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 5, 2020

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 Capital Market

Item 2.02 Results of Operations and Financial Condition.

On November 5, 2020, TFF Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2020. 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 5, 2020 regarding the Registrant's financial results for its fiscal quarter ended September 30, 2020	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: November 5, 2020

/s/ Kirk Coleman

Kirk Coleman,
Chief Financial Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

TFF Pharmaceuticals Reports Third Quarter 2020 Financial and Business Results

Signs Letter of Intent with Felix Biotechnology to license Thin Film Freezing technology for their bacteriophage products for lung inhalation

Signs worldwide co-development agreement with Augmenta Bioworks for monoclonal antibody therapeutics

Reports positive preclinical immunogenicity and efficacy for dry powder universal influenza formulation in collaboration with the University of Georgia

Reports positive Phase I initial efficacy data on Tacrolimus Inhalation Powder; Voriconazole Inhalation Powder program progresses to Phase II trial

Conference call and live webcast scheduled today, Thursday, November 5, 2020 at 4:30pm ET

AUSTIN, TX – November 5, 2020 --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, 2020, as well as provided a business update on recent corporate and clinical developments. The Company will discuss its clinical, corporate and financial highlights on a conference call and live webcast, scheduled today, Thursday, November 5, 2020 at 4:30pm ET.

“This has been another quarter of strong clinical progress and exceptional partnering activity for TFF Pharmaceuticals, further validating the dual-track business model we’ve established for the company, and demonstrating the technological capability and market potential of our Thin Film Freezing platform,” said Glenn Mattes, President and CEO of TFF Pharmaceuticals.

“The two new agreements recently announced with Felix Biotechnology and Augmenta Bioworks represent the potential first-of-their-kind dry powder inhalation reformulations of bacteriophages and monoclonal antibodies, respectively,” said Mattes. “This is the culmination of months of work by our scientific staff to take large, complex biologics and reformulate them for better efficacy, delivery and storage characteristics, thus enhancing their therapeutic value and market potential.”

“Our ongoing work with the University of Georgia has successfully reformulated, for the first time, a potential universal flu vaccine into a dry powder for inhalation. This reformulation suggests immunogenicity and efficacy equivalent to liquid formulations, and could allow this protein vaccine to be more stable and long-lasting - removing logistical cold chain challenges that could limit the eventual distribution of a universal flu vaccine,” said Mattes.

“Our three internal development programs continue to advance in the clinic,” continued Mattes. “Our lead clinical program, Voriconazole Inhalation Powder, the first clinical study ever in healthy subjects of a direct-to-lung, dry-powder formulation for the treatment of Invasive Pulmonary Aspergillosis (IPA) successfully completed Phase 1 dosing and will enter Phase 2 trials.”

“Our second clinical trial program, the Phase 1 dosing of healthy subjects of Tacrolimus Inhalation Powder, an important immunosuppressive agent for the prophylactic treatment of lung transplant rejection, has shown no clinically significant drug-associated adverse events, while achieving substantial immunosuppressive blood levels,” said Mattes. “And finally, our niclosamide program is on track and we are moving forward with both the oral and inhaled versions.”

“This quarter, we also took important steps to expand our manufacturing capacity to develop and produce products currently in assessment with pharmaceutical company partners, and give us a secure third source for Thin Film Freezing dry powder inhalation products,” continued Mattes.

“Despite the ongoing effects of the global pandemic, we continue to execute on our core strategies, thanks to the incredible efforts of our scientists, staff and business partners,” concluded Mattes. “We are excited to further progress with our breakthrough TFF platform technology and we look forward to reporting on new developments in upcoming quarters.”

Conference Call and Webcast Information

The Company will host a conference call today, Thursday, November 5, 2020, at 4:30 pm, Eastern Time, to review their clinical, corporate and financial highlights. To participate in the conference call, please dial the following numbers prior to the start of the call:

U.S. Dial-In Number: Toll-Free: (877) 784-1702
International Dial-In Number (857) 770-0110
Conference ID: 9498042

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://edge.media-server.com/mmc/p/wiw3v2y6**. 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 Corporate and Clinical Highlights:

- **Letter of Intent with Felix Biotechnology:** On November 5, TFF announced signing a Letter of Intent with Felix Biotechnology, Inc of San Francisco reflecting the non-binding agreement in principle of the parties to negotiate and enter into a Collaboration, Development and License Agreement. Under the proposed agreement, Felix Biotechnology will obtain a non-exclusive license to TFF’s thin-film freezing technology to develop and manufacture dry powder formulations of specified Felix bacteriophage products for inhalation delivery directly to the lungs of patients. Felix would agree to pay TFF Pharmaceuticals an upfront payment, development milestones, commercial milestones and royalties on net sales of the Felix phage products. The Letter of Intent is subject to certain conditions, including Felix’s completion of its Series A financing.

