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, 2023

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 Capital Market

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

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

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

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

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

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

The number of shares of the registrant's common stock outstanding as of November 13, 2023 was 59,133,574.

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 "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.
- The report of our independent registered public accounting firm for the year ended December 31, 2022 states that due to our lack of revenue from commercial operations, significant losses and need for additional capital there is substantial doubt about our ability to continue as a going concern.
- Our business could be adversely affected by conditions in the U.S. and global economies, the United States and global financial markets and adverse geopolitical and macroeconomic developments, including rising inflation rates and the Ukrainian/Russian and Israeli/Palestinian conflicts.
- 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, in part, the licensing of our TFF Platform to other pharmaceutical companies, however as of the date of this report, we have not out-licensed our TFF Platform to other pharmaceutical companies. 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 may take to establish a new licensing relationship.
- Our business model also depends on our successful development, regulatory approval and commercialization of our product candidates, which may never occur. Our TFF VORI and TFF TAC product candidates are currently undergoing Phase 2 clinical trials, however, there can be no assurance that either trial will be successful or that we will continue clinical development TFF VORI and TFF TAC in support of an approval from the FDA or comparable foreign regulatory authorities for any indication
- Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome.
- 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.
- 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.
- 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.
- COVID-19 has impacted and could continue to adversely impact our business
- We will be completely dependent on third parties to manufacture our product candidates for clinical and commercial purposes, 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.
- 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.
- 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.
- Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues.
- 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.
- 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 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, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,725,755	$ 16,612,315
Research and development tax incentive receivable	361,485	186,507
Prepaid assets and other current assets	805,659	2,226,344
Total current assets	10,892,899	19,025,166
Operating lease right-of-use asset, net	139,230	196,044
Property and equipment, net	2,064,354	3,078,342
Note receivable - Augmenta	1,781,000	1,812,975
Other assets	7,688	7,688
Total assets	$ 14,885,171	$ 24,120,215
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 983,287	$ 919,607
Accrued compensation	-	4,430
Deferred research grant revenue	76,000	126,000
Current portion of operating lease liability	82,725	80,625
Total current liabilities	1,142,012	1,130,662
Operating lease liability, net of current portion	52,230	110,094
Total liabilities	1,194,242	1,240,756
Commitments and contingencies (see Note 4)		
Stockholders' equity:		
Common stock; $0.001 par value, 90,000,000 shares and 45,000,000 shares authorized as of September 30, 2023 and December 31, 2022, respectively; 59,133,574 and 36,193,085 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	59,134	36,193
Additional paid-in capital	127,404,746	120,070,983
Accumulated other comprehensive loss	(203,712)	(139,295)
Accumulated deficit	(113,569,239)	(97,088,422)
Total stockholders' equity	13,690,929	22,879,459
Total liabilities and stockholders' equity	$ 14,885,171	$ 24,120,215

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,	
	2023	2022	2023	2022
Grant revenue	$ 234,763	$ 87,586	$ 619,543	$ 183,025
Operating expenses:				
Research and development	2,386,707	4,025,940	9,087,264	14,360,293
General and administrative	2,268,656	3,342,266	8,058,235	10,238,744
Total operating expenses	4,655,363	7,368,206	17,145,499	24,599,037
Loss from operations	(4,420,600)	(7,280,620)	(16,525,956)	(24,416,012)
Other income (expense):				
Interest income	88,810	6,119	160,009	19,184
Change in fair value of note receivable	(77,454)	-	(114,870)	-
Total other income, net	11,356	6,119	45,139	19,184
Net loss	$ (4,409,244)	$ (7,274,501)	$ (16,480,817)	$ (24,396,828)
Net loss per share, basic and diluted	$ (0.09)	$ (0.29)	$ (0.41)	$ (0.96)
Weighted average common shares outstanding, basic and diluted	47,441,693	25,451,691	39,983,825	25,399,352

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Net loss	$ (4,409,244)	$ (7,274,501)	$ (16,480,817)	$ (24,396,828)
Other comprehensive loss:				
Foreign currency translation adjustments	(38,182)	(103,226)	(64,417)	(161,426)
Comprehensive loss	$ (4,447,426)	$ (7,377,727)	$ (16,545,234)	$ (24,558,254)

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, 2023 AND 2022

	Common Stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance, January 1, 2023	36,193,085	$ 36,193	$120,070,983	$ (139,295)	$ (97,088,422)	$ 22,879,459
Stock-based compensation	-	-	751,821	-	-	751,821
Costs related to ATM	-	-	(17,920)	-	-	(17,920)
Foreign currency translation adjustment	-	-	-	(18,669)	-	(18,669)
Net loss	-	-	-	-	(7,051,367)	(7,051,367)
Balance, March 31, 2023	36,193,085	36,193	120,804,884	(157,964)	(104,139,789)	16,543,324
Stock-based compensation	-	-	825,719	-	-	825,719
Costs related to ATM	-	-	(59,229)	-	-	(59,229)
Foreign currency translation adjustment	-	-	-	(7,566)	-	(7,566)
Net loss	-	-	-	-	(5,020,206)	(5,020,206)
Balance, June 30, 2023	36,193,085	36,193	121,571,374	(165,530)	(109,159,995)	12,282,042
Sale of common stock in public offering, net of offering costs	22,880,400	22,881	5,041,841	-	-	5,064,722
Sale of common stock through ATM	60,089	60	25,212	-	-	25,272
Stock-based compensation	-	-	766,319	-	-	766,319
Foreign currency translation adjustment	-	-	-	(38,182)	-	(38,182)
Net loss	-	-	-	-	(4,409,244)	(4,409,244)
Balance, September 30, 2023	59,133,574	$ 59,134	$127,404,746	$ (203,712)	$(113,569,239)	$ 13,690,929
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 through ATM, 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

