

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 11, 2022

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)

1751 River Run, Suite 400 Fort Worth, Texas 76107
(Address of principal executive offices)

(817) 438-6168
(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 11, 2022, TFF Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2022. 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 11, 2022 regarding the Registrant’s financial results for its fiscal quarter ended June 30, 2022.	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: August 11, 2022

/s/ Kirk Coleman

Kirk Coleman,
Chief Financial Officer

TFF Pharmaceuticals Reports Second Quarter 2022 Financial Results and Provides Business Update*Phase 2 Inhaled Voriconazole Powder and Inhaled Tacrolimus Powder Programs Continue to Advance**Expands R&D Operations with New Austin, TX Facility**Recent Feasibility Work Confirms Utility of Thin Film Freezing in Developing Next- Generation Vaccines**Conference Call and Webcast Scheduled Today, Thursday, August 11, 2022, at 4:30 PM ET*

FORT WORTH, TX – Aug. 11, 2022 --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 of 2022 and provided an update on recent corporate and clinical developments. The Company will discuss the highlights on a conference call and webcast, scheduled for today, Thursday, August 11, 2022, at 4:30 PM ET.

“We enter the second half of 2022 with significant momentum based upon the continued advancement of our internal pipeline coupled with growing recognition that our Thin Film Freezing technology has the potential to revolutionize drug delivery across a diverse array of molecules,” said Glenn Mattes, CEO of TFF Pharmaceuticals. “We have initiated Phase 2 studies for our two lead internal product candidates, Inhaled Voriconazole Powder (TFF VORI) and Inhaled Tacrolimus Powder (TFF TAC), and we are engaged in active outreach with a number of companies that have expressed interest in these two innovative programs. Importantly, the VORI and TAC programs also serve to further validate the clinical utility of Thin Film Freezing technology, sending a clear signal to the industry that applications of our technology continue to grow and advance further into human testing.

“Our partnering activity also remains robust, and we are now working with three additional top 20 pharma companies. With more than 20 disclosed collaborations and well over 50 material transfer agreements, we continue to make significant progress with our industry and academic partners, consistently demonstrating how Thin Film Freezing offers a unique and versatile solution for significantly improving formulations for safer, more targeted drug delivery. We expect many of these programs to advance further into preclinical and clinical testing later this year. As the success of our partnerships continues to grow, we also anticipate that many of our existing partners will expand their relationship with TFF as well as open up the opportunity for developing new relationships.

“To accommodate current and future demand for Thin Film Freezing partnerships, in July we announced the opening of a new R&D facility located in Austin, Texas that provides us with significantly more laboratory space. This 3,500 square foot facility includes a dedicated lab for downstream processing of preclinical products created via Thin Film Freezing, which will complement the company’s existing formulation development capabilities. As TFF expands its in-house and partnered research, including applications in biologics, the Austin facility will also allow us to accommodate larger equipment to facilitate scale-up and manufacturing for preclinical studies.

“A major reason for our R&D expansion also relates to the increased feasibility work surrounding our next-generation vaccine programs. There is a growing body of scientific evidence suggesting that, when compared to conventional delivery, mucosal-based delivery of vaccines may reduce the burden of infectious diseases by providing first-line protection at viral entry points.¹ We have successfully completed multiple feasibility studies with Thin Film Freezing demonstrating how our unique, dry powder-based formulations can be successfully delivered to both lung and nasal regions to elicit a robust host immune response. As this area of work continues to grow, we look forward to providing additional updates on our vaccine applications later this year.

“We have recently delivered the final published clinical study report for Inhaled Niclosamide Powder to our partner, UNION Therapeutics. Union is working diligently to provide TFF with feedback on their option to license Niclosamide Inhalation Powder. We continue to believe that the widespread availability of potent antiviral medicines is key to significantly lowering mortality and morbidity associated with COVID-19 infection.

“We believe the second half of the year is shaping up to be a very exciting period for TFF Pharmaceuticals. As a reminder, we spent the first half of 2022 positioning the company for significant growth by advancing our two lead pipeline assets into Phase 2 testing, forging important new strategic alliances, expanding the applications of our technology platform across a wide spectrum of molecules, and making key senior level appointments to help drive our growth while optimizing our capital and operational efficiencies. We look forward to announcing additional progress throughout the remainder of 2022.”

