

Corporate Investor Presentation February 2024

BETTER DELIVERY, BETTER THERAPY | Powerful Drug Delivery Solutions



Safe Harbor Statement

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements concerning TFF Pharmaceuticals, Inc. ("TFF", "TFF Pharmaceuticals", 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:

- the expected reception of the initial data readouts for TFF VORI and TFF TAC and the ability of such data to support a decision to move to Phase 3 clinical trials for either TFF VORI or TFF TAC;
- the expectation that the initial data readouts for TFF VORI and TFF TAC will be consistent with the final data from the completed Phase 2 clinical trials and related Expanded Access Programs for TFF VORI and TFF TAC;
- the success of our clinical trials;
- 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) the risk that the final data from the completed Phase 2 clinical trials and related Expanded Access Programs for TFF VORI and TFF TAC will not be consistent with the initial data initial data readouts for TFF VORI and TFF TAC, (ii) the risk that the Company may not be able to successfully conclude clinical testing of TFF VORI, TFF TAC or any of its other dry powder product candidates, (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) success in early phases of pre-clinical and clinicals trials do not ensure later clinical trials will be successful, (vi) the risk that the Company may not be able to obtain additional working capital as and when needed and (vii) those other risks disclosed in the section "Risk Factors" included in the Company's Quarterly Report on Form 10-Q filed with the SEC on November 14, 2023. 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.



Investment Highlights

Proprietary Lung Drug Delivery Process	 Thin Film Freezing (TFF) is a unique, patented technology with proven ability to convert a wide range of poorly water-soluble drugs into inhalable dry powder formulations Robust IP estate with over 170 patents issued or pending
Strong Internal Pipeline	 TFF VORI (inhaled voriconazole dry powder) for invasive pulmonary aspergillosis: driving efficacy, minimizing systemic toxicities and drug-drug interactions TFF TAC (inhaled tacrolimus dry powder) for lung transplantation: decreasing rejection, minimizing systemic toxicities and drug-drug interactions Both programs qualify for 505(b)2 pathway
Positive Initial Clinical Data	 Recent data supports Company moving into Phase 3 Favorable efficacy, safety and tolerability in both programs
Broadly Applicable Platform	 Created dry powder formulations for a variety of small and large molecules Significant number of collaborations in place



Lower efficacy, Higher adverse events



Higher efficacy, Lower adverse events



Thin Film Freezing Process

Bulk drug material



Proprietary freezing process

- Use proprietary combination of freezing rate and liquid surface to volume ratio
- Confers advantages in engineering particles for various routes of administration
- Stabilizes biologics not achievable with other process technologies

Drying and lyophilization



Brittle matrix powder





TFF Platform Advantages

Compared to spray drying and spray freeze drying, which may result in larger particles, lower yield, variable particle sizes, and require harsher processing conditions, the TFF platform advantages include:

Potential to prevent molecular damage from

- Thermal degradation
- Shear Stress
- Air/Water Denaturation

Suitability for dry powder inhalers

- Nanoaggregate particles (better absorption)
- Higher yield
- Uniform particle size
- Gentle processing (good for labile molecules)

TFF technology enables the generation of dry powder formulations optimized for inhalational delivery via an easy-to-use dry powder inhaler



Delivering Value with Internal Pipeline



- \geq \$1 billion market opportunity for each asset¹
- > 70 granted U.S. and ex-U.S. patents and patent applications with patent term extending to 2043
- Broad claim scope covering TFF's proprietary platform technology and its application



TFF VORI

Voriconazole Inhalation Powder Clinical Development Program



TFF VORI: Addressing Significant Unmet Need for Pulmonary Fungal Infections

TFF VORI is in Phase 2 development for the treatment of pulmonary fungal infections including invasive pulmonary aspergillosis (IPA)

- IPA primarily impacts immune compromised patients (hematologic malignancies, solid organ, and stem cell transplant recipients)
- Oral and intravenous voriconazole is first-line therapy for the treatment of IPA
- Narrow therapeutic window associated with oral and IV voriconazole
 - Significant toxicities
 - Liver toxicity, arrhythmias and QT prolongation, infusion related reactions, visual disturbances, severe cutaneous adverse reactions, photosensitivity and renal toxicity¹
 - Drug-drug interactions
- High unmet medical need with ~30% mortality in 12 weeks² due to high rate of toxicity and drug-drug interactions limiting systemic dosing and overall efficacy

~250,000 invasive aspergillosis (IA) patients worldwide³

≥\$1 billion peak TFF VORI global gross sales forecast⁴

Increase lung delivery to drive efficacy while minimizing systemic exposures, toxicities, and drug-drug interactions

