

Advanced Technology for Better Drug Delivery Options



Corporate Investor Presentation

SAFE HARBOR STATEMENT

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements concerning TFF Pharmaceuticals, Inc. ("TFF", the "Company," "we," "us," and "our"). The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements concerning the following:

- our future financial and operating results;
- our intentions, expectations and beliefs regarding anticipated growth, market penetration and trends in our business;
- the timing and success of our plan of commercialization;
- our ability to successfully develop and clinically test our product candidates; and
- our ability to file for FDA approval of our product candidates through the 505(b)(2) regulatory pathway.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially. Among those factors are: (i) no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, (ii) 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 (iii) those other risks disclosed in the section "Risk Factors" included in the Company's 2019 Annual Report on Form 10-K filed March 26, 2020 with the SEC. 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.

This document contains only basic information concerning TFF. Because it is a summary it does not contain all of the information you should consider before investing. Please refer to our reports and registration statements on file with the SEC for more comprehensive information concerning TFF Pharmaceuticals.





COMPANY OVERVIEW

- The company's Thin Film Freezing platform converts poorly absorbed drugs into inhalable dry powder formulations, targeting multiple \$Billion-plus markets
- Expects two NDA filings within 24 months at a clinical and development cost of approx. \$27MM
- CEO Glenn Mattes experienced pharma industry executive (Centocor, Johnson & Johnson, Rhone-Poulenc Rorer)
- Three product candidates under development and in the clinic
- Three strategic transactions completed
- Multiple business development opportunities underway
- Robust IP estate including 42 patents issued and/or pending

TFF LEADERSHIP



GLENN MATTES

President & Chief Executive Officer

- 30 years of business leadership experience in development and commercial launches of global therapeutics
- Former CEO of Tibotec Therapeutics, a J&J company, and Rhone-Poulenc Rorer/Canada, and in addition to other senior C-suite positions at Centocor and J&J
- Critical roles in launch of J&J's first two HIV/AIDS therapeutics, as well as other drugs Doxil, Procrit, Remicade, Taxotere and Lovenox
- Appointed to the President's Advisory Council on HIV/AIDS by President George W. Bush and the US Secretary of Health and Human Services

BOARD OF DIRECTORS

Highly experienced healthcare and life science finance executives

- Former CEOs, Institutional fund founder and Board-level roles
- Deep functional experience in all areas of healthcare companies
- Commercially successful enterprises
- Track record of numerous significant exits and transactions



THIN FILM FREEZING



A REVOLUTIONARY PLATFORM FOR ENABLING INHALABLE DRUGS

Industry-validated, peer-reviewed and scalable platform

- Platform has been tested in a clinical setting
 - Voriconazole Inhalation Powder Phase 1 trial completed
 - Tacrolimus Inhalation Powder Phase 1 trial underway
- More than two dozen finished formulations of high-value drugs, both small molecules & biologics
- TFF Pharmaceuticals is manufacturing drugs for clinical studies using GMP standards
- Strong IP portfolio: TFF process, multiple drug opportunities, internally-developed products
- Orphan-drug designation for Tacrolimus Inhalation Powder
- Pursuing ODD for Voriconazole Inhalation Powder



THIN FILM FREEZING

A REVOLUTIONARY TECHNOLOGY FOR ENABLING INHALABLE DRUGS

Two NDA filings expected within 24 months

Initial NDA Filing (TFF VORI)

• Expected in 20 months via 505(b)(2) pathway

Second NDA Filing (TFF TAC)

