TFF Pharmaceuticals Reports First Quarter 2021 Financial Results and Provides Business Update

May 13, 2021

Pivotal Trials to Begin in 2H-2021 for Voriconazole Inhalation Powder for the Treatment of Invasive Pulmonary Aspergillosis (IPA) and Tacrolimus Inhalation Powder for Immunosuppression in Solid Organ Transplantation

Patent Filed for Once-a-Day Dosing for Tacrolimus Inhalation Powder, Achieving Therapeutic Blood Levels with a Single Low Dose

Science Day to be Held in June to Highlight Thin Film Freezing Platform Technology

Conference Call and Live Webcast Scheduled Today, Thursday, May 13, 2021, at 4:30pm EDT

AUSTIN, Texas--(BUSINESS WIRE)--May 13, 2021-- 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, 2021, 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 13, 2021, at 4:30pm EDT.

“We continue to make progress with our clinical development programs: Voriconazole Inhalation Powder and Tacrolimus Inhalation Powder,” said Glenn Mattes, President and CEO of TFF Pharmaceuticals. “This progress, along with better-than-expected clinical data, will allow us to initiate clinical trials designed to achieve registration for both of these important programs by the end of 2021.”

“The data we have seen from our Tacrolimus Inhalation Powder trial suggests that we can achieve efficacious immunosuppressive blood levels of tacrolimus with an inhaled, once-a-day, low-dose formulation,” said Mattes. “We believe that inhaled tacrolimus’ ability to reduce the fluctuations of bioavailability offers a compelling advantage over oral tacrolimus, as physicians often attribute the peaks and troughs of oral delivery with suboptimal efficacy and exacerbated side effects.”

“We have filed a US patent based on this once-a-day dosing development, which could have major implications for lung transplant patients, and potentially for heart, kidney and liver transplant patients as well,” continued Mattes. “Based on our recent research, we believe the peak yearly sales of tacrolimus in all four indications could exceed $1 billion dollars.”

“This quarter, we’ve also made notable progress with a number of our strategic partners,” said Mattes. “Our collaborations with UNION therapeutics on niclosamide and Augmenta Bioworks on monoclonal antibodies are progressing on plan, and our partner in the cannabis space, PLUS Products, is seeing positive initial manufacturing data and strong market interest.

“Also, our scientific collaboration partners at the University of Texas at Austin generated meaningful new data that continues to demonstrate the advantages of our Thin Film Freezing platform over other competing technologies,” said Mattes. “This is true for both small molecule therapeutic applications, as well as high molecular weight biologics like proteins, including monoclonal antibodies, messenger RNA, and plasmid DNA, where our technology offers the only viable solution for dry powder reformulation.”

“To highlight these important scientific developments to as broad an audience as possible, we are pleased to announce that the Company will host a virtual Science Day in June,” said Mattes. “This event will provide a scientific perspective on our Thin Film Freezing platform technology from external scientific key opinion leaders.”

“The growing portfolio of business development partnerships and the pace of our clinical and scientific progress continued to be impressive during the quarter,” concluded Mattes. “This remains a testament to the outstanding efforts of our professionals, as well as the continued recognition that our technology can have game-changing consequences for the industry.”

Conference Call and Webcast Information

The Company will host a conference call today, Thursday, May 13, 2021, 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: 5777388

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/o4wvnbiv**. 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** In March, we announced the successful completion of the Phase 1 clinical trial and final

data for Voriconazole Inhalation Powder for the treatment of invasive pulmonary aspergillosis (IPA).

TFF demonstrated that doses of 10, 20, 40, and 80 mg could be delivered twice daily using a dry powder inhaler device with no significant adverse events. Evaluation of the pharmacokinetic profile of the Voriconazole Inhalation Powder demonstrated that mean peak plasma voriconazole levels reached concentrations of 227 ng/mL following repeated dosing at 80 mg twice daily for 7 days, without any reports of significant adverse events. Based on the results of the Phase 1 trial, the Company will study the 80 mg dose of Voriconazole Inhalation Powder for the upcoming pivotal trial where it will be compared to the oral form of voriconazole.

TFF has completed dosing in a GLP 13-week chronic toxicology study and has successfully completed the first of two dosing cohorts in asthma patients to evaluate safe dosing in patients with hyperreactive airways. There have been no serious adverse events reported in these cohorts. The Company is currently in active preparations for an end of Phase 1 meeting with the FDA, and we anticipate this meeting will be held after the dosing in this Phase 1b asthma study is complete. We then expect to initiate a pivotal clinical trial designed to demonstrate efficacy for treating patients with IPA or for preventing infection in patients at high risk for developing IPA infections.

- **Tacrolimus Inhalation Powder:** Enrollment in the final cohort of our Phase 1 study is ongoing and is expected to be completed shortly. Earlier in March, we announced the successful completion of the single ascending dose (SAD) portion of the Phase 1 study of Tacrolimus Inhalation Powder. In the SAD phase of the trial, we safely administered single doses of 0.5, 1.0, 2.5 and 5 mg to healthy normal volunteers. We had planned to dose an additional cohort of subjects at 10 mg, but cancelled this cohort after reaching efficacious dose levels below 10 mg. In the multiple ascending dose (MAD) part of the study, we dosed subjects in cohort 1 and 2 with twice daily doses of 0.5 and 1.0 mg over 7 days. These dose levels reached steady-state concentrations that are associated with effective immunosuppression. Of particular note, we dosed cohort-3 subjects with a single 1.5 mg dose each day for 7 days, and these subjects were able to reach efficacious immunosuppressive levels from once-a-day dosing with a low-dose concentration of inhaled tacrolimus.

