UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): November 15, 2021

TFF PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-39102**	**82-4344737**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

3801 S. Capital of Texas Hwy, Suite 330
Austin, Texas 78704
(Address of principal executive offices)

(737) 802-1973
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions.

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14d-2(b)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock: Par value $.001	TFFP	Nasdaq Global Market

Item 2.02 Results of Operations and Financial Condition.

On November 15, 2021, TFF Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2021. A copy of the press release is attached as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

The information in this Item 2.02, including the press release attached as Exhibit 99.1 hereto, is furnished pursuant to Item 2.02 but shall not be deemed "filed" for any purpose, including for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits

(d)	**Exhibits**	**Method Filing**
The following exhibit is furnished with this report:		
Exhibit 99.1	Press release dated November 15, 2021 regarding the Registrant's financial results for its fiscal quarter ended September 30, 2021.	Filed Electronically herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TFF PHARMACEUTICALS, INC.

Dated: November 15, 2021

/s/ Kirk Coleman

Kirk Coleman,
Chief Financial Officer

EXHIBIT 99.1

TFF Pharmaceuticals Reports Third Quarter 2021 Financial Results and Provides Business Update

Positive Updates Announced for Inhaled Voriconazole and Tacrolimus Programs;
Both Programs Advancing into Phase 2 Testing

Continued Progress with Partnered Antiviral Programs for AUG-3387 and Niclosamide

Thin Film Freezing Applications Continue to Expand Across Diverse Set of Drug Candidates; IP Estate Now Includes Over 120 Patents Granted or Pending

Conference Call and Webcast Scheduled Today, Monday, November 15, 2021,
at 4:30 PM ET

AUSTIN, TX -- November 15, 2021 --TFF Pharmaceuticals, Inc. (NASDAQ: TFFP), a clinical-stage biopharmaceutical company focused on developing and commercializing innovative drug products based on its patented Thin Film Freezing (TFF) technology platform, today reported financial results for the third quarter ended September 30, 2021, and also provided an update on recent corporate and clinical developments. The Company will discuss the highlights on a conference call and webcast, scheduled today, Monday, November 15, 2021, at 4:30 PM ET.

“Over the last three months, we have made significant progress in every aspect of our business,” said Glenn Mattes, CEO of TFF Pharmaceuticals. “Starting with our two lead in-house programs, Inhaled Voriconazole and Tacrolimus Powder, we achieved important clinical milestones that we believe will drive significant shareholder value. With respect to voriconazole, the safety results from both our Phase 1 and Phase 1b studies have allowed us to select a dose to study in our upcoming Phase 2 programs, which we plan to initiate around year-end.”

“Results from our Phase 1 study for Inhaled Tacrolimus Powder indicate that our inhaled product has an acceptable safety profile to achieve the appropriate balance of local and systemic concentrations for immunosuppression at the site of the lung transplant while minimizing the risk of supra-therapeutic exposure well known to cause significant renal toxicity in patients. Based on the data, we expect to initiate the Phase 2 program shortly.”

“We are also making outstanding progress in our two antiviral-focused partnerships, which provided yet another major source of external validation showing how our Thin Film Freezing technology can be applied to both small molecules and biologics. In October, TFF Pharmaceuticals and Augmenta announced the publication of positive *in vivo* data showing that the dry powder formulation of COVID-19 antibody AUG-3387 neutralizes SARS-CoV-2 infection and reduces viral load in a well-accepted preclinical model. The data from the AUG-3387 animal efficacy trial confirmed activity in the most virulent COVID-19 variants, including Delta, Lambda, and Mu. For niclosamide, a broad-spectrum antiviral, just two weeks after receiving approval from Health Canada, we enrolled and dosed the first patient in the Phase 1 trial.”

“From our perspective, momentum only continues to build across the breadth of our diverse portfolio. The progress we have made and expect to make moves our entire internal portfolio closer to monetization and meaningful revenue streams for TFF.”

“Looking ahead, we believe 2022 is shaping up to be another year of significant accomplishments. As our clinical programs with inhaled tacrolimus and voriconazole continue to advance, we expect to generate substantial proof-of-concept data within each program’s targeted patient populations. Both the Inhaled Voriconazole and Inhaled Tacrolimus Powder Phase 2 programs will be designed with an interim analysis of data, and we expect these datasets will be available by mid-2022. We will begin a process in the first quarter of 2022 to identify license partners to ultimately commercialize these assets. We have already received interest from pharmaceutical companies and will use the interim data as the inflection point to pursue the partnerships.”

