TFF Pharmaceuticals Reports First Quarter 2022 Financial Results and Provides Business Update

May 11, 2022

Announced Collaboration with Catalent to Further Expand Thin Film Freezing Applications with a Focus on Biologic Drug Development

Announced Second CRADA Agreement with USAMRIID and Geneva Foundation
to Develop Novel Therapies Using Thin Film Freezing to Combat SARS-CoV-2, Ebola, and Marburg Viruses

Initiated Phase 2 Trials of Inhaled Voriconazole Powder and Inhaled Tacrolimus Powder With Interim Data for Each Program Expected Later in 2022

Significant Progress Made in Inhaled Niclosamide Powder Program

Multiple Abstracts Highlighting Applications of Thin Film Freezing Presented at Respiratory Drug Delivery (RDD) Meeting

Conference Call and Webcast Scheduled Today, Wednesday, May 11, 2022 at 4:30 PM ET

FORT WORTH, Texas, May 11, 2022 (GLOBE NEWSWIRE) -- 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 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, Wednesday, May 11, 2022, at 4:30 PM ET.

“During the first quarter, we made solid progress in expanding existing collaborations and forging new partnerships,” said Glenn Mattes, CEO of TFF Pharmaceuticals. “Most notably, we announced a strategic collaboration with Catalent that will enable their customers to gain access to our Thin Film Freezing technology, with an emphasis on applications in biologic drug development. We also expanded our activities with USAMRIID and the Geneva Foundation by signing a second CRADA agreement that will utilize our Thin Film Freezing technology to optimize the formulation of new, development-stage therapeutics aimed at combating exceptionally dangerous viruses, including SARS-CoV-2, Ebola, and Marburg. Based upon the robust pace of our ongoing partnering discussions, we remain confident that 2022 will see TFF pharmaceuticals enter into new collaborations while expanding many of our existing partnerships.

“With respect to our pipeline development, we made considerable progress across several programs during the quarter. We initiated Phase 2 studies for our Inhaled Voriconazole Powder and Inhaled Tacrolimus Powder, and we anticipate interim readouts for both trials later in the year. With each program having the potential to meaningfully advance the current standard of care in their respective indications, we believe positive readouts are likely to attract significant partnership interest.

The Inhaled Niclosamide Powder program has also made important progress. In April, we announced positive safety and pharmacokinetic data from a Phase 1 study, demonstrating that Niclosamide Inhalation Powder was well tolerated with no serious adverse events across all subject cohorts. We believe the Niclosamide program is yet another example of how Thin Film Freezing technology can be successfully applied in the clinic to deliver efficacious levels of drug more safely to patients.

“In early May, we were pleased to announce that Dr. Bill Williams, co-inventor of the Thin Film Freezing technology, and several of his colleagues from the University of Texas at Austin presented five abstracts at this year’s Respiratory Drug Delivery meeting related to applications of Thin Film Freezing. We believe this body of research underscores the unique and versatile nature of Thin Film Freezing technology and provides us with even more confidence that the pharmaceutical applications of our technology platform will only continue to grow over time.

“As our platform continues to expand, TFF is also making the appropriate level of investment to recruit exceptional talent to help manage this growth. During the quarter, we announced the appointment of Anthony Hickey, Ph.D. as Chief Scientific Officer and Brandi Roberts to our Board of Directors. We also made senior level appointments in key areas of our business, including product manufacturing, government and strategic initiatives, and regulatory affairs.

“The advancement of our internal pipeline candidates such as Inhaled Voriconazole and Tacrolimus Powder programs, coupled with the robust pace of ongoing partnering activity, strengthens our belief that our continued investment in Thin Film Freezing will translate into significant commercial success and value for our shareholders.”

Conference Call and Webcast Information

The Company will host a conference call today, Wednesday, May 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: 1-844-825-9789

International Dial-In Number: 1-412-317-5180

Conference ID: 10166801

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://viavid.webcasts.com/starthere.jsp?ei=1546904&tp_key=ca1cf4dc0b

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:

- **Board of Director Appointment:** In March, the Company announced the appointment of Brandi Roberts to the TFF Pharmaceuticals' Board of Directors. Ms. Roberts has over 25 years of public accounting and finance experience, including 22 years at publicly traded pharmaceutical, medical technology, and life science companies. Ms. Roberts has served as the Chief Financial Officer of Longboard Pharmaceuticals, Inc. since January 2021. Previously, Ms. Roberts served as Chief Financial Officer of Lineage Cell Therapeutics, Inc. from January 2019 to January 2021. Prior to joining Lineage, she served as Chief Financial Officer of REVA Medical, Inc. Ms. Roberts previously served as Chief Financial Officer of Mast Therapeutics, Inc. from January 2013 to April 2017, and as its Senior Vice President, Finance, from March 2011 to January 2013. Previously, she held senior positions at Alphatec Spine, Inc., Artes Medical, Inc., Stratagene Corporation, and Pfizer, Inc. Ms. Roberts currently serves as Chair of the Southern California Chapter of the Association of Bioscience Financial Officers and has served on the Board of Temple Therapeutics BV since November 2019. Ms. Roberts is a certified public accountant with the State of California and received her B.S. degree in business administration from the University of Arizona and her M.B.A. from the University of San Diego.

- **Appointment of Chief Scientific Officer:** In March, the Company announced the appointment of Anthony Hickey, Ph.D. as Chief Scientific Officer. Dr. Hickey is Professor Emeritus in Pharmacoengineering and Molecular Pharmaceutics at the Eshelman School of Pharmacy of the University of North Carolina at Chapel Hill. Dr. Hickey is also Adjunct Professor of biomedical engineering at the University of North Carolina (UNC) School of Medicine.

- **Expanded Leadership Team:** In March, the Company also announced the appointment of three additional seasoned executives to help lead the company:

    - **John Koleng, Ph.D., R.Ph. - Vice President of Product Development and Manufacturing**
      Dr. Koleng has more than 20 years of experience in the pharmaceutical industry. He was an executive with three drug development companies, Oticara, Via Therapeutics, and CloXero Therapeutics, and co-founded AlphaVektor, LLC and Axxis Innovations, Inc. John is an industry-recognized expert in drug development including nasal/pulmonary products and injectables. John previously served as a consultant to TFF and is an inventor on several patent applications filed on behalf of TFF. He has a B.S. in Pharmacy and a Ph.D. in Pharmaceutics, both from the University of Texas at Austin where he currently is an Adjunct Assistant Professor of Pharmaceutics and serves on the College of Pharmacy Dean's Advisory Council. He is a registered pharmacist.

    - **Greg J. Davenport, Ph.D**. - **Vice President of Government and Strategic Initiatives** Dr. Davenport brings over 28 years of pharmaceutical product development and government contracting experience as a C-Level Executive in the life sciences. Greg is a founding partner of Dport Federal Group, LLC, a consulting firm that assists various clients in the life science and pharmaceutical industries seeking to conduct business with the Federal Government. At TFF, Dr. Davenport oversees academic, government, and industry infectious disease and biodefense collaborations, while also pursuing non-dilutive funding to advance TFF's technology platform and products to address government and commercial needs. Greg earned a B.S. from Dillard University and received his Ph.D. in Molecular Biology from Howard University.

    - **Paul Manley** - **Head of Regulatory Affairs**
      Mr. Manley has accumulated 30+ years of business and senior management experience in regulatory affairs, compliance and overall drug development across a range of therapeutic areas. Paul's corporate career encompasses senior management and technical leadership positions within the U.S. and Europe in both large corporations (VP, Global Regulatory Affairs – Oncology, Johnson & Johnson) and start-ups (VP, Regulatory Affairs and Compliance, Genta Incorporated). In 2007, Paul established Orvieto Consulting, LLC, providing strategic advice to numerous companies across a wide range of scientific disciplines.

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

    - In May, the Company announced multiple presentations highlighting the broad applicability of its Thin Film Freezing Technology at the Respiratory Drug Delivery Meeting (RDD)

    - 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.

- In March, TFF entered into a collaboration agreement with Catalent focused on providing access to the innovative TFF technology to Catalent's large number of clients, which has the potential to increase the adoption of the pulmonary and nasal route for the systemic delivery of biotherapeutics. In addition, Catalent will become the CDMO of choice for these referred clients and Catalent will assume a priority position in collaborations using TFF's proprietary process for biologic drug manufacturing.

- In February, announced that results from its recently completed *in vitro* neutralization and viral replication assays indicate that the Niclosamide Inhalation Powder completely inhibited viral replication of both the Delta and Omicron variants of SARS-CoV-2. Compared to data from previously published studies, the results demonstrate that Niclosamide Inhalation Powder appears to be the most potent inhibitor of SARS-CoV-2 replication, including the Omicron variant. Results from these studies also confirm previous findings which validated the potent antiviral efficacy of Niclosamide in a human airway model.