- **Worldwide Joint Development Agreement with Augmenta Bioworks:** On November 2, TFF announced that it had entered into a worldwide joint development and collaboration agreement with Augmenta Bioworks of Menlo Park, CA to develop novel commercial products incorporating Augmenta's human-derived monoclonal antibodies (mAbs) for potential COVID-19 therapeutics. These products will be developed utilizing TFF Pharmaceutical's Thin-Film Freezing technology to manufacture dry powder formulations of these specific mAbs for inhalation delivery directly to the lungs of patients. Under the Agreement, TFF Pharmaceuticals will also have an option to develop an additional Augmenta mAb for indications other than COVID-19.

- **University of Georgia Universal Influenza Vaccines:** In October, TFF reported positive preclinical immunogenicity and efficacy data from a UGA-developed universal Influenza hemagglutinin (HA) recombinant vaccine that had been reformulated using the Company's Thin Film Freezing process. The Company reported that this reformulated, dry powder HA vaccine elicited equivalent neutralizing antibodies and protection against influenza virus infection compared to liquid formulations. In April of 2020, TFF Pharmaceuticals and the University of Georgia's Center for Vaccines and Immunology entered into a Research and Development Agreement to test the immunogenicity and efficacy of universal influenza HA recombinant vaccines following the TFF process.

- **Tacrolimus Inhalation Powder:** The Company reported successfully completing the single ascending dosing of four cohorts of healthy subjects in its Phase 1 trial of Tacrolimus Inhalation Powder. The dosing completed to date suggests that Tacrolimus Inhalation Powder is well tolerated with no reports of clinically significant drug-associated adverse events and provide substantial systemic blood levels, from just a single dose, that approach those levels associated with effective immunosuppression in heart, lung, kidney and liver transplant patients. Tacrolimus is an important immunosuppressive agent for the prophylactic treatment of lung transplant rejection.

- **Voriconazole Inhalation Powder:** TFF's lead clinical program, Voriconazole Inhalation Powder, to treat the severe and life-threatening disease of Invasive Pulmonary Aspergillosis, or IPA, successfully completed the clinical portion of its Phase 1 trial and progressed to Phase 2. Top-line data from the Phase I single ascending dose and multiple ascending dose portions of the trial indicated that when dosed up to 80mg twice daily, Voriconazole Inhalation Powder showed no signs of the clinically significant hepatic or visual toxicities that were previously reported for the oral or intravenous forms of voriconazole. Phase 2 studies will assess the efficacy of the dry powder formulation for the treatment of IPA.

- **COVID-19/SARS-CoV-2 Drug Repurposing Feasibility Projects:** TFF is actively reviewing previously FDA approved drugs that may be repurposed to combat the novel coronavirus behind the COVID-19 pandemic outbreak. The Company is reviewing libraries of compounds that could potentially benefit from the characteristics of the TFF technology in developing a dry powder product delivered directly to the lung that is capable of targeting SARS-CoV-2 and potentially similar viruses such as SARS-CoV, MERS-CoV and other endemic coronaviruses.

  During the quarter, the inventor of the Company's TFF technology, Dr. Robert O. (Bill) Williams III, published new animal pharmacokinetics data evaluating the development of remdesivir as a dry powder for inhalation by Thin Film Freezing. Top-line results of the study conducted by Dr. Williams' team of researchers at the University of Texas at Austin's Division of Molecular Pharmaceutics and Drug Delivery, concluded that TFF technology can produce high potency remdesivir dry powder formulations for inhalation suitable to treat patients with COVID-19 on an outpatient basis and earlier in the disease course where effective antiviral therapy can reduce related morbidity and mortality.

- **Worldwide Licensing Agreement with UNION Therapeutics:** As announced previously during the quarter, on August 12, 2020, the Company signed a worldwide exclusive licensing agreement with UNION Therapeutics for its Thin Film Freezing technology used in combination with niclosamide.

- **Private Financing Round:** As announced previously on August 13, 2020, the Company closed on a private placement of up to $25,913,550, before deducting placement agent and other offering expenses, of common shares of the Company. Net proceeds from the financing are being used to accelerate the expansion of the Company's internal development portfolio beyond its programs for Voriconazole and Tacrolimus inhalation powders.

