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): March 26, 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 March 26, 2020, TFF Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2019. 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 March 26, 2020 regarding the Registrant's financial results for its fiscal quarter and year ended December 31, 2019	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: March 26, 2020

/s/ Glenn Mattes
Glenn Mattes,
President and Chief Executive Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

TFF Pharmaceuticals Reports Fourth Quarter Results and Full Year 2019 Financial and Business Results

Conference call and live webcast scheduled for Thursday, March 26, 2020 at 4:30pm EDT

AUSTIN, TX -- March 26, 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 fourth quarter and full year ended December 31, 2019, 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, March 26, 2020 at 4:30pm EDT.

“TFF Pharmaceuticals has made tremendous progress in a short period of time as a public company,” said Glenn Mattes, President and CEO of TFF Pharmaceuticals. “We’ve achieved important early milestones in our Phase 1 clinical trial of our Voriconazole Inhalation Powder, to treat the severe and life-threatening disease of Invasive Pulmonary Aspergillosis, or IPA. This is the first clinical study ever in healthy subjects of a direct-to-lung, Thin Film Freezing (TFF) dry-powder formulation.

“Our groundbreaking TFF technology continues to garner considerable attention from potential industry partners, as well as governmental agencies,” continued Mattes. “And, due to its capabilities to potentially mitigate the need for cold chain storage and distribution of vaccines, interest from some of the largest developers of vaccines and anti-virals, as well. We feel we have untapped potential in this technology and are eager to further advance it for drugs for chronic respiratory diseases and lung conditions, as well as new chemical entities and existing therapies for a multitude of indications.”

Conference Call and Webcast Information

The Company will host a conference call today, Thursday, March 26, 2020, 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: (800) 816-3024
International Dial-In Number (857) 770-0106
Conference ID: 7695599

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/k9qym597. 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:** At the end of 2019, TFF's lead clinical program, Voriconazole Inhalation Powder, to treat the severe and life-threatening disease of Invasive Pulmonary Aspergillosis, or IPA, began dosing subjects in its Phase 1 clinical trial. To date, the Company has successfully completed all four dosing cohorts in the single ascending dose (SAD) phase of the trial, ahead of anticipated schedule. Enrollment of the first cohort in the multiple ascending dose (MAD) portion of the study has also been completed. The Data Safety Monitoring Board (DSMB) has approved escalation to the next dose level. The Company anticipates a Phase I study database lock by the end of Q2-2020, with 6-month toxicology studies complete by the end of Q4-2020.

- **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 continent, the Company's CRO partner informed us there would be a delay in initiating the trial. We are currently monitoring the situation in Australia and are closely looking into alternative trial sites.

- **Strategic Business Development and Partnership Activities – Commercial Pharma and Biopharmaceutical companies:** In December 2019, TFF Pharmaceuticals entered into a feasibility agreement with the University of Texas at Austin (UT-Austin) and an undisclosed leading worldwide biopharmaceutical company ("Partner No. 1"), to explore using the Company's Thin Film Freezing technology platform to formulate, perform testing on and collaborate on optimization work for two proprietary compounds of Partner No.1. This work is ongoing.

  TFF is collaborating with a large multi-national pharma company ("Partner No. 2") and UT-Austin to explore using the Company's Thin Film Freezing technology platform to formulate a liquid vaccine product candidate of Partner No. 2 into a dry powder formulation for reconstitution. The Company, with the assistance of UT-Austin, has successfully taken the partner's vaccine, which contains an aluminum adjuvant, and formulated it using the Company's Thin Film Freezing technology. The Company has performed internal testing and the TFF reconstituted dry powder has the same properties as the initial liquid vaccine. The TFF dry powder vaccine has been delivered to Partner No. 2 for internal testing, which includes animal testing, and such testing has confirmed that the TFF dry powder formulation meets the same specifications as the liquid vaccine currently in development. Ongoing formulation optimization and additional testing is underway.

TFF continues to engage with several leading multi-national pharma companies in an effort to enter into feasibility projects taking the partner's product candidates, whether small molecule, large molecule, biologics, enzymes, antibodies, gene therapy, DNA derived therapy and/or vaccines, to utilize the Company's Thin Film Freezing technology platform to deliver new and innovative products directly to the lung.