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,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (16,480,817)	$ (24,396,828)
Adjustment to reconcile net loss to net cash used in operating activities:		
Stock based compensation	2,343,859	3,328,344
Interest accrued on note receivable	(82,895)	-
Change in fair value of note receivable	114,870	-
Write-off of construction-in-process	747,348	-
Depreciation and amortization	371,814	267,311
Changes in operating assets and liabilities:		
Receivable due from collaboration agreement	-	(184,272)
Research and development tax incentive receivable	(211,785)	(103,307)
Prepaid assets and other current assets	1,416,302	1,433,966
Accounts payable	66,910	148,657
Accrued compensation	(4,430)	(416,910)
Deferred revenue	(50,000)	312,710
Operating lease obligation	(55,764)	(29,869)
Net cash used in operating activities	(11,824,588)	(19,640,198)
Cash flows from investing activities:		
Purchases of property and equipment	(48,359)	(1,410,159)
Net cash used in investing activities	(48,359)	(1,410,159)
Cash flows from financing activities:		
Sale of common stock in public offering, net of offering costs	5,064,722	-
Sale of common stock through ATM, net of offering costs	25,272	404,555
Payment of offering costs in connection with ATM	(77,149)	-
Proceeds from issuance of common stock for stock option exercises	-	10,185
Net cash provided by financing activities	5,012,845	414,740
Effect of exchange rate changes on cash and cash equivalents	(26,458)	(11,965)
Net change in cash and cash equivalents	(6,886,560)	(20,647,582)
Cash and cash equivalents at beginning of period	16,612,315	33,794,672
Cash and cash equivalents at end of period	$ 9,725,755	$ 13,147,090
Supplemental disclosure of non-cash investing and financing activities:		
Receivable for option exercise	$ -	$ 100,637
ROU asset obtained for new operating lease	$ -	$ 238,021

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

NOTE 1 - ORGANIZATION AND DESCRIPTION OF BUSINESS

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

NOTE 2 - GOING CONCERN AND MANAGEMENT'S PLANS

The accompanying condensed consolidated financial statements have been prepared under the assumption the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

For the nine months ended September 30, 2023 and 2022, the Company reported a net loss of $16.5 million and $24.4 million, respectively, and negative cash from operations of $11.8 million and $19.6 million, respectively. As of September 30, 2023, the Company had cash and cash equivalents of approximately $9.7 million, a working capital surplus of approximately $9.8 million and an accumulated deficit of $113.6 million. 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.

Management believes that the Company does not have sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing. Additionally, in view of the Company's expectation to incur significant losses for the foreseeable future it will be required to raise additional capital resources in order to fund its operations, although the availability of, and the Company's access to such resources, is not assured. Accordingly, management believes that there is substantial doubt regarding the Company's ability to continue operating as a going concern through at least the next twelve months from the date of this filing.

August 2023 Underwritten Public Offering

On August 17, 2023, the Company completed an underwritten public offering ("August 2023 Offering"), selling 22,880,400 shares of common stock, including 2,984,400 shares of common stock issued pursuant to the full exercise by the underwriter of its over-allotment option, at an offering price of $0.25 per share. The Company received gross proceeds of approximately $5.7 million. The Company received net proceeds of approximately $5.1 million, after deducting underwriting discounts and offering-related expenses.

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, 2023 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, 2023 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, 2022.

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.

Fair Value Option - Convertible Note Receivable

The guidance in Accounting Standards Codification ("ASC") 825, *Financial Instruments*, provides a fair value option election that allows entities to make an irrevocable election of fair value as the initial and subsequent measurement attribute for certain eligible financial assets and liabilities. The Company has elected to measure its convertible note receivable using the fair value option. Under the fair value option, bifurcation of an embedded derivative is not necessary, and all related gains and losses on the host contract and derivative due to change in the fair value will be reflected in other income (expense), net in the condensed consolidated statements of operations. Interest accrues on the unpaid principal balance on a quarterly basis and is recognized in interest income in the condensed consolidated statements of operations.

The decision to elect the fair value option is determined on an instrument-by-instrument basis and must be applied to an entire instrument and is irrevocable once elected. Pursuant to this guidance, assets and liabilities are measured at fair value based, in part, on general economic and stock market conditions and those characteristics specific to the underlying investments. The carrying value is adjusted to estimated fair value at the end of each quarter, required to be reported separately in our condensed consolidated balance sheets from those instruments using another accounting method.

Fair Value of Financial Instruments

Authoritative guidance requires disclosure of the fair value of financial instruments. The Company measures the fair value of certain of its financial assets and liabilities on a recurring basis. A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value which is not equivalent to cost will be classified and disclosed in one of the following three categories:

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

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

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

Revenue Recognition

Feasibility Agreements

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 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.

Grants

The Company accounts for grants awarded from a government-sponsored entity for research and development related activities that provide for payments for reimbursed costs, which includes overhead and general and administrative costs, as well as an administrative fee. The Company recognizes revenue from grants as it performs services under the arrangements. Associated expenses are recognized when incurred as research and development expense. Revenue and related expenses are presented gross in the consolidated statements of operations.

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.

As the Company has determined that it has reasonable assurance that it will receive the cash refund for eligible research and development expenditures, 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, 2023 and 2022. In addition, the Company is also eligible to receive amounts from the United States Internal Revenue Service ("IRS") related to research and development tax credits for expenditures.

The research and development incentive receivable represents amounts due in connection with the Australian Tax Incentive and from the IRS. The Company has recorded a research and development tax incentive receivable of $361,485 and $186,507 as of September 30, 2023 and December 31, 2022, respectively, in the condensed consolidated balance sheets. The Company recorded a reduction to research and development expenses of $88,947 and $211,785 during the three and nine months ended September 30, 2023, respectively, and $25,544 and $103,307 during the three and nine months ended September 30, 2022, 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.

For the nine months ended September 30, 2023 and 2022, 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:

	For The Nine Months Ended September 30,	
	2023	**2022**
Stock Options	5,327,820	2,866,439
Warrants	6,205,400	414,233
	11,533,220	3,280,672

* *On an as-converted basis*

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires the Company’s management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates include the fair value of the convertible note receivable, 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

The Company's business may be adversely affected by the continuing fallout from the COVID-19 pandemic. While the COVID-19 pandemic has abated in the last several months, many of the consequences of the COVID-19 pandemic continue to cause disruption and increased costs for businesses. In the case of clinical stage biopharmaceutical companies, the Company believes there continue to be, among other things, supply chain disruptions that are causing delays in the delivery of drug candidates and comparator products and healthcare staffing shortages that are causing delays in the establishment of test sites and the conduct of clinical trials.

