# TFF Pharmaceuticals Reports Fourth Quarter and Full Year 2020 Financial and Business Results

March 10, 2021

*Reports positive Phase 1 study results for Voriconazole Inhalation Powder and Tacrolimus Inhalation Powder*

*Awarded subcontract license by U.S. government agency to formulate biologic countermeasures to be used by the U.S. military*

*Announces feasibility agreements with Greenlight Biosciences for Covid-19 mRNA Vaccine Reformulation and NeuroRx for Covid-19 therapeutic for critically ill patients*

*Conference call and live webcast scheduled today, Wednesday, March 10, 2021 at 4:30pm EST*

AUSTIN, Texas--(BUSINESS WIRE)--Mar. 10, 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 fourth quarter and full year ended December 31, 2020, 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, Wednesday, March 10, 2021 at 4:30pm EST.

“2020 was a remarkable year of accomplishment and building momentum for TFF Pharmaceuticals, due to success in achieving key milestones in our two-pronged business model of internal development of high-value, high-need therapeutics, combined with a focused and aggressive approach to seek out partners, licensees and collaborators for our breakthrough Thin Film Freezing platform technology,” said Glenn Mattes, President and CEO of TFF Pharmaceuticals.

“Our internal development programs are progressing ahead of expectations, as we are seeing very positive clinical results in both Phase 1 trials for our Voriconazole Inhalation Powder program, to treat the severe and life-threatening disease of Invasive Pulmonary Aspergillosis, as well as for our Tacrolimus dry-powder program for the prevention of lung transplant rejection.”

“Final data for our Voriconazole product, the first-ever clinical study of a direct-to-lung, Thin Film Freezing (TFF) dry-powder formulation, resulted in blood levels greater than two-fold higher than those shown to clear complex IPA infections, with no significant adverse events,” said Mattes. “And our Tacrolimus product was able to reach therapeutic blood levels of 5-16 ng/mL in all patients from a single inhaled dose of 5 mg of our reformulated Inhalation Powder, without significant adverse events. Both these very significant results bode well for our upcoming pivotal trials for these drugs, which address large markets with unmet needs.”

“We are also honored to announce today a strategically important contract for the Company with a major government research agency to formulate dry powder versions of a suite of biological countermeasures that is intended for use by our nation’s military forces,” continued Mattes. “This is another meaningful event for TFF as we continue to build our portfolio of development agreements with pharmaceutical companies, the government and academia. We look forward to providing more details on this contract pending security review and approval of further news distribution from the government and the prime contractor.”

“And our ubiquitous and disruptive Thin Film Freezing technology continues to garner considerable attention from potential industry partners,” said Mattes. “With the potential to mitigate the need for cold chain storage and distribution of vaccines, as well as the first-of-its-kind capability to reformulate large, complex biologic molecules, thin film freezing has generated strong interest from biotechnology companies, as well as some of the largest developers of vaccines and anti-virals.”

“This is evident by the recent feasibility collaborations by GreenLight Biosciences, a pioneering mRNA company, to reformulate their mRNA Covid-19 vaccine candidate, and by NeuroRx, to reformulate their product candidate, ZYESAMI, a therapeutic for seriously ill Covid-19 patients,” said Mattes. “The interest from these two companies, among many others, demonstrates the growing recognition that our technology can dramatically advance potential vaccines and therapeutics.”

“Our progress this year has firmly solidified the enormous potential on our Thin Film Freezing technology to the vaccine, biotechnology and drug development communities,” concluded Mattes. “The breakthrough and disruptive capabilities of our platform technology, and our ability to leverage this across both internal development programs and external business development opportunities has helped expand the depth of our business and will continue to fuel our future growth.”

**Conference Call and Webcast Information**

The Company will host a conference call today, Wednesday, March 10, 2021, at 4:30 pm, Eastern Standard 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: (877) 784-1702
International Dial-In Number (857) 770-0110
Conference ID: 9195779

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/ev6cv5ub** . 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 2021, 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), an inhaled dry powder version of voriconazole.

  Through completion of the Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) cohorts, 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. There was no evidence of treatment-related or dose-related trends in the reporting of treatment emergent adverse events, throughout the study. No subjects experienced any dose limiting toxicity events during the study.

  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.