Financial Results

For the nine months ended September 30, 2020, compared to the prior year

- **Research and Development (R&D) expenses:** R&D expenses for the nine months ended September 30, 2020 were $7.6 million, compared to $5.6 million for the same period in 2019.

- **General & Administrative (G&A) expenses:** G&A expenses for the nine months ended September 30, 2020 were $5.1 million, compared to $1.7 million for the same period of 2019.

- **Net Loss:** TFF Pharmaceuticals reported a net loss for the nine months ended September 30, 2020 of $12.7 million, compared to a net loss of $7.2 million for the same period of 2019.

- **Shares Outstanding:** Weighted average common shares outstanding, basic and diluted, for the nine months ended September 30, 2020 were 20,810,004, compared with 4,400,000 for the same period in 2019.

- **Total Assets:** As of September 30, 2020, we had total assets of approximately $43.2 million and working capital of approximately $40.6 million. At the end of the quarter, our liquidity included approximately $41.6 million of cash and cash equivalents.

- **Shelf-registration statement on Form S-3**: On November 5, TFF Pharmaceuticals filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission for future offerings of up to $100 million of the Company's common stock.

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 Tac-Lac Inhalation Powder. The Company plans to add to this pipeline by collaborating with large pharmaceutical partners. The TFF Platform is protected by 42 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, the recent agreements with Augmenta Bioworks and Felix Technology, the potential license of our technology to UNION therapeutics and the Company's plans to add to its existing pipeline of product candidates and license its technology to other third-parties. 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 results obtained in dry powder formulation and in vitro testing of the Company's product candidates may not be indicative of results obtained in future preclinical or clinical trials; (ii) the risk that the Company's dry powder formulation of its product candidates may not advance through the preclinical development and clinical trial process on a timely basis, or at all; (iii) the risk that the results of such trials will not warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; (iv) the risk that the Company may not be able to successfully conclude clinical testing or obtain pre-market approval of its product candidates; (v) the risk that the Company's agreements with Felix Technology and UNION will not lead to definitive license agreements; (vi) the fact that no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product; (vii) the Company has no current agreements or understandings with any large pharmaceutical companies for the development of a drug product incorporating the TFF Platform; and (viii) those other risks disclosed in the section "Risk Factors" included in the Company's 2019 Annual Report on Form 10-K filed with the SEC on March 26, 2020. 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 AND COMPREHENSIVE LOSS

	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Operating expenses:				
Research and development	$ 2,823,669	$ 2,563,528	$ 7,626,982	$ 5,554,046
General and administrative	2,254,912	300,640	5,147,639	1,721,691
Total operating expenses	5,078,581	2,864,168	12,774,621	7,275,737
Loss from operations	(5,078,581)	(2,864,168)	(12,774,621)	(7,275,737)
Other income:				
Interest income	20,546	25,865	102,809	67,699
Total other income	20,546	25,865	102,809	67,699
Net loss	(5,058,035)	(2,838,303)	(12,671,812)	(7,208,038)
Preferred stock dividend	—	(258,635)	—	(768,876)
Net loss applicable to common stock	(5,058,035)	(3,096,938)	(12,671,812)	(7,976,914)
Other comprehensive loss:				
Foreign currency translation adjustments	(28,172)	—	(67,663)	—
Comprehensive loss	$ (5,086,207)	$ (3,096,938)	$ (12,739,475)	$ (7,976,914)
Net loss applicable to common stock per share, basic and diluted	$ (0.24)	$ (0.70)	$ (0.61)	$ (1.81)
Weighted average common shares outstanding, basic and diluted	20,867,526	4,400,000	20,810,004	4,400,000

TFF PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 41,617,891	$ 28,094,936
Prepaid assets and other current assets	595,016	1,092,462
Total current assets	42,212,907	29,187,398
Property and equipment, net	945,365	—
Total assets	$ 43,158,272	$ 29,187,398
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,573,384	$ 410,638
Total current liabilities	1,573,384	410,638
Accrued research and development expense	—	1,132,013
Total liabilities	1,573,384	1,542,651
Commitments and contingencies		
Stockholders' equity:		
Common stock; $0.001 par value, 45,000,000 shares authorized; 22,226,284 and 18,450,992 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	22,226	18,451
Additional paid-in capital	70,014,551	43,338,710
Accumulated other comprehensive loss	(67,663)	—
Accumulated deficit	(28,384,226)	(15,712,414)
Total stockholders' equity	41,584,888	27,644,747
Total liabilities and stockholders' equity	$ 43,158,272	$ 29,187,398

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