- **Potential mRNA Product Candidates:** The Company is applying its Thin Film Freezing platform technology to advanced delivery systems that incorporate siRNA, mRNA and DNA delivery, by leveraging its unique ability to convert liquid forms that are injected into stable dry powder forms that can be delivered by needle-free means such as inhalation and intranasally, as well as reconstituted into a liquid form for reconstitution. TFF, working in collaboration with UT Austin, has performed initial proof of concept work utilizing the Company's TFF technology in order to successfully formulate mRNA into a dry powder. The TFF generated mRNA dry powder has favorable aerosol properties which allows for the delivery of mRNA directly to the lung via oral inhalation in an effort to treat certain debilitating pulmonary diseases. This preliminary proof of concept work is ongoing. Simultaneously, TFF continues to engage in exploratory discussions with multiple potential partners in a focused effort to collaborate in performing feasibility work on the partner's proprietary mRNA respiratory product candidates using the Company's TFF technology.

- **Strategic Business Development and Partnership Activities – Governmental and Defense Contracting Agencies:** TFF continues to engage with a number of government and defense contracting agencies in an effort to utilize the Company's Thin Film Freezing technology platform to formulate dry powder vaccines for delivery via reconstitution or lung inhalation or nasal inhalation. The Company's testing confirms that Thin Film Freezing maintains the vaccine's particle size distribution and immunogenicity, is robust for extended periods at room temperature, withstands unintentional freezing, and can be stored and shipped free of cold-chain handling, displays extended stability for stockpiling – dry powder storage over liquid, and provides for needle-free vaccination (nasal or inhalation administration). The Company continues its ongoing discussions with each of these government agencies in an effort to partner its TFF technology and obtain development funding.

  On February 20, 2020, the Company, along with its potential partner, submitted a proposal to Defense Advanced Research Projects Agency (DARPA) through the Broad Agency Announcement (BAA) process for the Personalized Protective Biosystem (PPB) program. The Company expects to be notified of the award, if an award is granted, within 60 to 90 days after the date of submission. Should the Company be awarded this contract, the Company shall utilize its TFF technology to develop dry powder formulations of the countermeasures for inhalation delivery to the lung using a dry powder inhaler device, develop powder formulations of the countermeasures for ocular delivery as a liquid using a dropper, and develop powder formulations of the countermeasures for dermal delivery as a cream. Company submitted this proposal to DARPA and DARPA may, or may not, award the Company this contract. Should DARPA award the Company this contract, DARPA would fund all activities contained in the awarded contract.

- **CBD Development Studies:** The Company is also engaged in the development of a dry powder formulation of cannabidiol, or CBD, which has been reported to be used by some for the treatment of various epilepsy syndromes as well as anxiety, insomnia, and different types of pain. We are in the early stages of developing an inhaled dry powder form of CBD that could be used to support or to treat a variety of health issues that may benefit from CBD administration. We are also actively engaged in discussions with several third parties concerning our grant of a license to our TFF technology platform in the field of use of CBD.

- **COVID-19/ SARS-CoV-2 Feasibility Projects:** TFF is performing an exhaustive exercise reviewing all 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 would 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 endemic coronaviruses. Simultaneously, the Company is in discussions with multiple potential partners that have treatments in development that target SARS-CoV-2. These discussions focus on the key differentiating characteristics of the TFF technology in treating this respiratory disease such as quick onset of action, better absorption, lower dose, better safety profile, less systemic absorption, improved stability, ease of use, and direct delivery of the compound to the lung.

- **Strategic Business Development and Partnership Activities – Ex-US Opportunities:** The Company is executing on its strategy to expand it partnerships into other regions of the world. Recently, on March 9, 2020, the Company announced its engagement with Torreya Partners as its strategic advisor for the countries of China and South Korea. Torreya will lead the partnering efforts in these countries. Subsequently, on March 12, 2020, the Company announced its engagement with J.S. Cole and Associates to act as the Company's strategic advisor in Japan. The Company continues to evaluate other potential regions of the world in an effort to partner its lead product candidates and innovative technology.

