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): August 12, 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)

2600 Via Fortuna, Suite 360
Austin, Texas 78746
(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 August 12, 2021, TFF Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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 August 12, 2021 regarding the Registrant's financial results for its fiscal quarter ended June 30, 2021.	Filed Electronically herewith

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: August 12, 2021

/s/ Kirk Coleman

Kirk Coleman,
Chief Financial Officer

EXHIBIT 99.1

FOR IMMEDIATE RELEASE

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

Additional Data Readouts and Initiation of Pivotal Trials for Inhaled Tacrolimus and Voriconazole Programs Expected in 2H 2021

Multiple Ascending Dose (MAD) Study Demonstrates Inhaled Tacrolimus Inhalation Powder Achieves Blood Levels Sufficient for Efficacious Immunosuppression

Formation of Scientific Advisory Board to Enable Continued Innovation and Clinical Development
Partnerships with Pharma, Academic Institutions and Government Continue to Advance
Conference Call and Webcast Scheduled Today, Thursday, August 12, 2021,
at 4:30pm EDT

AUSTIN, TX — August 12, 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 second quarter ended June 30, 2021, and also provided an update on recent corporate and clinical developments. The Company will discuss the clinical, corporate and financial highlights on a conference call and webcast, scheduled today, Thursday, August 12, 2021, at 4:30pm EDT.

“As we advance both our internal programs and external partnerships, TFF Pharmaceuticals continues to demonstrate the transformative potential of our proprietary Thin Film Freezing (TFF) drug delivery platform to improve upon pharmacokinetic and clinical profiles of currently approved therapies, while also formulating novel small molecule and biologic-based therapeutics that address serious unmet medical need,” said Glenn Mattes, President and CEO of TFF Pharmaceuticals.

“During this quarter, we announced data from a multiple ascending dosing study showing that our Inhaled Tacrolimus Powder has superior bioavailability as compared to the oral dosage form of tacrolimus, and that relatively low doses as compared to the oral dosage form were able to generate blood concentration levels of tacrolimus known to be sufficiently immunosuppressive in preventing organ rejection following lung transplants. Our toxicology studies demonstrated that the lung concentrations are three- to four-fold higher than blood concentrations and together these data suggest that we can achieve sufficient drug levels in the lung to prevent rejection, while at the same time, mitigating the potential for renal toxicity. We believe this improved pharmacokinetic profile could result in superior safety compared to the oral product without sacrificing efficacy.”

Mr. Mattes continued, “I am also pleased to report that our internal CMC and drug manufacturing projects remain on track to fully support our product supply needs for our planned pivotal trials for Inhaled Voriconazole Powder and Inhaled Tacrolimus Powder. Our TFF-TAC program represents a potential significant advancement in a field that has seen very little innovation in decades, and we look forward to presenting additional data for this program later in the year.”

“We are also excited to announce significant advances on the partnering front. Most recently, TFF and its partner, Augmenta Bioworks, announced the selection of a lead monoclonal antibody, AUG-3387, which is being developed for the prevention and treatment of COVID-19 and, importantly, has been shown to effectively neutralize the Delta variant in *in vitro* studies. The relationship with Augmenta is a prime example of how our Company’s Thin Film Freezing technology can be applied to proprietary, biologic-based therapeutics addressing a large unmet medical need in public health. This remains a highly active area of collaboration and partnerships for our company, as we now have in place several programs focused on the application of our TFF technology to biologic drugs.”

Importantly, all of our pharmaceutical company partnerships continue to advance, which include collaborations with Union Therapeutics Felix Therapeutics, GreenLight Biosciences, NeuroRx, PLUS Products, and Felix Biotechnology. In addition, we currently have ongoing projects with the majority of the top 20 pharmaceutical companies, where we are applying our thin film freezing technology to their products, and in some cases, working on multiple product formulation opportunities for individual companies. In addition, our academic and government partnerships and contracts are progressing and producing meaningful new data.”