- 1. Voriconazole Package Insert; Warning and Precautions section, 5.2 and 5.3
- 2. Maertens et. al. Lancet 2016; 387:760-769.
- 3. Bongomin et. al. Journal of Fungi. 2017
- I. Internal estimates. Assumes indication for acute treatment of IPA

TFF VORI: Phase 2 Trial Design in Patients with Invasive Pulmonary Aspergillosis

- Design: Open label randomized study; TFF VORI vs. oral voriconazole
- **Duration**: 13 weeks of treatment
- Endpoints: Safety/tolerability, clinical response, radiologic response, mycologic response, all-cause mortality





TFF VORI: Expanded Access Program (EAP)

- The Expanded Access Program (EAP) enrolls patients with the following diagnoses who have limited or no other treatment options or who have had an unfavorable response to adequate standard of care therapy:
 - Pulmonary aspergillosis:
 - Invasive pulmonary aspergillosis (IPA)
 - Chronic pulmonary aspergillosis (CPA)
 - Allergic bronchopulmonary aspergillosis (ABPA)
 - Aspergillus tracheobronchitis
 - Aspergillus bronchoanastomotic infection
 - Voriconazole responsive pulmonary fungal infections
- US expanded access protocol prepared and submitted to the FDA: <u>https://clinicaltrials.gov/ct2/show/NCT05897294</u>
- Available in the US, Canada, Australia, UK, and select EU countries



TFF VORI: Summary of Results

IPA a pulmonary fungal infection with ~30% mortality in 12 weeks

Efficacy

- Of the five patients treated for at least 8 weeks with TFF VORI:
 - All five patients achieved a clinical response (improvement in signs, symptoms and/or spirometry)
 - All five patients achieved a mycologic response (no evidence of aspergillus infection)
 - Three of four patients achieved a radiologic response (improved radiologic findings: 4 patients with baseline and follow-up chest CT)
 - No need for continued anti-fungal use after treatment with TFF VORI in all five patients

Safety

- Of the 7 patients treated with TFF VORI for any length of time:
 - No all-cause mortality
 - No IPA-related mortality
 - No TFF VORI discontinuation due to an AE
 - Majority of TEAEs deemed unrelated to TFF VORI
 - Majority of TEAEs were Grade 2 or lower in severity
 - No hepatic toxicity
 - No visual disturbances



Data is from pre-database lock; Data cut off date: 11/17/23; TEAE: treatment emergent adverse event

TFF VORI: Efficacy Assessment

Patients who completed at least 8 weeks of treatment

Patient	Treatment duration	Clinical response		Mycologic response	Radiologic response	CLAD	Completed treatment	All-cause mortality
		Improved signs and symptoms	Stable or improved spirometry	No evidence of infection	Improved CT findings			
Oral 1	13 weeks	\checkmark	\checkmark	\checkmark	\checkmark	No	Yes	No
TFF VORI 1	13 weeks	\checkmark	\checkmark	\checkmark	\checkmark	Yes	Yes	No
TFF VORI 2	8+ weeks	Pending	\checkmark	\checkmark	\checkmark	No	Νο	No
TFF VORI 4	24 weeks	\checkmark	\checkmark	\checkmark	\checkmark	Yes	Yes	No
TFF VORI 5	12 weeks	\checkmark	\checkmark	\checkmark	No	Yes	Yes	No
TFF VORI 6	12 weeks	\checkmark	\checkmark	\checkmark	Not assessed	No	Yes	No



Data is from pre-database lock; Data cut off date: 11/17/23

TFF VORI: Patient TFF VORI 4 (EAP)

50-yr-old white male lung transplant recipient with **CLAD** presented with moderate cough, dyspnea (shortness of breath) and respiratory insufficiency and BAL* evidence of Scedosporium, which is voriconazole sensitive, and Lomentospora

Patient	Treatment duration	Clinical response		Mycologic response	Radiologic response	All-cause mortality
		Improved signs and symptoms	Stable or improved spirometry	No evidence of infection	Improved CT findings	
TFF VORI 4	24 weeks	\checkmark	\checkmark	\checkmark	\checkmark	No

Total Symptom Scores

PHARMACEUTICALS



Follow up mycologic assessment:

BAL* culture for Scedosporium negative

*BAL: bronchoalveolar lavage

TFF VORI: Patient **TFF VORI 4 (EAP)**

(a)