“Importantly, the applicability of Thin Film Freezing in creating successful formulations in biologics and complex molecules continues to grow. For example, we have recently seen a strong uptick in the number of mAbs and mRNA-based therapeutics being evaluated by our large pharma partners, and we expect this trend will continue. The applicability of our Thin Film Freezing technology across a broad array of different molecules has also enabled us to greatly expand our IP estate. TFF now has approximately 120 patents either granted or pending both in the United States and the rest of the world.”

“Without question, another important source of expanding applications of Thin Film Freezing comes from our academic and government collaborations, and I am pleased to report that each of these highly valued partnerships are proceeding very well. Our work with Dr. Ted Ross at the University of Georgia in testing a universal flu vaccine has proceeded to the animal testing phase, and our work with Dr. Drew Weissman at the University of Pennsylvania is now in full swing looking at the application of Thin Film Freezing technology in mRNA vaccines and therapeutics. Noting the potential of our technology platform, Dr. Weismann provided the following comment: ‘*The freeze-dried powder formulation by TFF has enormous potential to move the mRNA-LNP vaccine platform to efficient worldwide use by allowing room temperature storage and the development of oral inhaled delivery*.’”

“We have also made substantial progress with the Defense Advanced Research Projects Agency (DARPA) Personalized Protective Biosystem (PPB) contract on formulating countermeasures and the development of novel vaccines at the United States Army Medical Institute of Infectious Diseases (USAMRIID) is also progressing. We expect a second Cooperative Research and Development Agreement (CRADA) shortly expanding the work we are doing in the vaccine arena.”

“On the partnering front, the number of drug candidates being evaluated by our partners continues to grow and, just as importantly, we are seeing an expansion in the diversity of molecules being tested with our Thin Film Freezing technology. We expect to sign meaningful partnering transactions in the very near future. It is abundantly clear that the interest from our pharmaceutical, academic and government partners in our platform formulation technology continues to grow, and we are highly confident this interest will create multiple pathways toward increasing shareholder value.”

Conference Call and Webcast Information

The Company will host a conference call today, Monday, November 15, 2021, at 4:30 PM Eastern Standard Time to review the clinical, corporate and financial highlights. To participate in the conference call, please dial the following numbers prior to the start of the call:

Domestic Dial-In Number –Toll-Free: (866) 269-4261
International Dial-In Number: (323) 289-6581
Conference ID: 6229028

The call will also be broadcast live over the Web and can be accessed on TFF Pharmaceuticals’ Website, https://tffpharma.com or directly at https://78449.themediaframe.com/dataconf/productusers/vvdb/mediaframe/46954/indexl.html

Please access the Company's website at least 15 minutes ahead of the conference to register, download, and install any necessary audio software. The conference call will also be available for replay for one month on the Company's website in the Events Calendar of the Investors section.

Recent Clinical and Corporate Highlights:

- **Voriconazole Inhalation Powder (TFF VORI):** In November, TFF announced the completion of dosing in the Phase 1b clinical trial of Voriconazole Inhalation Powder (TFF VORI), a next-generation, direct-to-lung, inhaled dry powder version of voriconazole for the treatment and prevention of Invasive Pulmonary Aspergillosis (IPA) (NCT #04576325). This study assessed the safety and tolerability of patients with mild to moderate asthma, a population at high risk of developing IPA, in two cohorts of eight patients. Initial data from the study suggests that TFF VORI is well tolerated in asthma patients, supporting the Company’s progress to a Phase 2 study in IPA patients.

The observational data from the Phase 1b trial indicates that TFF VORI is well tolerated in asthma patients. Voriconazole is recommended as the first line treatment for IPA according to the Infectious Disease Society (IDSA) - Practice Guidelines for the Diagnosis and Management of Aspergillosis (2016), but oral voriconazole is associated with significant drug-drug interactions and toxicities. Delivery of voriconazole directly to the lung may allow for a product that has greater efficacy than orally administered voriconazole and that has improved safety through reduced systemic toxicities and reduced drug-drug interactions.

To date, observational data from this trial support the inclusion of patients that have hyperreactive airway disease comorbidities in the Phase 2 trial. This suggests TFF VORI also may have the potential to treat Allergic Bronchopulmonary Aspergillosis (ABPA), which impacts up to 2.5%[1] of asthma patients.

- **Tacrolimus Inhalation Powder (TFF TAC):** In September, TFF announced topline results from the recently completed Phase 1 clinical trial for Tacrolimus Inhalation Powder showing a promising safety profile and demonstrating therapeutic drug levels can be achieved at low doses.

  Topline pharmacokinetic data from the Phase 1 study included:

  - In the SAD phase of the study, inhaled delivery of tacrolimus resulted in mean trough blood levels of 10 ng/mL 12 hours post-dosing for subjects that received a dose of 5 mg, which falls within the desired range for maintenance immunosuppression following lung transplant.