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.

During 2020, the Company experienced a temporary suspension of dosing in the Phase I clinical trial for TFF TAC due to the COVID-19 pandemic and the pandemic has otherwise caused minor slowing in the timing of certain non-clinical and clinical activities by the Company and its collaborators and service providers during 2020 to date. However, the COVID-19 pandemic has not caused the Company to forego, abandon or materially delay any proposed activities. While the Company believes it has been able to effectively manage the disruption caused by the COVID-19 pandemic to date, there can be no assurance that its operations, including the development of its drug candidates, will not be disrupted or materially adversely affected in the future by the COVID-19 pandemic or an epidemic or outbreak of an infectious disease like the outbreak of COVID-19.

In February 2022, Russia commenced a military invasion of Ukraine causing ongoing geopolitical turmoil, including continuing military action in the region and sanctions imposed on Russia.

These and other events have caused and may continue to cause significant disruption, instability and volatility in the global economy and financial markets, resulting in inflation, rising interest rates, tightening of credit markets and bank failures, the actual or anticipated occurrence of which may have an adverse impact on the Company's business or ability to access capital markets in the future.

On August 30, 2023, the Company received a notice from the Nasdaq Stock Market, LLC ("Nasdaq") stating that the staff of the Nasdaq has determined that the Company will be eligible for an additional 180 calendar day period to regain compliance with the minimum bid price requirement in Nasdaq Listing Rule 5450(a)(1). As previously reported by the Company, on March 2, 2023, the Company received a notice ("Notice") of delisting from the Nasdaq because the closing bid price of the Company's common stock over the previous 30 consecutive trading-day period had fallen below $1.00 per share. Pursuant to the Notice and Rule 5810(c)(3)(A) of the Nasdaq Listing Rules, the Company had an initial 180 days from the date of the Notice, or until August 29, 2023, to regain compliance with the minimum bid price requirement in Rule 5450(a)(1) by achieving a closing bid price for the Company's common stock of at least $1.00 per share over a minimum of 10 consecutive business days. The Company now has until February 26, 2024 to regain compliance with the minimum bid price requirement in Nasdaq listing Rule 5450(a)(1). If the Company does not regain compliance with Rule 5450(a)(1) by achieving a closing bid price for the Company's common stock of at least $1.00 per share over a minimum of 10 consecutive business days by February 26, 2024, the Nasdaq will commence suspension and delisting procedures.

Recent Accounting Standards

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging -Contracts in Entity' Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity' Own Equity* ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU also removes certain settlement conditions that are required for equity-linked contracts to qualify for the derivative scope exception, and it simplifies the diluted earnings per share calculation in certain areas. The provisions of ASU 2020-06 are applicable for fiscal years beginning after December 15, 2023, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. The Company adopted ASU 2020-06 on January 1, 2023, which did not result in a material impact on its condensed consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, Fin*ancial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments*. The ASU amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that aren't measured at fair value through net income (loss). For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction in carrying value of the asset. Entities will no longer be permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses should be recognized. This new guidance is effective in the first quarter of 2023 for calendar-year SEC filers that are smaller reporting companies as of the one-time determination date. Early adoption is permitted beginning in 2019. The Company has adopted the new guidance as of January 1, 2023, and it did not have a material impact on its condensed consolidated financial statements and related disclosures.

The Company's management does not believe that any other recently issued, but not yet effective, accounting standards if currently adopted would have a material effect on the consolidated financial statements.

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 $37,080 per year. The Company 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 did not renew the lease upon its expiration. 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.

Supplemental balance sheet information related to leases was as follows:

	September 30, 2023	December 31, 2022
Operating leases:		
Operating lease right-of-use assets	$ 139,230	$ 196,044
Operating lease liability - current portion	$ 82,725	$ 80,625
Operating lease liability - long-term portion	52,230	110,094
Total operating lease liabilities	$ 134,955	$ 190,719

Supplemental lease expense related to leases was as follows:

Lease	Statement of Operations Classification	For The Three Months Ended September 30, 2023	For The Three Months Ended September 30, 2022	For The Nine Months Ended September 30, 2023	For The Nine Months Ended September 30, 2022
Operating lease cost	Research and development	$ 22,275	$ 22,275	$ 66,825	$ 29,700
Short-term lease cost	Research and development	-	6,244	-	18,733
Short-term lease cost	General and administrative	21,570	21,000	64,910	62,659
Total lease expense		$ 43,845	$ 49,519	$ 131,735	$ 111,092

Other information related to operating leases:

	September 30, 2023	December 31, 2022
Weighted-average remaining lease term	1.7 years	2.4 years
Weighted-average discount rate	8%	8%

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

	For The Nine Months Ended September 30, 2023	For The Nine Months Ended September 30, 2022
Cash paid for operating lease liabilities	$ 65,775	$ 29,869

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

Fiscal Year Ending December 31,	
2023 (Remaining)	$ 18,000
2024	91,000
2025	38,000
Total minimum lease payments	147,000
Less: Imputed interest	(9,000)
Total	$ 138,000

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 - CONVERTIBLE NOTE RECEIVABLE - AUGMENTA

Effective January 1, 2023, the Company and Augmenta Bioworks, Inc. ("Augmenta") entered into a convertible note purchase agreement ("Augmenta Note") pursuant to which a receivable due from Augmenta in connection with a joint development agreement was converted into the Augmenta Note. Under the terms of the Augmenta Note, Augmenta agreed to pay the principal amount of $1,812,975 to the Company. The Augmenta Note accrues interest at a rate of 6% per annum and has a maturity date of the earlier of (i) January 1, 2026 ("Maturity Date"), or (ii) upon the occurrence and during the continuance of an event of default. Accrued interest shall be payable at maturity.

The Company has the following optional conversion rights under the Augmenta Note:

- The Company may convert, at any time and at its option, all outstanding principal and accrued and unpaid interest into shares of Augmenta common stock at a price per share equal to an amount obtained by dividing $15,000,000 by the number of outstanding shares of Augmenta common stock on a fully diluted basis ("Conversion Price").