“Results in the second half should further advance preclinical and clinical progress on both internal and partnered programs as well as generate material new business development opportunities. We believe these anticipated results will reinforce the applicability of TFF’s proprietary technology for the use in improving human health across a number of therapeutic areas”

He continued, “As a result of our continued progress across these programs, we have also made key leadership appointments to support both our manufacturing operations and the expansion of our government/academic institution partnership team.

I am also delighted to announce the formation of TFF's Scientific Advisory Board, a group of extraordinarily accomplished individuals who will impart a wealth of invaluable scientific and medical expertise as we accelerate multiple programs from early-stage development to advanced clinical testing, both for our proprietary drug programs and our partnered opportunities."

"In the second half of the year, TFF will build on these significant accomplishments as we move our internal programs into pivotal testing. On the business development front, we expect to advance our programs with existing partners, while signing new licensing transactions with pharmaceutical and biotechnology companies."

Conference Call and Webcast Information

The Company will host a conference call today, Thursday, August 12, 2021, at 4:30 pm, Eastern Daylight 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 http://public.viavid.com/index.php?id=146022. 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):** As noted on the first quarter update, TFF has successfully completed the first of two dosing cohorts in a Phase 1b reactive airway study, which is evaluating safe dosing of TFF VORI in asthma patients with hyperreactive airways. The safety profile for TFF VORI continues to look favorable, with no serious adverse events reported in these cohorts. Top-line data from the study is expected in the third quarter of 2021. The Company continues preparations for an end of Phase 1 meeting with the FDA, and anticipates this meeting will also be held in the third quarter, after the dosing in this Phase 1b reactive airway study is complete.

Earlier in the year, TFF announced the successful completion of the Phase 1 clinical trial and final data for Voriconazole Inhalation Powder for the treatment of invasive pulmonary aspergillosis (IPA). Based on the results of the Phase 1 trial, the Company will study the 80 mg dose of Voriconazole Inhalation Powder for the upcoming pivotal trial where it will be compared to the oral form of voriconazole. The Company expects to initiate a pivotal trial of TFF VORI in the fourth quarter of 2021, which will be designed to assess efficacy for treating patients with IPA or for preventing infection in patients at high risk for developing IPA infections.

- **Tacrolimus Inhalation Powder (TFF TAC):** In July, the Company announced completion of enrollment and preliminary data from its Phase 1 trial of Tacrolimus Inhalation Powder (TFF TAC). In the Single Ascending Dose (SAD) phase of the trial, single doses of inhaled tacrolimus of 0.5 mg, 1.0 mg, 2.5 mg to 5.0 mg were administered to healthy subjects. In the subjects that received inhaled tacrolimus in the low dose group, the mean trough blood levels reached 1.1 ng/mL, while blood levels in the highest dose group reached 10.0 ng/mL. Following lung transplant, it is desirable for patients to achieve maintenance tacrolimus blood levels from 5-15 ng/mL to prevent acute allograft rejection.

  In addition, when subjects received inhaled tacrolimus dosing at 2.5 mg while fasting or 30 minutes after a high-fat meal, there were no significant differences in systemic exposure demonstrating that delivery by inhalation was not associated with food effects in this cohort of subjects. By contrast, the rate and extent of absorption of tacrolimus is significantly decreased when tacrolimus is administered orally when taken with food, and this effect is most pronounced after a high-fat meal.

  In the Multiple Ascending Dose (MAD) phase, repeated dosing of inhaled tacrolimus every 12 hours over 7 days demonstrated that subjects receiving doses of 0.5 mg twice daily and 1.0 mg twice daily achieved 12-hour trough steady state blood levels that averaged 6.8 and 14.9 ng/mL, respectively. Importantly, these data demonstrate that low dosing of Tacrolimus Inhalation Powder (0.5-1.0 mg) can achieve blood levels that are believed to be sufficient for efficacious immunosuppression.