  - As previously reported in July, subjects from the MAD phase of the study who received doses of 0.5 mg twice daily and 1.0 mg twice daily achieved 12-hour trough steady state blood levels of tacrolimus that averaged 6.8 and 14.9 ng/mL, respectively, demonstrating that Inhaled Tacrolimus Powder can achieve blood levels generally deemed to be sufficient for efficacious immunosuppression.

  - New data reported today showed that once daily dosing with 1.5 mg of Inhaled Tacrolimus Powder resulted in mean 12-hour trough blood levels of 6.3 ng/mL and mean 24-hour trough blood levels of 4.8 ng/mL, consistent with the desired therapeutic ranges for lung transplant patients.

1 Denning DW, Pleuvry A, Cole DC. Global burden of allergic bronchopulmonary aspergillosis with asthma and its complication chronic pulmonary aspergillosis in adults. Med Mycol. 2013 May;51(4):361-70. doi: 10.3109/13693786.2012.738312. Epub 2012 Dec 4. PMID: 23210682. Accessed November 5, 2021.

TFF Pharmaceuticals expects to take critical steps toward beginning its Phase 2 clinical study of Inhaled Tacrolimus Powder by the end of 2021. The goal of the Phase 2 study, which will be an open-label study conducted in lung transplant patients who are experiencing kidney toxicity, is to test the hypothesis that Inhaled Tacrolimus Powder can provide adequate systemic exposure while maintaining higher drug levels in the lung, thereby reducing the risk of acute allograft rejection and improving symptoms of renal toxicity. We intend for patients currently receiving oral tacrolimus to transition to a flexible dosing regimen of inhaled tacrolimus. We expect the inhalation dose will be able to be adjusted weekly to achieve the desired blood level assigned by each patient's physician and ongoing biomarker-based assessments.

- **Scientific Advisory Board (SAB)**: On November 1, TFF Pharmaceuticals held a first meeting with its Scientific Advisory Board, comprised of globally-recognized thought leaders in their respective fields of study. The SAB will advise TFF Pharmaceuticals across a range of issues, including internally developed programs and select external projects.

- **Strategic Business Development and Partnership Activities – Biopharmaceutical Companies and Research Institutions:**

    - In October, TFF announced approval from Health Canada to begin a Phase 1 clinical trial of a dry powder formulation of niclosamide, an antiviral treatment with potential to address COVID-19 and other infectious diseases. The Phase 1 study was cleared by Health Canada via a No Objection Letter (NOL) received on October 22, 2021. TFF Pharmaceuticals enrolled and dosed the first patient in the study today; enrollment is expected to be completed by early Q1 2022.

    - In October, TFF and Augmenta Bioworks announced the publication of a research paper highlighting positive preclinical study results of AUG-3387, a monoclonal antibody (mAb) therapy being developed in collaboration between the two companies for the treatment of SARS-CoV-2 infection. The findings have been published online through the *bioRxiv p*reprint server, under the title "AUG-3387, a Human-Derived Monoclonal Antibody Neutralizes SARS-CoV-2 Variants and Reduces Viral Load from Therapeutic Treatment of Hamsters In Vivo."

    - In July, TFF and Augmenta published positive *in vitro* data indicating that AUG-3387 binds to and neutralizes the SARS-CoV-2 Delta variant (B.1.617.2). The Delta variant is the current dominant strain of SARS-CoV-2 in the U.S., Europe and other geographic regions around the world.

Financial Results

For the three months ended September 30, 2021, compared to the prior year:

- **Research and Development (R&D) expenses:** R&D expenses for the third quarter of 2021 were $6.3 million, compared to $2.8 million for the same period in 2020.

- **General & Administrative (G&A) expenses:** G&A expenses for the third quarter of 2021 were $2.4 million, compared to $2.3 million for the same period of 2020.

- **Net Loss:** TFF Pharmaceuticals reported a net loss for the third quarter of 2021 of $8.7 million, compared to a net loss of $5.1 million for the same period of 2020.

About TFF Pharmaceuticals' Thin Film Freezing Technology Platform

TFF Pharmaceuticals' Thin Film Freezing (TFF) platform was designed to improve the solubility and absorption of poorly water-soluble drugs and is particularly suited to generate dry powder particles with properties targeted for inhalation delivery, especially to the deep lung, an area of extreme interest in respiratory medicine. The TFF process results in a "Brittle Matrix Particle," which possesses low bulk density, high surface area, and typically an amorphous morphology, allowing the particles to supersaturate when contacting the target site, such as lung tissue. Based upon laboratory experiments the aerodynamic properties of the particles are such that the portion of a drug deposited to the deep lung has the potential to reach as high as 75 percent.

