

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): May 14, 2020

TFF PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-39102

(Commission File Number)

82-4344737

(I.R.S. Employer
Identification Number)

2600 Via Fortune, 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 May 14, 2020, TFF Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 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 May 14, 2020 regarding the Registrant’s financial results for its fiscal quarter ended March 31, 2020	Filed Electronically herewith
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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: May 14, 2020

/s/ Kirk Coleman

Kirk Coleman,
Chief Financial Officer



FOR IMMEDIATE RELEASE

TFF Pharmaceuticals Reports First Quarter 2020 Financial and Business Results

*Maintains clinical progress with lead programs, Voriconazole Inhalation Powder
and Tacrolimus Inhalation Powder*

Thin Film Freezing platform technology employed in numerous partnership programs for vaccine and anti-viral applications

Conference call and live webcast scheduled for Thursday, May 14, 2020 at 5:00pm EDT

AUSTIN, TX -- May 14, 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 first quarter ended March 31, 2020, as well as provided a business update on recent corporate and clinical developments. The Company will discuss the clinical, corporate and financial highlights on a conference call and live webcast, scheduled today, Thursday, May 14, 2020 at 5:00pm EDT.

“This has been another quarter of major accomplishment for TFF Pharmaceuticals,” said Glenn Mattes, President and CEO of TFF Pharmaceuticals. “We’ve maintained the clinical momentum behind our two lead programs, Voriconazole Inhalation Powder, the first clinical study ever in healthy subjects of a direct-to-lung, Thin Film Freezing (TFF) dry-powder formulation, and Tacrolimus Inhalation Powder for use in solid organ transplants, despite a challenging clinical trial environment due to the Covid-19 pandemic.”

“And importantly, this quarter we’ve further validated the broad potential of our Thin Film Freezing platform technology, in ways we might not have imagined even just months ago,” said Mattes.

“To help meet the challenge of the global pandemic, our Thin Film Freezing technology has the potential to be able to repurpose and better deliver existing approved drugs that may have therapeutic potential against the SARS-CoV-2 virus,” continued Mattes. “We are actively engaged with several leading research institutions, as well as a number of biopharmaceutical companies, to study the incorporation of our technology with vaccines and anti-virals with the goal of providing more effective real-world delivery capabilities. And today, we are announcing an initial collaboration with one of the country’s industry leaders, PLUS Products, Inc. to develop an entirely new delivery modality for cannabinoid products using our TFF technology.”

“We believe TFF Pharmaceutical’s unique ability to rapidly investigate, prototype and develop a wide variety of compounds using our technology allows us to be nimble in responding to market conditions and to be able to take advantage of opportunities as they arise,” concluded Mattes.

Conference Call and Webcast Information

The Company will host a conference call today, Thursday, May 14, 2020, at 5:00 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:

U.S. Dial-In Number: Toll-Free: (800) 816-3024
International Dial-In Number (857) 770-0106
Conference ID: 7287036

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/rwrfx2up>. 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’s lead clinical program, Voriconazole Inhalation Powder, to treat the severe and life-threatening disease of Invasive Pulmonary Aspergillosis, or IPA, successfully completed all four dosing cohorts in the single ascending dose (SAD) phase of the trial, and is progressing in the multiple ascending dose (MAD) portion of the study even in the midst of the Covid pandemic. We expect Phase 1 SAD/MAD dosing to be completed by mid-July, with topline results reported in September of this year.
- **Tacrolimus Inhalation Powder:** TFF’s second clinical program, Tacrolimus Inhalation Powder, is an inhaled dry powder version of tacrolimus, one of the most commonly administered immunosuppressive drug used in solid organ transplants. The Company intended to begin Single Ascending Dose Phase I studies by the end of Q1-2020 in Australia, with Multiple Ascending Dose studies beginning in Q2-2020. However, with the spread of COVID-19 across the Australian continent, the Company’s CRO partner informed us there would be a delay in initiating the trial. The trial has been approved by Australian regulatory authorities and dosing will proceed once the risk to the subjects from COVID-19 has been sufficiently addressed. We note that the per capita coronavirus infection rates are low in Australia and testing is being expanded to the general population. We anticipate being able to start the trial by the end of June of this year.
- **License agreement for use of TFF technology in the cannabis market**
TFF has sublicensed its Thin Film Freezing technology on an interim basis to an unaffiliated third-party, who will in turn work with PLUS Products, Inc., one of the country’s market leaders, to develop and commercialize non-therapeutic cannabis and cannabis-derived products, including cannabidiol (CBD). Subject to PLUS’ development and evaluation of their cannabis and cannabis-derived products, TFF Pharmaceuticals expects to sign a Long-term License Agreement, pursuant to which TFF Pharmaceuticals expects to receive licensing fees, along with future product sale royalties. TFF believes its Thin Film Freezing technology has the potential of being a new delivery modality for these products as a consumer friendly, alternative to vaping and combustion delivery methods.