Data is from pre-database lock; Data cut off date: 11/17/23

TFF VORI: Safety Data

	Oral (n=2)	TFF VORI (n=7)	
Number of TEAEs	13	14	
Number of patients with any TEAEs	2 (100%)	2 (29%)	
Number of related TEAEs	0	0	
Number of possibly or probably related TEAEs	8	5	
Number of patients with possibly or probably related TEAEs	1 (50%)	2 (29%)	• N
Number of Grade 3 and above TEAEs	2	3	w
Number of patients with Grade 3 or above TEAEs	1 (50%)	1 (14%)	
Number of SAEs	1	3	
Number of patients with SAEs	1 (50%)	1 (14%)	
Number of related, possibly related or probably related SAEs	0	0	
Number of TEAEs that occurred in more than 2 patients	0	0	
Number of patients who experienced deaths	1 (50%)	0	
Number of patients who discontinued study treatment due to an AE	1 (50%)	0	
Number of patients with visual disturbance	1 (50%)	0	
Number of patients with Hepatic toxicity	1 (50%)	0	
Data is from pre-database lock; Data cut off date: 11/17/23	• TE • SA	AE: treatment emergent adv E: serious adverse event	verse event

No bronchospasm or wheezing reported





15

TFF TAC

Tacrolimus Inhalation Powder Clinical Development Program



TFF TAC: Addressing Significant Unmet Need in Lung Transplant Rejection

TFF TAC is in Phase 2 development for prevention of rejection in lung transplant recipients

- Tacrolimus is first-line calcineurin inhibitor for prevention of rejection in lung transplant
- Significant toxicities associated with oral tacrolimus
- TFF TAC delivers tacrolimus directly to the lung to drive efficacy through immune suppression locally in the lung, where inflammation leads to rejection and allograft failure, while limiting systemic exposure thus systemic toxicities
- High unmet medical need with ~50% mortality in 5 years¹ due to narrow therapeutic index:
 - Too little immune suppression leads to acute rejection or chronic rejection leading to chronic lung allograft dysfunction (CLAD)
 - Too much immune suppression leads to infections, chronic kidney disease, and post transplant lymphoproliferative disease

~40,000 new and existing patients worldwide²

≥\$1 billion peak TFF TAC global gross sales forecast³

Increase lung delivery to drive efficacy while minimizing systemic exposures and toxicities



- 1. Costa, Benvenuto, and Sonett, Best Practice & Research Clinical Anesthesiology, 2017
- 2. UpToDate; OPTN, UNOS, and Transplant Literature

Internal estimates

TFF TAC: Phase 2 Trial Design in Lung Transplant Patients

- Design: Open label study of TFF TAC in lung transplant patients who require reduced tacrolimus blood levels due to kidney toxicity
- **Duration**: Part A: 12 weeks; Part B: optional safety extension
- Endpoints: Safety and tolerability, kidney function, acute allograft rejection





TFF TAC: No Clinical Evidence of Rejection on TFF TAC at a Fraction of the Oral Tacrolimus Dose

Assessment of Allograft Rejection:

- No clinical signs and symptoms suggestive of acute rejection
- No deterioration in spirometry
- No chest x-ray findings suggestive of acute rejection
- No need for pulse corticosteroids

- Biomarker assessment of rejection is pending
- Safety and tolerability of TFF TAC was compatible with oral tacrolimus; no wheezing or bronchospasm reported
- 3/3 patients who completed Part A chose to remain on TFF TAC and proceeded to Part B

Patient	TFF TAC Dose/Oral Tacrolimus Dose	Blood Levels on TFF TAC/Blood Levels on Oral Tacrolimus
Patient 1	~1:5	~1:2
Patient 2	1:4	2:3
Patient 3	1:11	~1:2
Patient 4	1:8	~1:2

Data suggest that TFF TAC prevents rejection at lower systemic exposures thus at lower risk of systemic toxicity



Data is from pre-database lock; Data cut off date: 11/29/23

TFF TAC: Safety Data

	TFF TAC (n=4)
Number of TEAEs	14
Number of patients with any TEAEs	4 (100%)
Number of related TEAEs	0
Number of probably or possibly related TEAEs	9
Number of patients with possibly or probably related TEAEs	2 (50%)
Number of Grade 3 and above TEAEs	2
Number of patients with Grade 3 or above TEAEs	1 (25%)
Number of SAEs	1
Number of patients with SAEs	1 (25%)
Number of possibly related SAEs	1
Number of TEAEs that occurred in more than 2 patients	0
Number of patients who experienced deaths	0
Number of patients who discontinued study treatment due to an AE	0
TEAE of worsening renal function*	1
TEAE of hand tremor**	1

No bronchospasm or wheezing reported	
SAE of viral lower respiratory tract infection, expected in immune suppression	n the setting of
*Worsening renal function presumed from transient deh unrelated to TFF TAC	ydration,

• **Hand tremor resolved after dose reduction at Day 4

- TEAE: treatment emergent adverse event
- SAE: serious adverse event

•

•



Data is from pre-database lock; Data cut off date: 11/29/23

External Pipeline

Leveraging TFF's Platform for Business Development Opportunities



Recent Government Collaborations



National Institute of Allergy and Infectious Diseases

National Institute of

Environmental Health Sciences

eidos



June 26, 2023

TFF Pharmaceuticals awarded \$2.97 million by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institute of Health (NIH), to develop a universal influenza vaccine using the company's Thin Film Freezing technology.