  TFF Pharmaceuticals expects to report top-line safety data in the third quarter of 2021 and believes the strong bioavailability data will enable initiation of a clinical trial in lung transplant patients in the second half of 2021. The Company expects that the dosing regimen for the study in lung transplantation will be tailored to potentially provide effective immunosuppression in the lung while reducing renal toxicities.

In June, TFF Pharma held a Science Day for investors, featuring key opinion leader (KOL) perspectives on Thin Film Freezing applications, with a focus on TFF Tacrolimus for lung transplant and TFF approaches to improving vaccines. Deborah Jo Levine, M.D., from UT Health San Antonio, provided background on lung transplantation, the current toxicity limitation of oral tacrolimus for immunosuppression, and the potential improvements with an inhaled formulation of tacrolimus (TFF TAC). Kartik Chandran, Ph.D., from the Albert Einstein College of Medicine, discussed the benefits of using the TFF technology to create a dry powder pulmonary formulation for the rVSV vaccine against COVID-19. Ted Ross, Ph.D., from the University of Georgia, discussed his experience utilizing the TFF process for creating a universal influenza vaccine for pulmonary delivery and its potential benefit over the existing annual vaccination. TFF Pharma's management team also provided an update on its internal pipeline and several upcoming planned clinical data releases for TFF TAC and TFF VORI (treatment of invasive fungal infections). The event and its presentation materials can be found on the TFF corporate website.

- **Strategic Business Development and Partnership Activities – Governmental and Defense Contracting Agencies:** Early in the second quarter, TFF announced that it is was awarded a contract with Leidos to participate in the Personalized Protective Biosystems (PPB) Program to develop next-generation chemical and biological protection for U.S warfighters and stability operators. The PPB research program is overseen by the Defense Advanced Research Projects Agency (DARPA) and aims to develop an integrated system that simultaneously reduces protective equipment needs while increasing protection for the individual against existing and future chemical and biological (CB) threats. TFF Pharmaceuticals will utilize its Thin Film Freezing platform to formulate a series of countermeasures designed to neutralize chemical and biological agents at the site of vulnerable tissue barriers, including the skin, eyes and respiratory system.

  We continue to engage and collaborate with various government and defense contracting agencies in an effort to utilize the Company's TFF technology platform to formulate dry powder vaccines and therapeutics for delivery via reconstitution for lung or nasal inhalation. This includes our 3-year Cooperative Research and Development Agreement (CRADA) with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) for biodefense countermeasures, and our early-stage universal influenza work with the University of Georgia's Center for Vaccines and Immunology, part of the NIH's Collaborative Influenza Vaccine Innovation Centers (CIVICs).

- **Strategic Business Development and Partnership Activities – Biopharmaceutical Companies and Research Institutions, Cannabis Development and Commercialization:** During the second quarter, TFF Pharmaceuticals and its partner, Augmenta Bioworks, selected a lead monoclonal antibody candidate, AUG-3387, for COVID-19. More specifically, Augmenta and TFF Pharmaceuticals plan to develop AUG-3387 as an inhaled therapy for the treatment of COVID-19 disease in two types of individuals: (1) those already infected with SARS-CoV2 who are at high risk for severe disease but who have not yet been hospitalized, and (2) for the prevention of SARS-CoV2 infection for individuals who are at high-risk for severe disease.

In vitro preclinical testing has demonstrated that AUG-3387 effectively neutralizes SARS-CoV2 and has activity against all variant strains tested to date, including major COVID variants of concern: Alpha (B.1.1.7), Beta (B1.1.351), Gamma (P.1) and Kappa (B.1.617.1) and Delta (B.1.617.2). TFF and Augmenta have an ongoing commitment to monitor activity of AUG-3387 against emerging SARS-CoV-2 variants and will be completing *in vivo* preclinical efficacy studies in the coming weeks. Continued scale-up manufacturing of AUG-3387 continues, and the Companies expect completion of toxicology studies to enable human clinical trials in the months ahead.

TFF also continues to work with its partner, PLUS Products, to develop Thin Film Freezing versions of cannabinoid products. PLUS Products is currently conducting consumer testing of specific formulations.