Conference Call and Webcast Information

The Company will host a conference call today, Thursday, August 11, 2022, at 4:30 PM, Eastern 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: 1-855-327-6837

International Dial-In Number: 1-631-891-4304

Conference ID: 10019661

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://viaid.webcasts.com/starthere.jsp?ei=1558913&tp_key=43b9453c47

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:

- In July, the Company announced a significant expansion of its R&D operations through the lease of a new research and development facility located in Austin, Texas. The new facility of over 3,500 square feet significantly increases TFF's total lab space, adding a dedicated lab for downstream processing of products created via Thin Film Freezing, which will complement the company's existing formulation development capabilities. The new space will be supervised by Donald Owens, Ph.D., Director of Product Development at TFF, and supported by John Koleng, Ph.D., R.Ph., Vice President of Product Development and Manufacturing. The company also plans to expand the product development team in Austin, which will be based at the new facility, to support the growing number of partnered projects.

Strategic Business Development and Partnership Activities – Biopharmaceutical Companies and Research Institutions:

- In July, Dr. Bill Williams, co-inventor of the Thin Film Freezing technology, published an editorial review article in *Biopharm International* entitled, "Improved Formulations to Enable Stable Delivery of Biologics". The article highlights the significant advantages of Thin Film Freezing over conventional freeze-drying processes, including improvements with respect to less particle aggregation and less protein denaturation, which can overcome challenges in the formulation and delivery of biologics.
- In May, the Company announced multiple presentations highlighting the broad applicability of its Thin Film Freezing Technology at the Respiratory Drug Delivery Meeting (RDD). Dr. Williams delivered a platform presentation with data on stabilizing and delivering antivirals, antibodies and vaccines using Thin Film Freezing technology in the fight against COVID-19 and other serious viral infections. Additionally, Dr. Williams and his colleagues presented five posters highlighting the broad applicability of Thin Film Freezing to improve drug development of biologics and small molecules for respiratory diseases, including pulmonary fibrosis and COVID-19. The findings from Dr. Williams' lab also highlighted how Thin Film Freezing can be used to facilitate delivery of other treatment modalities, such as gene therapy.
- In April, the Company announced safety and pharmacokinetic data from its Phase 1 study of Niclosamide Inhalation Powder, which is being developed as a potential treatment for COVID-19. The data showed that Niclosamide Inhalation Powder was well tolerated with no serious adverse events across all subject cohorts. TFF Pharmaceuticals believes the 6 mg dose level of Niclosamide Inhalation Powder is estimated to produce a concentration of $>100 \mu\text{M}$ in the epithelial lining fluid in the lung following delivery as a dry powder, which would be considered highly potent with respect to inhibiting viral replication. A single administration of 6 mg of Niclosamide Inhalation Powder to the lungs provided equal mean maximum drug concentration (C_{max}) in the blood as 100 mg delivered as a nebulized spray to the lungs and nasal cavity, as demonstrated in a recent publication.²

Financial Results

For the quarter ended June 30, 2022, compared to quarter ended June 30, 2021

- Cash Position: As of June 30, 2022, TFF Pharmaceuticals reported cash and cash equivalents of \$20.9 million.
- Research and Development (R&D) expenses: R&D expenses for the second quarter of 2022 were \$5.1 million, compared to \$2.8 million in 2021.
- General & Administrative (G&A) expenses: G&A expenses for the second quarter of 2022 were \$3.7 million, compared to \$2.4 million in 2021.
- Net Loss: TFF Pharmaceuticals reported a net loss for the second quarter of 2022 of \$8.7 million, compared to a net loss of \$4.7 million in 2021.

ABOUT TFF PHARMACEUTICALS' THIN FILM FREEZING TECHNOLOGY PLATFORM

TFF Pharmaceuticals' proprietary Thin Film Freezing (TFF) technology allows for the transformation of both existing compounds and new chemical entities into dry powder formulations exhibiting unique characteristics and benefits. The Thin Film Freezing process is a particle engineering process designed to generate dry powder particles with advantageous properties for inhalation, as well as parenteral, nasal, oral, topical and ocular routes of administration. The process can be used to engineer powders for direct delivery to the site of need, circumventing challenges of systemic administration and leading to improved bioavailability, faster onset of action, and improved safety and efficacy. The ability to deliver therapies directly to the target organ, such as the lung, allows TFF powders to be administered at lower doses compared to oral drugs, reducing unwanted toxicities and side effects. Laboratory data suggests the aerodynamic properties of the powders created by Thin Film Freezing can deliver as much as 75% of the dose to the deep lung. Thin Film Freezing does not introduce heat, shear stress, or other forces that can damage more complex therapeutic components, such as fragile biologics, and instead enables the reformulation of these materials into easily stored and temperature-stable dry powders, making therapeutics and vaccines more accessible for distribution worldwide. The advantages of Thin Film Freezing can be used to enhance traditional delivery or combined to enable next-generation pharmaceutical products.

