for clinical testing failing to enroll or remain enrolled in our trials at the rate we expect;

a facility manufacturing any of our product candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of product candidates in the manufacturing process;

any changes to our manufacturing process that may be necessary or desired;

subjects choosing an alternative treatment for the indications for which we are developing our product candidates, or participating in competing clinical studies;

subjects experiencing severe or unexpected drug-related adverse effects;

reports from clinical testing on similar technologies and products raising safety and/or efficacy concerns;

third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGMP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;

inspections of clinical study sites by the FDA, comparable foreign regulatory authorities, or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from usingsome or all of the data in support of our marketing applications;

third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;

one or more IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

deviations of the clinical sites from trial protocols or dropping out of a trial;

adding new clinical trial sites;

the inability of the CRO to execute any clinical trials for any reason; and

government or regulatory delays or “clinical holds” requiring suspension or termination of a trial.

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

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

failing to approve or challenging the prices charged for health care products;

introducing reimportation schemes from lower priced jurisdictions;

limiting both coverage and the amount of reimbursement for new therapeutic products;

denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and

refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

On August 16, 2022, Congress enacted the Inflation Reduction Act of 2022 which contains several provisions relating to prescription drug costs, including requirements for federal government price negotiations, rebate requirements, and caps on out-of-pocket spending for Medicare Part D enrollees. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Any product candidates we develop that incorporate CBD will be subject to U.S.

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

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

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

Individual states have also established controlled substance laws and regulations. Though state-controlled substance laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our product candidates as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We must also obtain separate state registrations,

permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

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

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

Risks Relating to Our Intellectual Property Rights

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

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights. Our commercial success will depend, in part, on our ability to successfully defend the patent rights subject to our patent license agreement with UT against third-party challenges and successfully enforcing these patent rights against third party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for

which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in the patent applications subject to the UT patent license agreement. The patents and patent applications relating to our TFF platform and related technologies may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies.

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

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

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

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

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts. Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third-party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among

patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize any of our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may:

result in costly litigation;

divert the time and attention of our technical personnel and management;

prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;

require us to cease or modify our use of the technology and/or develop non-infringing technology; or

require us to enter into royalty or licensing agreements.

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

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

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

Risks Related to Owning Our Common Stock

The market price of our shares may be subject to fluctuation and volatility. You could lose all or part of your investment. The market price of our common stock is subject to wide fluctuations in response to various factors, some of which are beyond our control. Since shares of our common stock were sold in our initial public offering in October 2019 at a price of $5.00 per share, the reported closing prices of our common stock have ranged from $1.43 to $21.14 through November 10, 2022. The market price of our shares on the NASDAQ Global Market may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to:

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

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our shares and result in substantial losses being incurred by our investors. In the past, following periods of market volatility, public company stockholders have often instituted securities class action litigation. If we were

involved in securities litigation, it could impose a substantial cost upon us and divert the resources and attention of our management from our business.

If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline. In addition, independent industry analysts may provide reviews of our product candidates and our TFF platform's capabilities, as well as those of our competitors, and perception of our offerings in the marketplace may be significantly influenced by these reviews. We have no control over what these industry analysts report, and because industry analysts may influence current and potential customers, our brand could be harmed if they do not provide a positive review of our products and platform capabilities or view us as a market leader.

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

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

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

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

We will remain an "emerging growth company" for up to five years, although we will lose that status sooner

if our revenues exceed $1.07 billion, if we issue more than $1 billion in non-convertible debt in a three year period, or if the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30 in any future year.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. Commencing with our annual report on Form 10-K for the fiscal year ended December 31, 2020, we are required to provide a report on management's assessment of our internal control over financial reporting. Once we are neither an emerging growth company nor a non-accelerated filed, we will be required to obtain an attestation from our independent registered public accounting firm on our internal control report. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retrospective changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common shares. There is also a risk that neither we nor our independent registered public accounting firm (when applicable in the future) will be able to conclude within the prescribed timeframe that internal controls over financial reporting is effective as required by Section 404. As a result, investors could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

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

We may be at an increased risk of securities class action litigation. Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. For example, on November 1, 2022, we issued a press release announcing certain delays in the distribution of patient data from our Phase 2 clinical trials for TFF Vori and TFF Tac-Lac. On the following day, November 2, 2022, the share price for our common stock on the NASDAQ Global Market declined 39%. On the very same day, November 2, 2022, a law firm claiming to represent investor plaintiffs in class action security litigation issued a press release stating that based on our November 1st press release and resulting decline in share price that it was conducting an investigation to determine whether we and certain of our officers or directors have engaged in securities fraud or other unlawful business practices. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

limit who may call stockholder meetings;

do not provide for cumulative voting rights; and

provide that all board vacancies may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum.

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

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

any derivative action or proceeding brought on our behalf;

any action asserting a claim of breach of a fiduciary duty owed to us or our stockholders by any of our directors, officers or other employees;

any action asserting a claim against us or any of our directors, officers or other employees arising pursuant to any provision of Delaware law or our charter documents; or

any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine, but excluding actions to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

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

Item 6. Exhibits

Exhibit No.	Description	Method of Filing
3.1	Second Amended and Restated Certificate of Incorporation	Incorporated by reference from the

	of the Registrant	Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
3.2	Amended and Restated Bylaws of the Registrant	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
31.1	Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed electronically herewith
31.2	Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed electronically herewith
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).	Filed electronically herewith
101.INS	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.DEF	Inline XBRL Taxonomy Extension Definition 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
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	Filed electronically herewith

SIGNATURES

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

TFF PHARMACEUTICALS, INC.

Date: November 14, 2022

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

Date: November 14, 2022

By: */s/ Kirk Coleman*
Kirk Coleman,
Chief Financial Officer

(Principal Financial Officer)