- If Augmenta completes a private placement sale of its preferred stock in the amount less than $15,000,000, the Company may convert, at its option, all outstanding principal and accrued and unpaid interest into shares of the same security in such financing at a per share price equal to the lower of the Conversion Price or the price per share sold in the financing.

In addition, the outstanding principal and accrued and unpaid interest under the Augmenta Note will automatically convert in the following scenarios:

- If Augmenta completes a financing with gross proceeds of at least $15,000,000 ("Qualified Financing") on or before the Maturity Date, then the outstanding principal and accrued and unpaid interest shall automatically convert into the same security at a price per share equal to the lower of the Conversion Price or the price per share sold in the Qualified Financing.

- If Augmenta completes an underwritten public offering with gross proceeds of at least $35,000,000 (“Qualified IPO”) on or before the Maturity Date, then the outstanding principal and accrued and unpaid interest shall automatically convert into the same security at a price per share equal to the lower of the Conversion Price or the price per share sold in the Qualified IPO.

- If a change of control occurs prior to the payment in full of the principal amount of the Augmenta Note, then the Company will be paid all outstanding principal and accrued and unpaid interest, plus a premium of 100% of the outstanding principal.

The Company has elected to measure the Augmenta Note at fair value in accordance with ASC 825 (see Note 6).

NOTE 6 - FAIR VALUE OF FINANCIAL ASSETS AND LIABILITIES

The carrying value of cash and cash equivalents, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The Augmenta Note is held at fair value.

The following table presents the Company’s assets and liabilities that are measured at fair value as of September 30, 2023:

	Fair value measured as of September 30, 2023			
	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets				
Augmenta Note at fair value	$ 1,781,000	$ -	$ -	$ 1,781,000

Level 3 Measurement

The following table sets forth a summary of the changes in the fair value of the Company’s Level 3 financial assets that are measured at fair value on a recurring basis:

	Fair Value of Level 3 Augmenta Note
Beginning balance, January 1, 2023	$ 1,812,975
Accrued interest receivable	82,895
Change in fair value	(114,870)
Ending balance, September 30, 2023	$ 1,781,000

The fair value of the Augmenta Note is measured using Level 3 (unobservable) inputs. The Company determined the fair value for the Augmenta Note using a probability weighted-scenario valuation model with the assistance of a third-party valuation specialist. The unobservable inputs include estimates of the equity value of Augmenta and the timing and probability of future financing events, optional conversion to common stock, and repayment at maturity. The conversion upon a qualified financing scenario valued the Augmenta Note based on a bond plus call option model. The optional conversion to common stock valued the Augmenta Note based on the present value of common stock, determined using an adjusted net assets method and option-pricing model, and implied number of common shares upon conversion. The repayment upon maturity is based on the total principal and accrued interest through the maturity date.

NOTE 7 - STOCKHOLDERS' EQUITY

Common Stock

August 2023 Offering

On August 17, 2023, the Company completed the August 2023 Offering, selling 22,880,400 shares of common stock, including 2,984,400 shares of common stock issued pursuant to the full exercise by the underwriter of its over-allotment option, at an offering price of $0.25 per share. The Company received gross proceeds of approximately $5.7 million. The Company received net proceeds of approximately $5.1 million, after deducting underwriting discounts and offering-related expenses. In connection with the August 2023 Offering, the Company issued to the underwriter a warrant to purchase 457,608 shares of common stock, exercisable at $0.3125 per share, commencing on the 180th day following the closing date of the August 2023 Offering and expiring five years from the closing date of the August 2023 Offering. The classification of the warrants was evaluated and the Company concluded they are considered equity instruments. The warrants were considered offering costs and netted against additional paid-in capital.

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. During the three months September 30, 2023, the Company sold 60,089 shares of its common stock at average price of $0.42 per share resulting in net proceeds of approximately $25,000.

NOTE 8 - STOCK BASED COMPENSATION

In January 2018, the Company's board of directors approved its 2018 Stock Incentive Plan ("2018 Plan"). The 2018 Plan provides for the grant of non-qualified stock options and incentive stock options to purchase shares of the Company's common stock, the grant of restricted and unrestricted share awards and grant of restricted stock units. The 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, 2023 and 2022 for stock options and warrants:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 251,397	$ 228,170	$ 756,511	$ 676,053
General and administrative	514,922	727,391	1,587,348	2,652,291
	$ 766,319	$ 955,561	$ 2,343,859	$ 3,328,344

As of September 30, 2023, there was approximately $4,712,000 of total unrecognized compensation expense related to non-vested share-based compensation arrangements that are expected to vest. This cost is expected to be recognized over a weighted-average period of 2.1 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:

	For The Nine Months September 30, 2023
Weighted average exercise price	$ 1.06
Weighted average grant date fair value	$ 0.70
Assumptions	
Expected volatility	92%-102%
Expected term (in years)	6.3 - 10.0
Risk-free interest rate	3.44%-4.19%
Expected dividend yield	0.00%

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

The following table summarizes stock option activity during the nine months ended September 30, 2023:

	Number of Shares	Weighted-Average Exercise Prices	Weighted-Average Remaining Contractual Term (In Years)	Intrinsic Value
Outstanding at January 1, 2023	2,909,057	$ 5.96	7.46	$ 24,279
Granted	2,759,950	1.06	-	-
Cancelled	(341,187)	7.15	-	-
Outstanding at September 30, 2023	5,327,820	$ 3.35	7.66	$ -
Exercisable at September 30, 2023	2,252,747	$ 4.72	5.78	$ -

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.

NOTE 9 - SBIR GRANT

On June 23, 2023, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, awarded the Company a Direct to Phase II Small Business Innovation Research ("SBIR") grant of approximately $2.84 million to continue development of a novel, pan-flu multivariant mucosal vaccine using the Company's Thin Film Freezing technology.

The purpose of the SBIR grant is to provide funding to support preclinical and IND enabling studies to advance the development of a shelf-stable dry powder formulation of a novel universal influenza virus vaccine, developed in the laboratory of Dr. Ted Ross at the Cleveland Clinic (previously of University of Georgia). Funding from the SBIR grant is expected to take place over three years.