  In January, announced the completion of enrollment of 40 healthy subjects for a Phase 1 clinical trial (NCT#05168644) of Niclosamide Inhalation Powder. The Company is developing Niclosamide Inhalation Powder in partnership with Union Therapeutics as a potential antiviral treatment to treat COVID-19 and other respiratory viral diseases.

- **Strategic Business Development and Partnership Activities – Governmental and Defense Contracting Agencies:**

  - In March, entered into a new Cooperative Research and Development Agreement with the United States Army Medical Research Institute of Infectious Diseases, also known as USAMRIID, and the Geneva Foundation, a nonprofit foundation that supports and advances innovative medical research within the U.S. Military. TFF Pharmaceuticals and USAMRIID will evaluate the immune response of a dry powder recombinant Vesicular Stomatitis Virus - Severe Acute Respiratory Syndrome Coronavirus-2 Glycoprotein vaccine formulated using TFF's Thin Film Freezing technology. The end goal is to develop a single, easily administered and temperature stable countermeasure to protect our warfighters against multiple viral pathogens such as SARS-CoV-2, Ebola, and Marburg.

Financial Results

For the quarter ended March 31, 2022, compared to quarter ended March 31, 2021

- Cash Position: As of March 31, 2022, TFF Pharmaceuticals reported cash and cash equivalents of $26.4 million.

- Research and Development (R&D) expenses: R&D expenses for first quarter of 2022 were $5.3 million, compared to $5.3 million in 2021.

- General & Administrative (G&A) expenses: G&A expenses for the first quarter of 2022 were $3.2 million, compared to $2.6 million in 2021.

- Net Loss: TFF Pharmaceuticals reported a net loss for the first quarter of 2022 of $8.4 million, compared to a net loss of $7.7 million in 2021.

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: Inhaled Voriconazole Powder and Inhaled Tacrolimus Powder. The Company plans to add to this pipeline by collaborating with large pharmaceutical partners. The TFF Platform is protected by over 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 and an Inhaled Niclosamide Powder for the treatment of COVID-19 infection, collaboration and

referral arrangement with Catalent, 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 or Niclosamide Powders or any of its dry powder product candidates, (ii) the risk that the Company may not achieve the favorable results expected from its collaboration and referral agreement with Catalent, ((iii) no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, (iv) the Company has no current agreements or understandings with any large pharmaceutical companies for the development of a drug product incorporating the TFF Platform, (v) the risk that the Company will not be able to conclude a long-term commercial agreement with any third-party, and (vi) 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.

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TFF PHARMACEUTICALS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Grant revenue	$ 67,435	$ 24,315
Operating expenses:		
Research and development	5,261,604	5,278,252
General and administrative	3,246,195	2,647,415
Total operating expenses	8,507,799	7,925,667
Loss from operations	(8,440,364)	(7,901,352)
Other income:		
Other income	57,177	231,278
Interest income	7,185	15,499
Total other income	64,362	246,777
Net loss	$ (8,376,002)	$ (7,654,575)
Net loss per share, basic and diluted	$ (0.33)	$ (0.33)
Weighted average common shares outstanding, basic and diluted	25,371,781	23,140,607

TFF PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2022	December 31, 2021

	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,414,170	$ 33,794,672
Receivable due from collaboration agreement	1,776,583	1,628,703
Research and development tax incentive receivable	1,168,830	966,646
Prepaid assets and other current assets	2,164,451	2,447,930
Total current assets	31,524,034	38,837,951
Property and equipment, net	2,258,738	1,859,860
Total assets	$ 33,782,772	$ 40,697,811
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,028,779	$ 1,493,842
Accrued compensation	-	416,910
Deferred research grant revenue	168,000	50,000
Total liabilities	2,196,779	1,960,752
Commitments and contingencies		
Stockholders' equity:		
Common stock	25,372	25,372
Additional paid-in capital	105,256,670	104,078,968
Accumulated other comprehensive loss	(1,687)	(48,921)
Accumulated deficit	(73,694,362)	(65,318,360)
Total stockholders' equity	31,585,993	38,737,059
Total liabilities and stockholders' equity	$ 33,782,772	$ 40,697,811

Source: TFF Pharmaceuticals, Inc.