  We have also completed a GLP 26-week chronic toxicology study that will be used to support registration, and we remain on track to begin the pivotal trial work designed to demonstrate efficacy of inhaled tacrolimus for the prevention of lung allograft rejection. The enhanced bioavailability of inhaled tacrolimus, coupled with its ability to bypass the gastrointestinal tract, could also result in expanded therapeutic applications into other solid organ transplants where significant drug-drug interactions and food effects are a factor.

- **Strategic Business Development and Partnership Activities – Governmental and defense contracting agencies:** In April, we announced that Leidos, a Fortune 500 information technology, engineering and science solutions and services leader, awarded the Company a subcontract to participate in the Personalized Protective Biosystems (PPB) Program to develop next-generation chemical and biological protection for U.S warfighters and stability operators. TFF Pharmaceuticals will utilize its Thin Film Freezing platform to formulate a series of countermeasures designed to neutralize chemical and biological agents at the site of vulnerable tissue barriers, including the skin, eyes and respiratory system.

  We continue to engage and collaborate with various government and defense contracting agencies in an effort to utilize the Company's TFF technology platform to formulate dry powder vaccines and therapeutics for delivery via reconstitution for lung or nasal inhalation. This includes our 3-year Cooperative Research and Development Agreement (CRADA) with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) for biodefense countermeasures, and our early-stage universal influenza work with the University of Georgia's Center for Vaccines and Immunology, part of the NIH's Collaborative Influenza Vaccine Innovation Centers (CIVICs).

  Strategic Business Development and Partnership Activities – Biopharmaceutical companies and research institutions: Under our worldwide licensing agreement with UNION therapeutics for thin film freezing technology used in combination with niclosamide, our oral and powdered niclosamide formulations are moving forward to first-in-human trials. Recent data from UNION suggests that niclosamide is effective against the new prevalent British B.1.1.7 and South African B.1.351 COVID-19 variants.

  "We are pleased with our ongoing collaboration with TFF Pharmaceuticals, and are happy to learn that the TFF niclosamide program is advancing through development," said Dr. Kim Kjøller, Chief Executive Officer of UNION therapeutics. "We share the desire to provide much-needed therapeutics to COVID-19 stricken patients across the patient continuum."

  In a second COVID-related collaboration, the worldwide joint venture between TFF and Augmenta Bioworks is now well underway. This innovative, first-of-its kind program will seek to apply our Thin Film Freezing technology to develop dry powder-based monoclonal antibodies targeting COVID-19.

"Our Joint Collaboration with TFF is right on track," said Christopher Emig, Ph.D., CEO and Co-founder of Augmenta Bioworks, Inc. "We are making great progress on our broadly neutralizing antibody therapy. We are looking forward to the results of our IND enabling studies and getting this much-needed therapeutic into the clinic as quickly as possible. Combining Augmenta's discovery capabilities with TFF's formulation and drug development expertise has been an incredibly fruitful partnership."

Cannabis Development and Commercialization: Our partner in the cannabis space, PLUS Products, has been producing thin film freezing formulations of cannabis and is planning to launch a new product based on this technology.

"The results on the preliminary manufacturing runs with the TFF technology have been even better than we had hoped," said Jake Heimark, CEO & Co-founder of PLUS Products. "And the concept research on dry powder inhalation with the retail distribution channels in California has created a high level of interest in the product category."

Public Offering: As announced previously on March 26, 2021, the Company closed on an underwritten offering of 2,140,000 shares of its common stock. Proceeds from the offering totaled approximately $30,000,000, before deducting underwriting discounts and other offering expenses. At the end of the quarter, with the net proceeds from this offering, the Company's liquidity included approximately $58.1 million in cash and cash equivalents.

Financial Results

For the three months ended March 31, 2021, compared to the prior year:

- **Research and Development (R&D) expenses:** R&D expenses for the first quarter of 2021 were $5.3 million, compared to $2.2 million for the same period in 2020.
- **General & Administrative (G&A) expenses:** G&A expenses for the first quarter of 2021 were $2.6 million, compared to $1.6 million for the same period of 2020.
- **Net Loss:** TFF Pharmaceuticals reported a net loss for the first quarter of 2021 of $7.7 million, compared to a net loss of $3.8 million for the same period of 2020.

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 Tacrolimus 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 various drugs, vaccines and biologics 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 dry powder versions of any drugs, vaccines or biologics, (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 2020 Annual Report on Form 10-K filed with the SEC on March 10, 2021. 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, 2021	Three Months Ended March 31, 2020
Grant revenue	$ 24,315	$ —
Operating expenses:		
Research and development	5,278,252	2,235,542
General and administrative	2,647,415	1,617,924
Total operating expenses	7,925,667	3,853,466
Loss from operations	(7,901,352)	(3,853,466)
Other income:		
Other income	231,278	—
Interest income	15,499	56,268
Total other income	246,777	56,268
Net loss	$ (7,654,575)	$ (3,797,198)
Net loss per share, basic and diluted	$ (0.33)	$ (0.20)
Weighted average common shares outstanding, basic and diluted	23,140,607	19,008,611

TFF PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 58,055,122	$ 35,300,805
Prepaid assets and other current assets	1,721,184	2,258,229
Total current assets	59,776,306	37,559,034
Property and equipment, net	1,577,441	1,102,808
Total assets	$ 61,353,747	$ 38,661,842
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,817,034	$ 1,297,725
Deferred research grant revenue	—	24,315
Total liabilities	1,817,034	1,322,040
Commitments and contingencies		
Stockholders' equity:		
Common stock	25,364	22,535
Additional paid-in capital	101,535,068	71,648,453
Accumulated other comprehensive loss	(89,496)	(51,538)
Accumulated deficit	(41,934,223)	(34,279,648)
Total stockholders' equity	59,536,713	37,339,802
Total liabilities and stockholders' equity	$ 61,353,747	$ 38,661,842

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