Revenue from the SBIR grant will be recognized in the period during which the related qualifying services are rendered and costs are incurred, provided that the applicable conditions under the SBIR grant have been met. The costs associated with the SBIR grant will be expensed as incurred and will be reflected as a component of research and development expense in the accompanying condensed consolidated statements of operations.

Funds received from the SBIR grant will be recorded as revenue as the Company is the principal participant in the arrangement because the activities under the SBIR grant 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 will classify 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 will record a grant receivable.

NOTE 10 - SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to September 30, 2023 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 2022 Annual Report on Form 10-K filed with the SEC on March 31, 2023.

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 II, Item 1A. "Risk Factors" in this report. 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. Based on our internal and sponsored testing and studies, we believe that our TFF platform can significantly improve the solubility of poorly water-soluble drugs, which make up approximately 40% of marketed pharmaceuticals worldwide, thereby improving the bioavailability and pharmacokinetics 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. When administered as an inhaled dry powder for treatment of lung disorders, we believe the TFF platform formulations can be used to increase efficacy and/or minimize systemic toxicities and drug-drug interactions.

As of the date of this report, we have two product candidates in clinical trials, TFF Voriconazole Inhalation Powder, or TFF VORI, and TFF Tacrolimus Inhalation Powder, or TFF TAC. To date, we have completed one Phase 1 study in healthy volunteers and one Phase 1b study in patients with asthma exploring the safety, tolerability and pharmacokinetics of TFF VORI. As of the date of this report, a Phase 2 clinical trial of TFF VORI in patients with invasive pulmonary aspergillosis has been initiated. We have also completed one Phase 1 study in healthy volunteers examining the safety, tolerability and pharmacokinetics of TFF TAC. As of the date of this report, a Phase 2 clinical trial of TFF TAC in lung transplant patients has been initiated.

On July 31, 2023, we announced the opening of an Expanded Access Program ("EAP") with Uniphar Durbin Ireland Limited enabling patients access to TFF VORI in the United States, Australia, United Kingdom, Canada and select countries in Europe. The EAP covers pulmonary aspergillosis including invasive pulmonary aspergillosis, chronic pulmonary aspergillosis, allergic bronchopulmonary aspergillosis, aspergillus tracheobronchitis, and aspergillus bronchoanastomotic infections as well as other voriconazole responsive fungal pulmonary infections.

We are also actively engaged in the analysis and testing of dry powder formulations of several drugs and vaccines through parenteral, topical, ocular, pulmonary and nasal applications through feasibility studies and material transfer agreements with U.S. and international pharmaceutical companies and certain government agencies. We intend to initially focus on the development of inhaled dry powder drugs for the treatment of pulmonary diseases and conditions. While the TFF platform was designed to improve solubility of poorly water-soluble drugs generally, the researchers at University of Texas at Austin, or UT, found that the technology was particularly useful in generating dry powder particles with properties which allow for superior inhalation delivery, especially to the deep lung, which is an area of extreme interest in respiratory medicine. We believe that our TFF platform can significantly increase the number of pulmonary drug products that can be delivered directly to the lung. We intend to design our dry powder drug products for use with dry powder inhalers, which are generally considered to be the most effective and patient-friendly of all breath-actuated inhalers. We plan to focus on developing inhaled dry powder formulations of existing off-patent drugs suited for lung diseases and conditions, which we believe includes dozens of potential drug candidates, many of which have a potential market of over $1 billion.

We intend to directly pursue the development of dry powder formulations of off-patent drugs through the U.S. Food and Drug Administration's, or FDA's, 505(b)(2) regulatory pathway and in corresponding regulatory paths in other foreign jurisdictions. The 505(b)(2) pathway contains full reports of investigations of safety and effectiveness but at least some of the information required for approval comes from studies not conducted by or for the NDA applicant. 505(b)(2) products have the potential advantage of significantly lower development costs and shorter development timelines versus traditional new molecular entities. The clinical requirements for a 505(b)(2) drug candidate can vary widely from product to product depending primarily on whether the product candidate claims a new indication, provides for a different route of administration or claims improved safety compared to the existing approved product, and may include bioequivalence trials, limited safety and efficacy trials, or full Phase I through III trials. Unless the FDA releases a guidance document, the clinical requirement for a 505(b)(2) product candidate is typically not known until the drug sponsor has a pre-IND and an end of Phase 2 meeting with the FDA. For example, based on our meetings to date with the FDA, we believe we may need to conduct additional clinical trials beyond the current Phase 2 trials for TFF VORI and TFF TAC prior to filing for marketing approval for either product.

TFF TAC has been awarded orphan drug status. We also believe that in some cases our other dry powder drug products may qualify for the FDA's orphan drug status.

We intend to commercialize our TFF platform and internally developed product candidates through the following means:

- We may out-license our internally developed product candidates, such as TFF VORI and TFF TAC, or agree to jointly develop such products with a third-party pharmaceutical company;

- Upon and subject to receipt of the requisite approvals, we may directly commercialize our internally developed product candidates through our internal direct sales and potentially in combination with third-party marketing and distribution partnerships; and

- We may pursue the licensing of our TFF platform or a joint development arrangement for a particular field of use with a third-party pharmaceutical company.

Results of Operations

To date, our operations have consisted of the development and early-stage testing, Phase 1 human clinical trials of our initial product candidates and the current Phase 2 clinical trials of our TFF VORI and TFF TAC. We have received limited grant revenue in connection with feasibility studies conducted by our potential partners, however we have not commenced commercial revenue-producing operations.

Three Months Ended September 30, 2023 Compared to the Three Months Ended September 30, 2022

The following table summarizes our results of operations with respect to the items set forth below for the three months ended September 30, 2023 and 2022 together with the percentage change for those items.

	For The Three Months Ended September 30,			
	2023	2022	Increase (Decrease)	Change
Grant revenue	$ 234,763	$ 87,586	$ 147,177	168%
Research and development expense	$ 2,386,707	$ 4,025,940	$ (1,639,233)	(41)%
General and administrative expense	2,268,656	3,342,266	(1,073,610)	(32)%
Total operating expense	$ 4,655,363	$ 7,368,206	$ (2,712,843)	(37)%

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, 2023 and 2022, we recognized $234,763 and $87,586, respectively, of grant revenue.