• Expected in 24 months via 505(b)(2) pathway

Successful Drug Re-formulation Work Completed

- TFF Niclosamide
- remdesivir

Business Development

 Broad array of TFF platform applications and partnership opportunities



TFF BRITTLE MATRIX PROCESS and POWDERS





TFF PLATFORM ADVANTAGES



	TFF	SPRAYDRYING	SPRAYFREEZE DRYING	NANO-MILLING		
POTENTIAL TO PREVENT MOLECULAR DAMAGE:						
THERMAL DEGRADATION	YES	NO	YES	YES		
SHEAR STRESS	YES	YES	YES	NO		
AIR/WATER DENATURATION	YES	NO	NO	YES		
SUITABILITY FOR DRY POWDER INHALERS:						
TECHNOLOGY DIFFERENTIATORS	•NANOAGGREGATE PARTICLES (HIGHER ABSORPTION) •HIGHER YIELD •UNIFORM PARTICLE SIZE •GENTLE PROCESSING (GOOD FOR LABILE MOLECULES)	• MICROPARTICLES • LOWER YIELD • HARDER PROCESSING CON- DITIONS	• MICROPARTICLES • LOWER YIELD • VARIABLE PARTICLE SIZE (NOT SUITABLE FOR DP) • CANNOT HANDLE VISCOUS SOLUTIONS	• MICROPARTICLES • CAN RESULT IN CRYSTALLLINE (INSOLUBLE IN THE LUNG) • HARSH PROCESSING CONDITIONS		

GMP MANUFACTURING READINESS

- TFF under contract with CoreRx and IriSys to manufacture nonclinical and clinical trial supplies for VORI and TAC. CoreRx has capacity to support long-term commercial supplies. Third CRO, Experic, to install Thin Film Freezing GMP processing line and specialized associated capabilities.
- TFF process scale currently in place to support material needs through Phase 2 clinical trials. Development capability at UT Austin continues to function well to support business development opportunities and product scouting.
- Work underway to identify equipment and vendors to encapsulate TFF powders at increased speed and scale to support increasing clinical supply needs and registration/early commercial requirements.
- TFF scale up underway at IriSys to support 6-month GLP studies.



TFF BUSINESS MODEL

A TWO-PRONGED STRATEGY FOR LEVERAGING TFF FORMULATIONS AND MAXIMIZING VALUE

IN-HOUSE DEVELOPMENT

- TFF VORI for IPA/ABPA
- TFF TAC for lung transplant and severe asthma
- TFF Niclosamide in early formulation development
- Monoclonal antibodies for COVID-19 (w/Augmenta Bioworks)

PHARMA LICENSING PLATFORM

- Pursue R&D collaborations to provide direct-to-lung, intranasal, topical and intra-ocular delivery for oncology, COPD, PAH, CF, biologics, and combinations in multiple therapeutic indications
- Enhance large pharma's patent position and breadth of formulation on marketed drugs and new chemical entities
- Compelling indications include insomnia, migraines, PAH, vaccines, cannabinoids and other products/platforms
- Thin Film Freezing will have a disruptive impact on biologics, vaccines, cannabinoids and other products/ platforms

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VORICONAZOLE INHALATION POWDER TARGET INDICATIONS

Voriconazole Inhalation Powder Target Indications:

Voriconazole Inhalation Powder is an azole antifungal being developed for the treatment of adults and pediatric patients 2 years-of-age and older with:

- Invasive Pulmonary Aspergillosis (IPA)
- Allergic Bronchopulmonary Aspergillosis (ABPA)





TFF VORI

Well tolerated, 3X better survival in pre-clinical testing

- Advantages over alternatives: Reduced side effects; direct to site of infection
- Alternatives: Oral and IV Amphotericin, Voriconazole and other Azoles, Candins

• Markets:

- Antifungal sales topped \$4B¹. However, an inhaled voriconazole for ABPA and unmet medical needs could achieve blockbuster status
- Market: IPA* 40K US annually representing >\$300MM⁴ opportunity, ABPA - \$1B annually⁴
- Proof of Concept: For IPA, 3X better animal survival vs. Amphotericin in preclinical animal testing
- Phase I trials complete, Phase II underway
- Safety: Phase I top-line data indicate that dosages up to 80mg twice daily showed no signs of the clinically significant hepatic or visual toxicities previously reported for the oral or intravenous forms
- Approximately \$11MM to get to an NDA filing by Q1 2022



TACROLIMUS INHALATION POWDER TARGET INDICATION

Tacrolimus Inhalation Powder Target Indication:

Either alone or in combination, Tacrolimus Inhalation Powder is being developed for the prophylaxis of organ rejection in patients receiving lung transplants.