- **Strategic Business Development and Partnership Activities – Research and Defense Contracting Agencies:** During the quarter, TFF Pharmaceuticals entered into a research collaboration with the University of Georgia’s Center for Vaccines and Immunology (CVI), along with the University of Texas at Austin (UT Austin), to evaluate the immunogenicity and efficacy of universal influenza vaccines following Thin Film Freezing. Researchers in the University of Georgia’s CVI are world-leaders in vaccine development. Under the terms of the collaboration, TFF Pharmaceuticals, along with UT Austin and the University of Georgia’s CVI, will collaborate to investigate TFF-formulated CVI recombinant universal influenza vaccines with the goal of eliciting broadly reactive immune responses and potentially providing longer-lasting protection against a wider variety of influenza viruses, in a pre-clinical challenge model.

Also during the quarter, TFF entered into a Cooperative Research and Development Agreement (CRADA) with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), the U.S Army's premier institution and facility for defensive research into countermeasures against biological warfare. TFF and USAMRIID will collaborate over a 3-year period to investigate Thin Film Freezing to formulate two different countermeasures, a monoclonal antibody against Alphaviruses (e.g. Venezuelan, Western, and Eastern equine encephalitis viruses) and a vesicular stomatitis virus vaccine against Filoviruses (e.g. Ebola, Marburg). USAMRIID will evaluate the immune responses induced by the dry powder formulations given by the pulmonary or intranasal route in a rodent model, as compared to the traditional routes of administration.

We are also actively engaged in a number of material transfer agreements and work projects with potential partners to evaluate our Thin Film Freezing platform with both large and small molecules, New Chemical Entities, vaccines and other exciting opportunities.

- **COVID-19/ SARS-CoV-2 Drug Repurposing Feasibility Projects:** TFF is actively reviewing previously FDA approved drugs that may be repurposed in an effort 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 Company and the inventor of its TFF technology, Dr. Robert O. (Bill) Williams III, focused on the existing antiviral drug, niclosamide, to enhance its effect as a potential COVID-19 therapy. Niclosamide is an FDA-approved oral anthelmintic drug that we believe has the potential to be repurposed to treat a variety of viral infections, such as severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV), Zika virus (ZIKV), and others. Our Thin Film Freezing technology is being evaluated to develop an inhaled form of niclosamide that could potentially enhance this promising drug’s bioavailability for treating respiratory modes of infection. If successful, TFF Pharmaceuticals would potentially progress to filing an IND for this compound with the FDA.

Financial Results

For the three months ended March 31, 2020, compared to the prior year

- **Research and Development (R&D) expenses:** R&D expenses for the first quarter of 2020 were \$2.2 million, compared to \$1.7 million for the same period in 2019.
- **General & Administrative (G&A) expenses:** G&A expenses for the first quarter of 2020 were \$1.6 million, compared to \$532,000 for the same period of 2019.
- **Net Loss:** TFF Pharmaceuticals reported a net loss for the first quarter of 2020 of \$3.8 million, compared to a net loss of \$2.2 million for the same period of 2019.

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 41 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 and license its technology to PLUS Products and 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) no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, (ii) the Company has no current agreements or understandings with any large pharmaceutical companies for the development of a drug product incorporating the TFF Platform, (iii) the risk that the Company will not be able to conclude a long-term commercial agreement with PLUS Products or any other third-party, (iv) the legal and regulatory risks associated with cannabis-based products and (v) 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

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Operating expenses		
Research and development	\$ 2,235,542	\$ 1,670,862
General and administrative	1,617,924	531,598
Total operating expenses	<u>3,853,466</u>	<u>2,202,460</u>
Loss from operations	(3,853,466)	(2,202,460)
Other income		
Interest income	56,268	19,645
Total other income	<u>56,268</u>	<u>19,645</u>
Net loss	(3,797,198)	(2,182,815)
Preferred stock dividend	—	(221,278)
Net loss applicable to common stockholders	<u>\$ (3,797,198)</u>	<u>\$ (2,404,093)</u>
Net loss applicable to common stock per share, basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.55)</u>
Weighted average common shares outstanding, basic and diluted	<u>19,008,611</u>	<u>4,400,000</u>

TFF PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	As of March 31, 2020 <u>(Unaudited)</u>	As of December 31, 2019
Assets		
Current Assets		
Cash and cash equivalents	\$ 25,731,010	\$ 28,094,936
Prepaid assets and other current assets	859,064	1,092,462
Total Assets	\$ 26,590,074	\$ 29,187,398
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 1,204,952	\$ 410,638
Total Current Liabilities	1,204,952	410,638
Accrued research and development expense	—	1,132,013
Total Liabilities	1,204,952	1,542,651
Stockholders' Equity:		
Common stock, \$0.001 par value, 45,000,000 shares authorized; 18,671,658 and 18,450,992 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	18,672	18,451
Additional paid-in capital	44,896,346	43,338,710
Accumulated other comprehensive loss	(20,283)	—
Accumulated deficit	(19,509,612)	(15,712,414)
Total Stockholders' Equity	25,385,123	27,644,747
Total Liabilities and Stockholders' Equity	\$ 26,590,074	\$ 29,187,398

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