Research and development expense was as follows for the periods indicated:

	For The Three Months Ended September 30,			
	2023	2022	Increase (Decrease)	Change
Manufacturing and related	$ 695,381	$ 1,996,789	$ (1,301,408)	(65)%
Clinical and preclinical	559,960	1,354,833	(794,873)	(59)%
Payroll, stock-based compensation and related	824,754	514,974	309,780	60%
Other	306,612	159,344	147,268	92%
Total research and development expense	$ 2,386,707	$ 4,025,940	$ (1,639,233)	(41)%

Research and development expense decreased during the three months ended September 30, 2023 compared to the three months ended September 30, 2022 due to a $1.3 million reduction in manufacturing and related expenses and a $0.8 million reduction in clinical and preclinical expenses, offset by increases of $0.3 million in payroll expense and $0.1 million in other research and development expenses. Research and development expenses during the three months ended September 30, 2022 were impacted by the initial set-up costs for the Phase 2 trial of TFF Vori, completion of the Phase 1 trial of TFF Niclosamide and the suspension of the joint development and collaboration agreement with Augmenta Bioworks, Inc.

General and administrative expense was as follows for the periods indicated:

	For The Three Months Ended September 30,			
	2023	2022	Increase (Decrease)	Change
Payroll, stock-based compensation and related	$ 1,032,286	$ 1,183,208	$ (150,922)	(13)%
Insurance and office expense	497,274	714,002	(216,728)	(30)%
Professional fees and patent expense	477,909	647,448	(169,539)	(26)%
Market research	91,755	388,631	(296,876)	(76)%
Consulting	61,500	318,108	(256,608)	(81)%
Other	107,932	90,869	17,063	19%
Total general and administrative expense	$ 2,268,656	$ 3,342,266	$ (1,073,610)	(32)%

General and administrative expense decreased during the three months ended September 30, 2023 compared to the three months ended September 30, 2022 due to decreases of $0.2 million in payroll related expenses, $0.2 million in insurance and office expenses, $0.2 million in professional fees and patent expenses, $0.3 million in market research expenses and $0.3 million in consulting expenses. The decrease in general and administrative expenses was due in part to strategic cost reduction efforts implemented by management.

The following table summarizes our interest income for the three months ended September 30, 2023 and 2022 together with the percentage change for those items.

	For The Three Months Ended September 30,			
	2023	2022	Increase (Decrease)	Change
Interest income	$ 88,810	$ 6,119	$ 82,691	1,351%
Change in fair value of note receivable	$ (77,454)	$ -	$ (77,454)	100%

Interest income increased during fiscal 2023 mainly due to the interest accrued on the note receivable and increased interest earned on cash equivalents. Other expense during fiscal 2023 is the change in the fair value of the note receivable.

We incurred a net loss of $4.4 million and $7.3 million for the three months ended September 30, 2023 and 2022, respectively.

Nine Months Ended September 30, 2023 Compared to the Nine Months Ended September 30, 2022

The following table summarizes our results of operations with respect to the items set forth below for the nine months ended September 30, 2023 and 2022 together with the percentage change for those items.

	For The Nine Months Ended September 30,			
	2023	2022	Increase (Decrease)	Change
Grant revenue	$ 619,543	$ 183,025	$ 436,518	239%
Research and development expense	$ 9,087,264	$ 14,360,293	$ (5,273,029)	(37)%
General and administrative expense	8,058,235	10,238,744	(2,180,509)	(21)%
Total operating expense	$ 17,145,499	$ 24,599,037	$ (7,453,538)	(30)%

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, 2023 and 2022, we recognized $619,543 and $183,025, respectively, of grant revenue.

Research and development expense was as follows for the periods indicated:

	For The Nine Months Ended September 30,			
	2023	2022	Increase (Decrease)	Change
Manufacturing and related	$ 3,871,180	$ 6,005,160	$ (2,133,980)	(36)%
Clinical and preclinical	2,146,325	6,268,219	(4,121,894)	(66)%
Payroll, stock-based compensation and related	2,345,856	1,545,510	800,346	52%
Other	723,903	541,404	182,499	34%
Total research and development expense	$ 9,087,264	$ 14,360,293	$ (5,273,029)	(37)%

Research and development expense decreased during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 due to a $4.1 million reduction in clinical and preclinical expenses and a $2.1 million reduction in manufacturing and related expenses, offset by increases of $0.8 million payroll expense and $0.2 million other research and development expenses. Research and development expenses during the nine months ended September 30, 2022 were impacted by the initial set-up costs for the Phase 2 trial of TFF Vori, completion of the Phase 1 trial of TFF Niclosamide and the suspension of the joint development and collaboration agreement with Augmenta Bioworks, Inc.

General and administrative expense was as follows for the periods indicated:

	For The Nine Months Ended September 30,			
	2023	2022	Increase (Decrease)	Change
Payroll, stock-based compensation and related	$ 3,579,064	$ 3,998,423	$ (419,359)	(10)%
Professional fees and patent expense	1,530,052	1,857,007	(326,955)	(18)%
Insurance and office expense	1,591,556	2,266,699	(675,143)	(30)%
Market research	517,608	954,709	(437,101)	(46)%
Consulting	446,800	916,475	(469,675)	(51)%
Other	393,155	245,431	147,724	60%
Total general and administrative expense	$ 8,058,235	$ 10,238,744	$ (2,180,509)	(21)%

General and administrative expense decreased during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 due to decreases of $0.4 million in payroll related expense, $0.3 million in professional fees and patent expenses, $0.7 million in insurance and office expenses, $0.4 million in market research expenses and $0.5 million in consulting expenses. The decrease in general and administrative expenses was due in part to strategic cost reduction efforts implemented by management.

The following table summarizes our interest income for the nine months ended September 30, 2023 and 2022 together with the percentage change for those items.

	For The Nine Months Ended September 30,			
	2023	2022	Increase (Decrease)	Change
Interest income	$ 160,009	$ 19,184	$ 140,825	734%
Change in fair value of note receivable	$ (114,870)	$ -	$ (114,870)	100%

Interest income increased during fiscal 2023 mainly due to the interest accrued on the note receivable and increased interest earned on cash equivalents. Other expense during fiscal 2023 is the change in the fair value of the note receivable.