About TFF Pharmaceuticals

TFF Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative drug products based on its patented Thin Film Freezing, or TFF, technology platform. Early testing confirms that the TFF platform can significantly improve the solubility and absorption of poorly water-soluble drugs, a class of drugs that comprises approximately one-third of the major pharmaceuticals worldwide, thereby improving their pharmacokinetics. TFF Pharmaceuticals has two lead drug candidates: Voriconazole Inhalation Powder and Tacrolimus Inhalation Powder. The Company plans to add to this pipeline by collaborating with large pharmaceutical partners. The TFF Platform is protected by over 120 patents issued or pending in the US and internationally. To learn more about TFF Pharmaceuticals and its product candidates, visit the Company's website at https://tffpharma.com.

SAFE HARBOR

This press release contains forward-looking statements regarding TFF Pharmaceuticals, Inc., including the benefits of the Company's TFF platform and its dry powder versions of Voriconazole and Tacrolimus, and the Company's plans to add to its existing pipeline of product candidates. Those forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause actual results to differ materially. Among those factors are: (i) the risk that the Company may not be able to successfully conclude clinical testing or obtain pre-market approval of its dry powder versions of Voriconazole and Tacrolimus, (ii) the risk that the Company may not be able to find a license partner to ultimately commercialize its dry powder versions of Voriconazole and Tacrolimus on terms favorable to the Company, or at all, (iii) no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, (iv) the Company has no current agreements or understandings with any large pharmaceutical companies for the development of a drug product incorporating the TFF Platform, (v) the risk that the Company will not be able to conclude a long-term commercial agreement with any third-party, and (v) those other risks disclosed in the section "Risk Factors" included in the Company's 2020 Annual Report on Form 10-K filed with the SEC on March 10, 2021. TFF Pharmaceuticals cautions readers not to place undue reliance on any forward-looking statements. TFF Pharmaceuticals does not undertake, and specifically disclaims, any obligation to update or revise such statements to reflect new circumstances or unanticipated events as they occur, except as required by law.

TFF PHARMACEUTICALS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Grant revenue	$ 50,000	$ —	$ 76,165	$ —
Operating expenses:				
Research and development	6,339,993	2,823,669	14,380,415	7,626,982
General and administrative	2,387,585	2,254,912	7,386,007	5,147,639
Total operating expenses	8,727,578	5,078,581	21,766,422	12,774,621
Loss from operations	(8,677,578)	(5,078,581)	(21,690,257)	(12,774,621)
Other income:				
Other income (expense)	(13,129)	—	659,695	—
Interest income	12,051	20,546	41,619	102,809
Total other income (expense)	(1,078)	20,546	701,314	102,809
Net loss	$ (8,678,656)	$ (5,058,035)	$ (20,988,943)	$ (12,671,812)
Net loss per share, basic and diluted	$ (0.34)	$ (0.24)	$ (0.85)	$ (0.61)
Weighted average common shares outstanding, basic and diluted	25,371,781	20,867,526	24,635,350	20,810,004

TFF PHARMACEUTICALS, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,715,743	$ 35,300,805
Receivable due from collaboration agreement	831,061	—
Research and development tax incentive receivable	1,111,540	—
Prepaid assets and other current assets	833,630	2,258,229
Total current assets	47,491,974	37,559,034
Property and equipment, net	1,810,235	1,102,808
Total assets	$ 49,302,209	$ 38,661,842
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,557,612	$ 1,297,725
Deferred research grant revenue	-	24,315
Total liabilities	1,557,613	1,322,040
Commitments and contingencies		
Stockholders' equity:		
Common stock	25,372	22,535
Additional paid-in capital	103,158,144	71,648,453
Accumulated other comprehensive loss	(170,328)	(51,538)
Accumulated deficit	(55,268,591)	(34,279,648)
Total stockholders' equity	47,744,597	37,339,802
Total liabilities and stockholders' equity	$ 49,302,209	$ 38,661,842

Company Contacts:

Glenn Mattes
President and CEO
TFF Pharmaceuticals, Inc
gmattes@tffpharma.com
737-802-1973

Kirk Coleman
Chief Financial Officer
TFF Pharmaceuticals, Inc.
kcoleman@tffpharma.com
817-989-6358

Investor Relations Contact:

Corey Davis, Ph.D.
LifeSci Advisors
212-915-2577
cdavis@lifesciadvisors.com

Media Contact:

Gwendolyn Schanker
LifeSci Communications
269-921-3607
gschanker@lifescicomms.com