May 4, 2023

TFF Pharmaceuticals enters into CRADA with the National Institute of Environmental Health Sciences (NIEHS) to develop dry powder formulations of Hyaluronan to prevent and treat respiratory diseases.

May 1, 2023

TFF Pharmaceuticals receives additional funding from Leidos to advance next generation countermeasures for military and healthcare personnel under the DARPA Personalized Protective Biosystems (PPB) program.



(DARPA

Recent grants and contracts with various government agencies is further validation of Thin Film Freezing's potential

Business Development Opportunities for TFF's Platform

Internal Pipeline

- TFF VORI (inhaled voriconazole dry powder)
- TFF TAC (inhaled tacrolimus dry powder)

Vaccines

 Reformulation and development of new vaccines for intranasal and inhalational delivery and eliminating need for cold chain supply requirements

New Chemical Entities (NCEs)

· Formulating new product opportunities for both small and large molecules



Biologics

- - Peptides
- Bacteriophages Peptoids

Government

• mAbs

- CRADA agreements with USAMRIID to formulate dry powder neutralizing antibodies against national priority biodefense threats
- CRADA agreement with NIEHS to develop dry powder formulations of Hyaluronan to prevent and treat respiratory diseases
- LEIDOS/DARPA contract
- SBIR with NIAID, Cleveland Clinic, and University of Georgia

Academia

R&D collaborations with the Albert Einstein College of Medicine, Georgia Tech, and UPenn to develop biologics



TFF Leadership



Harlan F. Weisman, M.D. Chief Executive Officer

- 30 years experience as a senior healthcare executive
- Former CEO of Flame Biosciences and Coronado Biosciences
- Former Group Company Chairman and President of J&J Pharmaceutical R&D



Zamaneh Mikhak, M.D. Chief Medical Officer

- Physician-scientist, board certified in Allergy/ Immunology, with extensive clinical, drug development, and basic and translational research experience
- Previously served in senior clinical research & development roles at Cogent Biosciences, Boston Pharmaceuticals, Kiniksa Pharmaceuticals



Kirk Coleman Chief Financial Officer

- Over 20 years of financial and accounting experience
- Previously served as an executive officer of Steelhead Capital Management, LLC and Bios Partners, LP



Anthony Hickey, Ph.D. Senior Scientific Advisor and Chairman of the Scientific Advisory Committee

- Professor Emeritus in Pharmacoengineering & Molecular Pharmaceutics at UNC Chapel Hill
- Former CEO of Cirrus Pharmaceuticals and CSO of Oriel Therapeutics; author of multiple texts on inhalation and pharmaceutical process engineering



TFF Board and Advisors

Board of Directors

Harlan F. Weisman, M.D. Chief Executive Officer

Thomas King Director

Catherine Lee, J.D. Director

Robert S. Mills Director

Michael Patane, Ph.D. Director

Brandi Roberts Director

Stephen Rocamboli Director



Johnson & Johnson



COLUMBIA LABORATORIES,INC.







Scientific Advisory Board

Anthony Hickey, Ph.D. Senior Scientific Advisor, and Chairman of the Scientific Advisory Committee

David N. Cornfield, M.D. Professor of Pulmonary Medicine, Stanford University

Prof. David Denning, FRCP, FRCPath, DCH, FMedSci Professor of Infectious Diseases, University of Manchester

Jay Peters, M.D. Chief of Pulmonary and Critical Care Medicine, University of Texas Health Science Center at San Antonio

Ted M. Ross, Ph.D. Professor, Center for Vaccines and Immunology, Department of Infectious Diseases, University of Georgia

Mike Saag, M.D. Professor of Medicine, University of Alabama at Birmingham

Drew Weissman, M.D., Ph.D. Roberts Family Professor, Vaccine Research at the Perelman School of Medicine, University of Pennsylvania



Key Takeaways

Revolutionary platform enabling inhalable drug delivery across the entire spectrum of pharmaceutical agents, targeting multiple \$1 billion+ markets



Proprietary Lung Drug Delivery Process

 Ability to convert a wide range of poorly water-soluble drugs into inhalable dry powder formulations



Strong Internal Pipeline

- Two proprietary drugs with >\$1 billion market potentials
- Lower risk clinical programs with positive Phase 2 initial data readouts
- Both with 505(b)(2) regulatory pathway





 Recent grants and contracts with various government agencies is further validation of Thin Film Freezing's potential



Experienced Management; IP Protection

 Proven management team with multiple successful exits
 Over 170 patents issued or pending