Financial Results

For the year ended December 31, 2019, compared to 2018

- **Cash Position:** As of December 31, 2019, TFF Pharmaceutics reported cash and cash equivalents of $28.1 million.

- **Research and Development (R&D) expenses:** R&D expenses for 2019 were $8.8 million, compared to $849,000 in 2018.

- **General & Administrative (G&A) expenses:** G&A expenses for 2019 were $3,165,000, compared to $3,049,000 in 2018.

- **Net Loss:** TFF Pharmaceuticals reported a net loss for 2019 of $11.87 million, compared to a net loss of $3.84 million in 2018.

For the three months ended December 31, 2019, compared to the prior year

- **Research and Development (R&D) expenses:** R&D expenses for the fourth quarter of 2019 were $3.3 million, compared to $89,000 for the same period in 2018.

- **General & Administrative (G&A) expenses:** G&A expenses for the fourth quarter of 2019 were $1.4 million, compared to $806,000 for the same period of 2018.

- **Net Loss:** TFF Pharmaceuticals reported a net loss for the fourth quarter of 2019 of $4.7 million, compared to a net loss of $872,000 for the same period of 2018.

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 39 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) 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 and (iii) 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 STATEMENTS OF OPERATIONS

	Three Months Ended December 31, 2019	Three Months Ended December 31, 2018	Twelve Months Ended December 31, 2019	January 24, 2018 to December 31, 2018
Operating expenses				
Research and development	$ 3,268,180	$ 89,454	$ 8,822,226	$ 848,809
General and administrative	1,443,640	805,549	3,165,331	3,049,337
Total operating expenses	4,711,820	895,003	11,987,557	3,898,146
Loss from operations	(4,711,820)	(895,003)	(11,987,557)	(3,898,146)
Other income				
Interest income	49,630	22,692	117,329	55,960
Total other income	49,630	22,692	117,329	55,960
Net loss	(4,662,190)	(872,311)	(11,870,228)	(3,842,186)
Preferred stock dividend	(106,483)	(222,834)	(875,359)	(728,350)
Deemed dividend for beneficial conversion feature of Series A Preferred Stock	$ (23,929,751)	$ -	$ (23,929,751)	$ -
Net loss applicable to common stock per share, basic and diluted	$ (2.00)	$ (0.25)	$ (5.31)	$ (1.31)
Weighted average common shares outstanding, basic and diluted	14,338,249	4,400,000	6,904,983	3,483,836

TFF PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

	As of December 31, 2019	As of December 31, 2018
Assets	**(Unaudited)**	**(Unaudited)**
Current Assets		
Cash and cash equivalents	$ 28,094,936	$ 10,261,671
Prepaid assets and other current assets	1,092,462	12,065
Total Current Assets	29,187,398	10,273,736
Deferred Offering Costs	-	127,768
Total Assets	$ 29,187,398	$ 10,401,504
Liabilities and Stockholders' Deficit		
Current Liabilities		
Accounts payable	$ 410,638	$ 428,645
Accrued dividends payable	-	728,350
Total Current Liabilities	410,638	1,156,995
Accrued research and development expense	1,132,013	-
Total Liabilities	1,542,651	1,156,995
Series A Preferred Stock		
Series A Preferred Stock, $0.001 par value, 10,000,000 shares authorized; 0 and 5,662,000 shares issued and outstanding as of December 31, 2019 and 2018 respectively	-	12,485,971
Stockholders' Equity (Deficit):		
Common stock, $0.001 par value, 45,000,000 shares authorized; 18,450,992 and 4,000,000 shares issued and outstanding as of December 31, 2019 and 2018, respectively	18,451	4,000
Additional paid-in capital	43,338,710	596,724
Accumulated deficit	(15,712,414)	(3,842,186)
Total Stockholders' Equity (Deficit)	27,644,747	(3,241,462)
Total Liabilities, Series A Preferred Stock and Stockholders' Equity (Deficit)	$ 29,187,398	$ 10,401,504

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