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 13, 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 August 13, 2020, TFF Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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 August 13, 2020 regarding the Registrant's financial results for its fiscal quarter ended June 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: August 13, 2020

/s/ Kirk Coleman

Kirk Coleman,
Chief Financial Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

TFF Pharmaceuticals Reports Second Quarter 2020 Financial and Business Results

Enters into worldwide license agreement with UNION Therapeutics for its Thin Film Freezing technology in combination with niclosamide

Closes on $25.9 million private financing to further advance its technology platform for inhalable drug products, vaccines, biologics and botanicals

Completes Phase 1 trial dosing for Voriconazole Inhalation Powder and begins Phase 1 trial for Tacrolimus Inhalation Powder

Conference call and live webcast scheduled for Thursday, August 13, 2020 at 4:30pm EDT

AUSTIN, TX – August 13, 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 June 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, August 13, 2020 at 4:30pm EDT.

“TFF Pharmaceutical’s accomplishments during the quarter, and in recent weeks, have truly demonstrated the capability and potential of our groundbreaking technology platform,” said Glenn Mattes, President and CEO of TFF Pharmaceuticals. “Most recently, our worldwide licensing agreement with UNION Therapeutics on our Thin Film Freezing technology for oral and inhalation versions of niclosamide has the potential to speed efforts to reformulate and investigate this very promising existing drug for COVID-19 therapies. It is gratifying to have our technology recognized by a company that has years of experience in working with niclosamide in a variety of therapeutic areas.”

“The recognition of the significance of our platform is further evidenced by our highly successful $25.9 million financing, completed on August 13, supported by a number of leading life science investment firms. These funds will be used to advance our clinical programs, the continued research and development of inhalable drug products, vaccines, biologics and botanicals and furthering ongoing business development and partnering initiatives.”

“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, with initial indications that doses of up to two times higher than those reported to be efficacious in the treatment of IPA appeared to be safe.”

“We also began our second clinical trial program with the Phase 1 dosing of healthy subjects of Tacrolimus Inhalation Powder, an important immunosuppressive agent for the prophylactic treatment of lung transplant rejection,” said Mattes. “This trial has successfully started despite a challenging clinical trial environment due to the Covid-19 pandemic.”

“And this quarter, we continue to see the broad capabilities of our platform to reformulate existing drugs into inhalation forms that may prove to be more effective,” said Mattes. “The inventor of our TFF technology, Dr. Robert O. (Bill) Williams III, demonstrated recently the ability to effectively reformulate remdesivir, one of the most important new COVID-19 therapeutics, into a dry powder form that could dramatically enhance its treatment options.”

“In a time of extraordinary need, we are very proud that our scientists, clinicians and collaborators have worked so diligently to help fulfill the promise of our technology and platform,” said Mattes. “This is ultimately what we envisioned when we began this Company, to be able to rapidly investigate, prototype and develop a wide variety of compounds using our technology for better efficacy and effect. We look forward to continued progress in these efforts in the quarters to come,” concluded Mattes.

Conference Call and Webcast Information

The Company will host a conference call today, Thursday, August 13, 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:

U.S. Dial-In Number: Toll-Free: (800) 816-3024
International Dial-In Number (857) 770-0106
Conference ID: 7516247

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/28vdaqxx. 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:

- **Worldwide Licensing Agreement with UNION Therapeutics:** On August 12, 2020, the Company announced a worldwide exclusive licensing agreement with UNION Therapeutics (UNION) for its Thin Film Freezing technology used in combination with niclosamide. UNION Therapeutics will acquire an option to obtain a worldwide exclusive license of TFF Pharmaceuticals Thin Film Freezing technology to be used in combination with oral and inhalation versions of niclosamide, potentially for COVID-19 as well as other therapies, and for its use in other UNION developed salts, derivatives and structurally related compounds.

- **Private Financing Round:** On August 11, 2020, the Company entered into a definitive agreement with a syndicate of high quality healthcare investors for the private placement of up to $25,913,550, before deducting placement agent and other offering expenses, of common shares of the Company. The placement closed on August 13th. Net proceeds from the financing will be used to accelerate the expansion of the company's internal development portfolio beyond its programs for Voriconazole and Tacrolimus inhalation powders.

- **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 with both Single Ascending Dose and Multiple Ascending Dose phases with 32 healthy subjects enrolled in each to evaluate the safety, tolerability and pharmacokinetic profile of Voriconazole Inhalation Powder. Initial topline results indicate that repeated doses of up to 80 mg/dose twice daily for 7-days in healthy normal volunteers were well tolerated.