We incurred a net loss of $16.5 million and $24.4 million for the nine months ended September 30, 2023 and 2022, respectively.

Financial Condition

As of September 30, 2023, we had total assets of approximately $14.9 million and working capital of approximately $9.8 million. As of September 30, 2023, our liquidity included approximately $9.7 million of cash and cash equivalents. On August 17, 2023, we completed an underwritten public offering, selling 22,880,400 shares of common stock, including 2,984,400 shares of common stock issued pursuant to the full exercise by the underwriter of its over-allotment option, at an offering price of $0.25 per share. We received gross proceeds of approximately $5.7 million. We received net proceeds of approximately $5.1 million, after deducting underwriting discounts and offering-related expenses. 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. During the nine months September 30, 2023, we sold 60,089 shares of its common stock at average price of $0.42 per share resulting in proceeds of approximately $25,000.

As of the date of this report, we will need additional capital to fund our operations over the 12 months following the date of this report. Accordingly, management believes that there is substantial doubt regarding the Company’s ability to continue operating as a going concern through at least the next twelve months from the date of this filing. 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. 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

Critical accounting policies are described in our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022. During the nine months ended September 30, 2023, there was a material change to our critical accounting policies previously disclosed regarding our accounting for a convertible note receivable utilizing the fair value option under Accounting Standards Codification (“ASC”) 825, *Financial Instruments*.

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. We account for our convertible note receivable under the fair value option election in accordance with Accounting Standards Codification 825, *Financial Instruments*, which is a material change to our critical accounting estimates as reported in our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 31, 2023.

Under the fair value option, bifurcation of an embedded derivative is not necessary, and all related gains and losses on the host contract and derivative due to change in the fair value will be reflected in other income (expense), net in the condensed consolidated statements of operations. Interest accrues on the unpaid principal balance on a quarterly basis and is recognized in interest income in the condensed consolidated statements of operations.

The decision to elect the fair value option is determined on an instrument-by-instrument basis and must be applied to an entire instrument and is irrevocable once elected. Pursuant to this guidance, assets and liabilities are measured at fair value based, in part, on general economic and stock market conditions and those characteristics specific to the underlying investments. The carrying value is adjusted to estimated fair value at the end of each quarter, required to be reported separately in our condensed consolidated balance sheets from those instruments using another accounting method.

To estimate the fair value of the convertible note receivable requires management to utilize unobservable inputs, such as the equity value of Augmenta, the timing and probability of future financing events, optional conversion to common stock, and repayment at maturity. If these estimates were changed, our change in fair value of the convertible note receivable could differ materially.

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, 2023.

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, 2023 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 2020 and 2021, we completed Phase I human clinical trials for our TFF VORI and TFF TAC product candidates and as of the date of this report we have Phase 2 clinical trials underway for both product candidates. 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, 2022 and 2021, we incurred a net loss of $31.8 million and $31.0 million, respectively, and for the nine months ended September 30, 2023 and 2022 we incurred a net loss of $16.5 million and $24.4 million, respectively. As of September 30, 2023, we had an accumulated deficit of $113.6 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 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 consolidated financial statements have been prepared assuming that we will continue as a going concern. Our ability to continue as a going concern will require us to obtain additional capital to fund our operations over the twelve months from the date of this report. As of September 30, 2023, we had total assets of approximately $14.9 million and working capital of approximately $9.8 million. As of September 30, 2023, our liquidity included approximately $9.7 million of cash and cash equivalents. We intend to seek additional funds through various financing sources, including the sale of our equity and debt securities, licensing fees for our technology and co-development and joint ventures with industry partners, with a preference towards licensing fees for our technology and co-development and joint ventures with industry partners. In addition, we will consider alternatives to our current business plan that may enable to us to achieve revenue producing operations and meaningful commercial success with a smaller amount of capital. However, there can be no guarantees that such funds will be available on commercially reasonable terms, if at all. If such financing is not available on satisfactory terms, we may be unable to further pursue our business plan and we may be unable to continue operations, in which case you may lose your entire investment. Obtaining additional financing contains risks, including:

- additional equity financing may not be available to us on satisfactory terms and any equity we are able to issue could lead to dilution for current stockholders;
- loans or other debt instruments may have terms and/or conditions, such as interest rate, restrictive covenants and control or revocation provisions;
- the current environment in capital markets combined with our capital constraints may prevent us from being able to obtain adequate debt financing; and
- if we fail to obtain required additional financing to grow our business we may need to seek bankruptcy protection in the near term.

The report of our independent registered public accounting firm for the year ended December 31, 2022 states that due to our lack of revenue from commercial operations, significant losses and need for additional capital there is substantial doubt about our ability to continue as a going concern.

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. We hold an exclusive worldwide, royalty bearing license to the patent rights for the TFF platform in all fields of use granted by the University of Texas at Austin, or UT. 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 through this "Risk Factor" section.

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 continuing fallout from the COVID-19 pandemic. While the COVID-19 pandemic has abated in the last several months, many of the consequences of the COVID-19 pandemic continue to cause disruption and increased costs for businesses. In the case of clinical stage biopharmaceutical companies, we believe there continue to be, among other things, supply chain disruptions that are causing delays in the delivery of drug candidates and comparator products and healthcare staffing shortages that are causing delays in the establishment of test sites and the conduct of clinical trials. As of the date of this report, the COVID-19 pandemic has had a relatively insignificant impact on our operations. During 2020, we experienced a temporary suspension of dosing in the Phase I clinical trial for TFF TAC due to the COVID-19 pandemic and the pandemic has otherwise caused minor slowing in the timing of certain non-clinical and clinical activities by us and our collaborators and service providers during 2020 to date. However, the COVID-19 pandemic 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. Further, the outbreak and any preventative or protective actions that our customers may take in respect of COVID-19 may result in a period of disruption to other work in progress. Our customers' businesses could be disrupted, and our future costs and potential revenues and technology evaluations could be negatively affected. Any resulting financial impact cannot be reasonably estimated at this time but may materially affect our business and financial condition. The extent to which COVID-19 impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

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 Societal CDMO, CoreRx, Inc. and Experic for their provision of certain product testing, development and clinical manufacturing services for our TFF VORI and TFF TAC 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.