TFF TAC

Already shown to be safe in healthy humans

- Advantages over alternatives: Reduced side effects; direct to site
- Alternatives: Oral and IV immunosuppressants
- Markets:
 - Lung Transplant addressable market: >\$1B⁵*
 - Severe Asthma >\$1B⁶ annually, growing to \$5.3B⁶ by 2023
- Safety:
 - Successfully completed single ascending dosing of four cohorts of healthy subjects in Phase 1 trial
 - Well tolerated with no reports of clinically significant drugassociated adverse events
 - Single dose provides substantial systemic blood levels that approach levels associated with effective immunosuppression in heart, lung, kidney and liver transplant patients.
- Proof of Concept:
 - Rat lung transplant, asthma, Peer-reviewed study
- Approximately \$15MM to get to an NDA filing by Q2 2022



TFF VORI AND TFF TAC SALES WORLDWIDE

TFF VORI*

- \$160MM in potential net peak sales worldwide
- Assuming acute IPA penetration of 18%; at risk penetration 2%

TFF TAC*

- \$400MM in potential net peak sales worldwide
- Assuming 27% penetration

MARKET ACCESS CONSIDERATION

Once TFF VORI and TFF TAC demonstrate a safety advantage, payer respondents said they would be covered no matter the cost.



*Forecasted



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UNDER CONSIDERATION FOR POTENTIAL DEVELOPMENT BY TFF

Vaccines	New Chemical Entities (NCEs)	Partnerships focused on Platforms	Government/ Academic partnerships	Botanicals
Reformulation & development of new vaccines TFF has ongoing discussions with multiple global pharma companies to test their proprietary compounds in the TFF technology platform.	Currently Evaluating: • PAH Potential Others: • COPD treatments • CF treatments • Respiratory distress syndrome	mRNA sRNA Macrophage Evaluating: • AAT for AAT deficiency Other potentials: • Migraine • Insomnia • Parkinson's	CRADA agreement with USAMARID to formulate dry powder neutralizing antibodies and vaccines against national priority biodefense threats R&D collaboration with the University of Georgia using TFF platform for a dry powder Universal Influenza Vaccine	Thin Film Freezing technology can effectively convert these compounds into a dry powder inhalation form, which can result in a rapid onset of action, with peak blood levels in minutes and with very positive bioavailability and absorption attributes



R&D to evaluate Thin Film Freezing technology to formulate dry powder universal influenza vaccines for pulmonary delivery with one of the world's leading research institution in vaccine development

- Collaboration between TFF, UT Austin and University of Georgia's world renowned Center for Vaccines and Immunology (CVI), lead by Ted Ross, Ph.D., Professor of Infectious Diseases at UGA.
- UT Austin will formulate hemagglutinin (HA) and neuraminidase (NA) proteins, with and without adjuvant, using the Company's Thin Film Freezing technology.



- Univ. of Georgia CVI will evaluate these TFF-formulated compounds to elicit broadly reactive immune responses and potentially provide longer-lasting protection against a wider variety of influenza viruses.
- Thin film freezing these compounds may allow them to be combined more readily into a dry powder, be shelf stable, and be delivered via lung or nasal inhalation.

National Priority Biodefense Vaccines -

Cooperative Research and Development Agreement (CRADA) with nation's top biodefense lab on dry powder vaccines for several of the world's deadliest viruses including Ebola, Marburg and a number of Alphaviruses

- 3-year collaboration between TFF and US Army to investigate Thin Film Freezing to formulate two different countermeasures, a monoclonal antibody against Alphaviruses (e.g. Venezuelan, Western, and Eastern equine encephalitis viruses) and a vesicular stomatitis virus vaccine against Filoviruses (e.g. Ebola, Marburg).
- Lead by Dr. John Dye, USAMRIID's chief of viral immunology, one of the scientists responsible for the development of the Ebola vaccine.
- The development of biodefense countermeasures that are potentially more easily administered via a pulmonary or intranasal route, and are temperature stable, could be an important advantage in environmentally hostile combat situations.







Monoclonal Antibodies for COVID-19

Worldwide Joint Development Agreement for COVID-19 monoclonal antibody therapies with Augmenta Bioworks. Collaboration on first-of-its-kind uses of Thin Film Freezing technology applied to monoclonal antibodies

- Joint Development Project to develop one or more commercial therapeutics based on, derived from, and/or incorporating Augmenta's human monoclonal antibodies to potentially treat patients with COVID-19. 50-50 split of all costs and expenses, and 50-50 split of all revenues, cash payments and/or future cash payments.
- Utilizing TFF Pharmaceuticals' Thin-Film Freezing technology to manufacture dry powder formulations of these specific mAbs for inhalation delivery directly to the lungs of patients, and parenteral administration.