- **Tacrolimus Inhalation Powder:** TFF's second clinical program, Tacrolimus Inhalation Powder, began Phase I trials. This single ascending dose (SAD) and multiple ascending dose (MAD) study will assess the safety, tolerability and pharmacokinetic profile of the Tacrolimus Inhalation Powder in healthy subjects. Tacrolimus is an important immunosuppressive agent for the prophylactic treatment of lung transplant rejection. Subjects were successfully enrolled and dosed at a single site in Australia under the Australian CTN process, despite the clinical trial challenges posed by the COVID-19 pandemic.

  In June, the U.S. Food and Drug Administration (FDA) granted orphan drug designation to Tacrolimus Inhalation Powder for prophylaxis of lung allograft rejection.

- **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 Company and the inventor of its TFF technology, Dr. Robert O. (Bill) Williams III, continued to evaluate the existing antiviral drug, niclosamide, to enhance its effect as a potential COVID-19 therapy. Niclosamide is an FDA-approved oral anthelminthic 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 will be evaluated by UNION therapeutics to develop an inhaled form of niclosamide that could potentially enhance this promising drug's bioavailability for treating respiratory modes of infection. If successful, UNION therapeutics or TFF Pharmaceuticals, depending on whether Union exercises its option, would potentially progress to filing an IND for this compound with the FDA.

Also, after the end of the quarter, Dr. Williams presented initial results of research evaluating the re-formulation of remdesivir to a dry powder form for COVID-19 antiviral treatment for inhalation using the Company's Thin Film Freezing technology. Dr. Williams' research team at the University of Texas at Austin's Division of Molecular Pharmaceutics and Drug Delivery developed inhaled forms of remdesivir for protecting and treating the respiratory mode of infection, including an amorphous brittle matrix powder made by Thin Film Freezing.

Financial Results

For the six months ended June 30, 2020, compared to the prior year

- **Research and Development (R&D) expenses:** R&D expenses for the six months ended June 30, 2020 were $4.80 million, compared to $2.99 million for the same period in 2019.

- **General & Administrative (G&A) expenses:** G&A expenses for the six months ended June 30, 2020 were $2.89 million, compared to $1.42 million for the same period of 2019.

- **Net Loss:** TFF Pharmaceuticals reported a net loss for the six months ended June 30, 2020 of $7.61 million, compared to a net loss of $4.37 million for the same period of 2019.

- **Shares Outstanding:** Weighted average common shares outstanding, basic and diluted, for the six months ended June 30, 2020 were 19,040,134, compared with 4,400,000 for the same period in 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 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 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 UNION will not exercise its option and that the collaboration will go no further than the investigator lead studies, (ii) if UNION does exercise its option to license TFF's technologies, the risk that UNION will not pursue the development of a product candidate under the license with TFF or, if it does, that such product candidate will obtain regulatory approval or commercial success, (iii) the risk that few, or none, of the conditions for the milestone or sales-based payment will be satisfied and TFF will receive little, or none, of such milestone and sales-based payments, (iv) 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, (v) 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 (vi) 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 June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Operating expenses:				
Research and development	$ 2,567,771	$ 1,319,656	$ 4,803,313	$ 2,990,518
General and administrative	1,274,803	889,453	2,892,727	1,421,051
Total operating expenses	3,842,574	2,209,109	7,696,040	4,411,569
Loss from operations	(3,842,574)	(2,209,109)	(7,696,040)	(4,411,569)
Other income:				
Interest income	25,995	22,189	82,263	41,834
Total other income	25,995	22,189	82,263	41,834
Net loss	(3,816,579)	(2,186,920)	(7,613,777)	(4,369,735)
Preferred stock dividend	—	(288,962)	—	(510,240)
Net loss applicable to common stock	(3,816,579)	(2,475,882)	(7,613,777)	(4,879,975)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(19,208)	—	(39,491)	—
Comprehensive loss	(3,835,787)	(2,475,882)	(7,653,268)	(4,879,975)
Net loss applicable to common stock per share, basic and diluted	$ (0.20)	$ (0.56)	$ (0.40)	$ (1.11)
Weighted average common shares outstanding, basic and diluted	19,071,658	4,400,000	19,040,134	4,400,000

TFF PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,924,119	$ 28,094,936
Prepaid assets and other current assets	610,376	1,092,462
Total assets	$ 22,534,495	$ 29,187,398
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 689,803	$ 410,638
Total current liabilities	689,803	410,638
Accrued research and development expense (see Note 5)	—	1,132,013
Total liabilities	689,803	1,542,651
Commitments and contingencies (see Note 4)		
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 June 30, 2020 and December 31, 2019, respectively	18,672	18,451
Additional paid-in capital	45,191,702	43,338,710
Accumulated other comprehensive loss	(39,491)	—
Accumulated deficit	(23,326,191)	(15,712,414)
Total stockholders' equity	21,844,692	27,644,747
Total liabilities and stockholders' equity	$ 22,534,495	$ 29,187,398

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