- **Tacrolimus Inhalation Powder:** In March 2021, we also announced the successful dosing completion in the Single Ascending Dose portion of the Phase 1 study of Tacrolimus Inhalation Powder and that the Multiple Ascending Dose portion is progressing. The SAD portion of the study indicated that TFF's Tacrolimus Inhalation Powder was able to reach therapeutic blood levels of 5-16 ng/mL in all patients from a single inhaled dose of 5 mg of Tacrolimus Inhalation Powder, without significant adverse events.

  The ability to reach therapeutic blood levels efficiently, with low doses of the inhaled powder, suggests that Tacrolimus Inhalation Powder may have application beyond lung transplant, potentially in heart, kidney and liver transplant patients.

- **Strategic Business Development and Partnership Activities – Governmental and defense contracting agencies:** TFF has been awarded a subcontract license by a U.S. government research agency to formulate dry powder versions of biologic countermeasures products to be used by the U.S. military. Our technology will be used to develop topical, ophthalmic and inhaled products, and as a result of this contract, TFF has been designated as an approved subcontractor vendor, which will facilitate additional work with the government. TFF will provide greater detail on the program pending security review approvals of further news distribution from the U.S. government and our prime contractor partner.

  In April of 2020, TFF Pharmaceuticals and USAMRIID, the U.S. Army's premier institution and facility for defensive research into countermeasures against biological warfare, entered into a 3-year Cooperative Research and Development Agreement (CRADA) to investigate Thin Film Freeze Drying of various biodefense countermeasures as needle-free, inhaled treatments that are temperature-insensitive.

  The first two countermeasures, a monoclonal antibody (mAbs) against Ebolavirus Zaire (EBOV) and a recombinant vesicular stomatitis virus (rVSV) vaccine candidate against Venezuelan equine encephalitis virus (VEEV), were TFFD formulated and tested for efficacy in a well-established in vitro neutralization assay. Data showed that the activity of the mAbs and rVSV vaccines were preserved after TFFD. Formulation optimization and long-term stability testing are ongoing and our next steps will be in vivo testing in appropriate animal models.

  TFF continues to engage and collaborate with various government and defense contracting agencies in an effort to utilize the Company's TFFD technology platform to formulate dry powder vaccines and therapeutics for delivery via reconstitution, or for lung or nasal inhalation.

- **Strategic Business Development and Partnership Activities – Biopharmaceutical companies and research institutions:** TFF recently announced a feasibility and material transfer agreement to evaluate a dry powder formulation of an early-stage Covid-19 mRNA vaccine candidate for Greenlight Biosciences. The goal of this feasibility work is to formulate and identify an optimal formulation of the Greenlight Biosciences mRNA product candidate in a dry powder form, which has superior stability as a dry powder, maintains the particle size of the mRNA, maintains a high encapsulation efficiency and has rapid reconstitution characteristics for injection.

  TFF also entered into a feasibility and material transfer agreement with NeuroRx to determine the compatibility of NeuroRx's ZYESAMI™ (aviptadil, previously RLF-100™) as a dry powder formulation using TFF's thin-film freezing technology. TFF intends to formulate and identify an optimal formulation of ZYESAMI in a dry powder form, with the goal of

providing superior aerosol properties for delivery directly to the lungs. ZYESAMI is a recombinant form of a naturally occurring peptide found in the lung called Vasoactive Intestinal Peptide (VIP), which has been found to have potent anti-inflammatory/anti-cytokine activity in animal models of respiratory distress, acute lung injury, and inflammation. The ability to deliver this drug directly to the lung via inhalation could have important therapeutic implications and potentially broaden the application of the drug to patients less severely affected with Covid-19.

In 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.

Our relationship with Felix Biotechnology is on track as we are working with their lead bacteriophage product for inhalation delivery directly to the lungs of patients. And our work with Augmenta Bioworks is on track as well. Our partnered lead monoclonal antibody product, targeting Covid-19 is scheduled to begin human trials later this year.

In April of 2020, TFF and the University of Georgia's  Center for Vaccines and Immunology entered into a research and development agreement to test the immunogenicity and efficacy of universal influenza hemagglutinin (HA) recombinant vaccines following the TFF process. In late 2020, we announced positive preclinical immunogenicity and efficacy data from TFF formulated UGA universal Influenza HA recombinant vaccines. Animals were vaccinated with HA vaccines with or without adjuvants and challenged with H1N1 and H3N2 influenza viruses. The TFF HA vaccines elicited equivalent neutralizing antibodies and protection against influenza virus infection compared to liquid formulations.

These results provide further evidence that Thin Film Freezing can convert liquid forms of vaccines that require cold chain storage into a much more stable dry powder form for ultimate use.