Unfavorable geopolitical and macroeconomic developments could adversely affect our business, financial condition or results of operations. Our business could be adversely affected by conditions in the U.S. and global economies, the United States and global financial markets and adverse geopolitical and macroeconomic developments, including rising inflation rates, the ongoing COVID-19 pandemic, the Ukrainian/Russian and Israeli/Palestinian conflicts and related sanctions, bank failures, and economic uncertainties related to these conditions.

For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In response to rising inflation, the U.S. Federal Reserve has raised, and may again raise, interest rates, which, coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks. The failures of Silvergate Bank, Silicon Valley Bank and Signature Bank in March 2023 and First Republic Bank in May 2023, and fears of other bank failures, may exacerbate these risks. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply disruption. Any of the foregoing could harm our business.

Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022 and the eruption of the Israeli/Palestinian conflict in October 2023, including as a result of economic sanctions and export controls against Russia and countermeasures taken by Russia. The full economic and social impact of these sanctions and countermeasures, in addition to the ongoing military conflicts in Ukraine and Gaza, which could conceivably expand, remains uncertain; however, both the conflicts and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, and/or supply chain continuity, in both Europe and globally, and has introduced significant uncertainty into global markets. While we do not currently operate in Russia, Ukraine or the Middle East, as the adverse effects of these conflicts continue to develop our business and results of operations may be adversely affected.

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, are established drugs that are off-patent, we have gained FDA agreement on the 505(b)(2) regulatory pathway for these product candidates. We believe that our initial drug product candidates will qualify for FDA approval through the FDA's 505(b)(2) regulatory pathway and through corresponding regulatory paths in other foreign jurisdictions. The clinical requirements for a 505(b)(2) drug candidate can vary widely from product to product depending primarily on whether the product candidate claims a new indication, provides for a different route of administration, or claims improved safety compared to the existing approved product, and may include bioequivalence trials, limited safety and efficacy trials, or full Phase I through III trials. 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, potentially including a full Phase I through Phase III development program, in order to obtain marketing approval.

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. Our proposed dry powder formulation of aluminum salt vaccines may not be off-patent. 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 2020 and 2021, we completed Phase I human clinical trials for our TFF VORI and TFF TAC product candidates, and in 2022 we initiated Phase 2 clinical trials for both product candidates. However, there can be no assurance that our Phase 2 clinical trials will be successful or that we will continue clinical development TFF VORI and TFF TAC 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 for TFF VORI and TFF TAC 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 IV clinical trials, and post-market surveillance to monitor safety and efficacy. Our product candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current cGMPs, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the FDA or a comparable foreign regulatory authority failing to grant permission to proceed and placing the clinical study on hold;
- subjects for clinical testing failing to enroll or remain enrolled in our trials at the rate we expect;
- a facility manufacturing any of our product candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of product candidates in the manufacturing process;

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

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

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

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

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 high and low sales prices of our common stock have ranged from $0.276 to $21.14 through October 31, 2023. The market price of our shares on the NASDAQ Capital Market may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated variations in our and our competitors' results of operations and financial condition;
- market acceptance of our product candidates;
- changes in earnings estimates or recommendations by securities analysts, if our shares are covered by analysts;
- development of technological innovations or new competitive products by others;
- announcements of technological innovations or new products by us;
- publication of the results of preclinical or clinical trials for our product candidates;
- failure by us to achieve a publicly announced milestone;

- delays between our expenditures to develop and market new or enhanced products and the generation of sales from those products;
- developments concerning intellectual property rights, including our involvement in litigation brought by or against us;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products;
- changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses;
- changes in our expenditures to promote our product candidates;
- our sale or proposed sale, or the sale by our significant stockholders, of our shares or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our shares; and
- general economic and market conditions and other factors, including factors unrelated to our operating performance.

We have received a notice of delisting or failure to satisfy a continued listing rule from the Nasdaq. On March 2, 2023, we received a notice of delisting from the Nasdaq Stock Market, LLC. The notice stated that we had fallen below compliance with respect to the continued listing standard set forth in Rule 5450(a)(1) of the Nasdaq Listing Rules because the closing bid price of our common stock over the previous 30 consecutive trading-day period had fallen below $1.00 per share.

Pursuant to the notice and Rule 5810(c)(3)(A) of the Nasdaq Listing Rules, we originally had 180 days from the date of the notice, or until August 29, 2023, to regain compliance with the minimum bid price requirement in Rule 5450(a)(1) by achieving a closing bid price for our common stock of at least $1.00 per share over a minimum of 10 consecutive business days. On August 30, 2023, we received a further notice from the Nasdaq stating that the staff of the Nasdaq has determined that we will be eligible for an additional 180 calendar day period to regain compliance with the minimum bid price requirement in Nasdaq Listing Rule 5450(a)(1). We now have until February 26, 2024 to regain compliance with the minimum bid price requirement in Nasdaq listing Rule 5450(a)(1). If we do not regain compliance with Rule 5450(a)(1) by achieving a closing bid price for our common stock of at least $1.00 per share over a minimum of 10 consecutive business days by February 26, 2024, the Nasdaq will commence suspension and delisting procedures.

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" through December 31, 2024, 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. 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. 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 of the Registrant	Incorporated by reference from the Registrant's Registration Statement on Form S-1 filed on August 20, 2019.
3.2	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation of the Registrant	Incorporated by reference from the Registrant's Annual Report on Form 10-K filed on March 31, 2023.
3.2	First Amended and Restated Bylaws of the Registrant	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on April 6. 2023.
4.1	Warrant dated August 17, 2023 issued to The Benchmark Company, LLC	Filed electronically herewith
31.1	Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed electronically herewith
31.2	Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed electronically herewith
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).	Filed electronically herewith
101.INS	Inline XBRL Instance Document	Filed electronically herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	Filed electronically herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed electronically herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed electronically herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed electronically herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed electronically herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	

SIGNATURES

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

TFF PHARMACEUTICALS, INC.

Date: November 14, 2023

By: */s/ Harlan Weisman*

Harlan Weisman,
Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2023

By: */s/ Kirk Coleman*

Kirk Coleman,
Chief Financial Officer
(Principal Financial Officer)