Letter of Intent for a Collaboration, Development and License Agreement. Felix Biotechnology would obtain worldwide license for Thin Film Freezing technology to develop a novel, bacteriophage-based biotherapeutic

- Under proposed CDLA agreement, Felix Biotechnology would obtain a worldwide license to Thin Film Freezing technology to develop and manufacture dry powder formulations of a novel, bacteriophage-based biotherapeutics for inhalation delivery directly to the lungs.
- In exchange for TFF technology license, Felix would agree to pay TFF Pharmaceuticals an upfront payment, development milestones, commercial milestones worth up to \$281 million, along with royalties on net sales of the Felix biotherapeutics.
- Reformulation of these unique, complex biologics using TFF technology is a first-of-its-kind breakthrough for a potentially more effective and targeted delivery mechanism to the deep lung of patients.





Leveraging existing drugs with known safety profiles and reformulating using Thin Film Freezing for optimum delivery and adsorption

- TFF Pharmaceuticals and UT Austin researchers using Thin Film Freezing technology to reformulate *niclosamide* to be inhaled directly into the lungs.
- Niclosamide (used since the 1960's) is more potent when compared with other drugs such as *chloroquine*, *lopinavir* and *remdesivir* because of its activity as an antiviral drug. But it is poorly absorbable when delivered orally.



- TFF-developed inhaled forms of *niclosamide* delivered directly to the COVID-19 lung infection site could be an effective prevention strategy and provide additional treatment options.
- TFF is performing an exhaustive exercise reviewing drugs previously approved by the FDA that may be repurposed to combat the novel coronavirus behind the COVID-19 pandemic.

CANNABIS MARKET OPPORTUNITY

To develop a THC/CBD inhalation product without carriers or ingredients associated with vaping lung injury, with a high consumer satisfaction experience, rapid onset of activity and consistent delivery

- Utilizing its Thin Film Freezing (TFF) technology, TFF Pharmaceuticals can generate dry powder inhaled versions of cannabinoids with lung friendly ingredients.
- TFF cannabinoid powders do not rely on the use of oils or liquid carriers to deliver the dose. Inhalation of the powder is achieved with a reusable passive dry powder inhaler device that does not require batteries or charging.
- With delivery directly to the lungs as a powder prepared using the TFF technology, the inhaled powder exhibits a rapid onset of action from a discreet inhalation.
- The TFF technology is a potential "game changer."







KEY TAKEAWAYS

- Revolutionary platform for enabling inhalable drugs
- Multiple \$Billion-plus markets
- GMP manufacturing established for clinical trials with leading CMO partners
- Accelerated 505(b)(2) regulatory pathway
- Two NDA filings for approximately \$27MM clinical cost
- Broad array of business development initiatives
- Proven team, multiple significant exits
- Strong patent portfolio: TFF process, drug opportunities, new IP development

ENDNOTES



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 Antifungal Market Growth-2013. Global Data Research Report <u>https://www.globaldata.com/</u> (last accessed February 15, 2019).

TFF Pharmaceuticals Estimates Q1 2019

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- COPD Market Growth 2017. Global Data Research Report <u>https://www.globaldata.com/</u> (last accessed February 22, 2019).
- 4. APBA Annual Market Growth, TFF Pharmaceuticals Estimates Q1 2019.
- 5. Lung Transplant Addressable Market Growth, TFF Pharmaceuticals Estimates Q1 2019.
- Severe Asthma Market Growth 2015. Global Data Research Report <u>https://www.globaldata.com/</u> (last accessed February 20, 2019).

TFF Pharmaceuticals Estimates Q1 2019

IMAGE CITATION:

Slide 6 – CHEST, Volume 144, Issue 4, Table of Contents, October 2013.

Article Title, "Safety and Tolerability of Single Dose Inhaled Dry Powder Tacrolimus in Healthy Subjects"



THANK YOU