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.

- **CBD Development and Commercialization:** Our partner in the cannabinoid space, PLUS Products, is now producing thin film freezing formulations of cannabinoids and is planning to launch a new product based on this technology toward the end of the second quarter of 2021.

**Financial Results**

**For the year ended December 31, 2020, compared to 2019**

- **Cash Position:** As of December 31, 2020, TFF Pharmaceuticals reported cash and cash equivalents of $35.3 million.
- **Research and Development (R&D) expenses:** R&D expenses for 2020 were $10.7 million, compared to $8.8 million in 2019.
- **General & Administrative (G&A) expenses:** G&A expenses for 2020 were $8.0 million, compared to $3.2 million in 2019.
- **Net Loss:** TFF Pharmaceuticals reported a net loss for 2020 of $18.6 million, compared to a net loss of $11.9 million in 2019.

**For the three months ended December 31, 2020, compared to the prior year**

- **Research and Development (R&D) expenses:** R&D expenses for the fourth quarter of 2020 were $3.1 million, compared to $3.3 million for the same period in 2019.
- **General & Administrative (G&A) expenses:** G&A expenses for the fourth quarter of 2020 were $2.9 million, compared to $1.4 million for the same period of 2019.
- **Net Loss:** TFF Pharmaceuticals reported a net loss for the fourth quarter of 2020 of $5.9 million, compared to a net loss of $4.7 million for the same period of 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 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 STATEMENTS OF OPERATIONS**

| | Three Months Ended December 31, 2020 | Three Months Ended December 31, 2019 | Year Ended December 31, 2020 | Year Ended December 31, 2019 |
|---|---|---|---|---|
| Operating expenses | | | | |
| Research and development | $ 3,054,583 | $ 3,268,180 | $ 10,681,565 | $ 8,822,226 |
| General and administrative | 2,864,446 | 1,443,640 | 8,012,085 | 3,165,331 |
| Total operating expenses | 5,919,029 | 4,711,820 | 18,693,650 | 11,987,557 |
| Loss from operations | (5,919,029) | (4,711,820) | (18,693,650) | (11,987,557) |
| Other income | | | | |
| Interest income | 23,607 | 49,630 | 126,416 | 117,329 |
| Total other income | 23,607 | 49,630 | 126,416 | 117,329 |
| Net loss | (5,895,422) | (4,662,190) | (18,567,234) | (11,870,228) |
| Preferred stock dividend | — | (106,483) | — | (875,359) |
| 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 | $ (0.26) | $ (2.00) | $ (0.91) | $ (5.31) |
| Weighted average common shares outstanding, basic and diluted | 22,759,329 | 14,338,249 | 20,425,162 | 6,904,983 |

**TFF PHARMACEUTICALS, INC.**
**CONDENSED BALANCE SHEETS**

| | As of December 31, 2020 | As of December 31, 2019 |
|---|---|---|
| **Assets** | **(Unaudited)** | **(Unaudited)** |
| **Current Assets** | | |
| Cash and cash equivalents | $ 35,300,805 | $ 28,094,936 |
| Prepaid assets and other current assets | 2,258,229 | 1,092,462 |
| Total Current Assets | 37,559,034 | 29,187,398 |
| **Property and equipment, net** | 1,102,808 | — |
| **Total Assets** | $ 38,661,842 | $ 29,187,398 |
| **Liabilities and Stockholders' Equity** | | |
| **Current Liabilities** | | |
| Accounts payable | $ 1,297,725 | $ 410,638 |
| Deferred research grant revenue | 24,315 | — |

| | | |
|---|---|---|
| **Total Current Liabilities** | 1,322,040 | 410,638 |
| Accrued research and development expense | — | 1,132,013 |
| **Total Liabilities** | 1,322,040 | 1,542,651 |
| **Stockholders' Equity:** | | |
| Common stock, $0.001 par value, 45,000,000 shares authorized; 22,534,874 and 18,450,992 shares issued and outstanding as of December 31, 2020 and 2019, respectively | 22,535 | 18,451 |
| **Additional paid-in capital** | 71,648,453 | 43,338,710 |
| **Accumulated other comprehensive loss** | (51,538) | — |
| **Accumulated deficit** | (34,279,648) | (15,712,414) |
| **Total Stockholders' Equity** | 37,339,802 | 27,644,747 |
| **Total Liabilities and Stockholders' Equity** | $ 38,661,842 | $ 29,187,398 |

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