ABOUT TFF PHARMACEUTICALS

TFF Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company engaging patented rapid freezing technology to develop and transform medicines into potent dry powder formulations for better efficacy, safety and stability. The company's versatile Thin Film Freezing (TFF) technology platform has broad applicability to convert any drug, including vaccines, small and large molecules and biologics, into an elegant dry powder highly advantageous for inhalation, with improved absorption so drugs can also be delivered to the eyes, nose and topically to the skin. TFF has two lead drug candidates in the clinic: Voriconazole Inhalation Powder and Tacrolimus Inhalation Powder, and continues to expand its pipeline by collaborating with a broad array of pharmaceutical companies, academic institutions and government partners to revolutionize healthcare around the globe. The TFF Platform is protected by 120+ patents issued or pending in the U.S. 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 expectations for its continued development of Inhaled Tacrolimus and Voriconazole Powders, the benefits of the Company's TFF platform 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 Inhaled Tacrolimus, Voriconazole Powders or any of its dry powder product candidates, (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 2021 Annual Report on Form 10-K filed with the SEC on March 24, 2022. 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.

1 <https://pubmed.ncbi.nlm.nih.gov/31669546/>

2 <https://www.sciencedirect.com/science/article/pii/S2666776221000612?via%3Dihub>

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TFF PHARMACEUTICALS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Grant revenue	\$ 28,004	\$ 1,850	\$ 95,439	\$ 26,165
Operating expenses:				
Research and development	5,110,805	2,762,170	10,372,409	8,040,422
General and administrative	3,690,010	2,351,007	6,936,205	4,998,422
Total operating expenses	<u>8,800,815</u>	<u>5,113,177</u>	<u>17,308,614</u>	<u>13,038,844</u>
Loss from operations	(8,772,811)	(5,111,327)	(17,213,175)	(13,012,679)
Other income:				
Other income	20,606	441,546	77,783	672,824
Interest income	5,880	14,069	13,065	29,568
Total other income	<u>26,486</u>	<u>455,615</u>	<u>90,848</u>	<u>702,392</u>
Net loss	<u>\$ (8,746,325)</u>	<u>\$ (4,655,712)</u>	<u>\$ (17,122,327)</u>	<u>\$ (12,310,287)</u>
Net loss per share, basic and diluted	<u>\$ (0.34)</u>	<u>\$ (0.18)</u>	<u>\$ (0.67)</u>	<u>\$ (0.51)</u>
Weighted average common shares outstanding, basic and diluted	<u>25,373,706</u>	<u>25,369,144</u>	<u>25,372,749</u>	<u>24,261,032</u>

TFF PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	<u>June 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
	<u>(Unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 20,890,253	\$ 33,794,672
Receivable due from collaboration agreement	1,812,975	1,628,703
Research and development tax incentive receivable	994,549	966,646
Prepaid assets and other current assets	1,483,953	2,447,930
Total current assets	<u>25,181,730</u>	<u>38,837,951</u>
Operating lease right-of-use asset, net	232,138	-
Property and equipment, net	2,332,254	1,859,860
Other assets	167,077	-
Total assets	<u>\$ 27,913,199</u>	<u>\$ 40,697,811</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,480,461	\$ 1,493,842
Accrued compensation	-	416,910
Deferred research grant revenue	268,000	50,000
Current portion of operating lease liability	79,050	-
Total current liabilities	<u>3,827,511</u>	<u>1,960,752</u>
Operating lease liability, net of current portion	146,188	-
Total liabilities	<u>3,973,699</u>	<u>1,960,752</u>
Commitments and contingencies (see Note 4)		
Stockholders' equity:		
Common stock	25,374	25,372
Additional paid-in capital	106,461,934	104,078,968
Accumulated other comprehensive loss	(107,121)	(48,921)
Accumulated deficit	(82,440,687)	(65,318,360)
Total stockholders' equity	<u>23,939,500</u>	<u>38,737,059</u>
Total liabilities and stockholders' equity	<u>\$ 27,913,199</u>	<u>\$ 40,697,811</u>