Formation of Scientific Advisory Board

TFF Pharmaceuticals also announced the formation of a 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. Below is a list of our advisors and their affiliated institutions:

- **David N. Cornfield, M.D.**
  Director of the Center for Excellence in Pulmonary Biology at Stanford, and Chief of the pediatric pulmonary, asthma, and sleep medicine divisions at Stanford University and Lucile Packard Children's Hospital

- **David Denning, FRCP, FRCPath, DCH, FMedSci**
  Professor of Infectious Diseases in Global Health, University of Manchester

- **Anthony Hickey, Ph.D.**
  Professor Emeritus in Pharmacoengineering and Molecular Pharmaceutics at the Eshelman School of Pharmacy of the University of North Carolina at Chapel Hill

- **Jay Peters, M.D.**
  Chief of Pulmonary and Critical Care Medicine at the University of Texas Health Science Center at San Antonio

- **Ted M. Ross, Ph.D.**
  Professor at the University of Georgia in the Animal Health Research Center, Center for Vaccines and Immunology, and the Department of Infectious Diseases

- **Mike Saag, M.D.**
  Professor of Medicine at UAB School of Medicine, Director of the UAB Center for AIDS Research and Associate Dean for Global Health.

- **Drew Weismann, M.D., Ph.D.**
  Roberts Family Professor in Vaccine Research at the Perelman School of Medicine at the University of Pennsylvania

Financial Results

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

- **Research and Development (R&D) expenses:** R&D expenses for the second quarter of 2021 were $2.8 million, compared to $2.6 million for the same period in 2020.

- **General & Administrative (G&A) expenses:** G&A expenses for the second quarter of 2021 were $2.4 million, compared to $1.3 million for the same period of 2020.

- **Net Loss:** TFF Pharmaceuticals reported a net loss for the second quarter of 2021 of $4.7 million, compared to a net loss of $3.8 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 58 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) no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, (iii) the Company has no current agreements or understandings with any large pharmaceutical companies for the development of a drug product incorporating the TFF Platform, (iv) 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 June 30, 2021	Three Months Ended June 30, 2020	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Grant revenue	$ 1,850	$ —	$ 26,165	$ —
Operating expenses:				
Research and development	2,762,170	2,567,771	8,040,422	4,803,313
General and administrative	2,351,007	1,274,803	4,998,422	2,892,727
Total operating expenses	5,113,177	3,842,574	13,038,844	7,696,040
Loss from operations	(5,111,327)	(3,842,574)	(13,012,679)	(7,696,040)
Other income:				
Other income	441,546	—	672,824	—
Interest income	14,069	25,995	29,568	82,263
Total other income	455,615	25,995	702,392	82,263
Net loss	$ (4,655,712)	$ (3,816,579)	$ (12,310,287)	$ (7,613,777)
Net loss per share, basic and diluted	$ (0.18)	$ (0.20)	$ (0.51)	$ (0.40)
Weighted average common shares outstanding, basic and diluted	25,369,144	19,071,658	24,261,032	19,040,134

TFF PHARMACEUTICALS, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 52,067,339	$ 35,300,805
Receivable due from collaboration agreement	489,221	—
Research and development tax incentive receivable	932,057	—
Prepaid assets and other current assets	1,968,726	2,258,229
Total current assets	55,457,343	37,559,034
Property and equipment, net	1,697,038	1,102,808
Total assets	$ 57,154,381	$ 38,661,842
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,509,224	$ 1,297,725
Deferred research grant revenue	25,000	24,315
Total liabilities	1,534,224	1,322,040
Commitments and contingencies		
Stockholders' equity:		
Common stock	25,372	22,535
Additional paid-in capital	102,301,550	71,648,453
Accumulated other comprehensive loss	(116,830)	(51,538)
Accumulated deficit	(46,589,935)	(34,279,648)
Total stockholders' equity	55,620,157	37,339,802
Total liabilities and stockholders' equity	$ 57,154,381	$ 38,661,842

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