



***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”, 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 2021 Annual Report on Form 10-K filed March 24, 2022 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.

# Investment Highlights

## Proprietary Pulmonary Drug Delivery Process

- Thin Film Freezing (TFF) is a unique, patented technology with proven ability to convert a wide range of poorly absorbed drugs into inhalable dry powder formulations

## Broadly Applicable Platform

- Have established POC for multiple small and large molecules
- Significant number of R&D partnerships in place which we believe will lead to licensing transactions of the technology

## Four Internal Programs

- Inhalable voriconazole (VORI) for infections overcomes problem of hepatic/visual toxicity
- Inhaled tacrolimus (TAC) for organ transplant has potential to avoid Prograf's renal toxicity
  - Phase 2 programs initiated at the close of 2021
- Inhaled niclosamide for COVID-19 and viral infections (w/ Union Therapeutics); completed Phase I trial
- AUG-3387 mAb for COVID-19 (w/ Augmenta Bioworks) in pre-clinical development

## Experienced Management; IP Protection

- Experienced senior management team with outstanding track record of success in a diverse set of competencies and related disciplines.
- Robust IP estate with over 120 patents issued or pending

# TFF Leadership



**Glenn Mattes**

*President & Chief Executive Officer*

- 30 years of business leadership experience
- Former CEO of Tibotec Therapeutics, a J&J company, and Rhone-Poulenc Rorer/Canada
- Senior C-suite positions at Centocor and J&J



**Chris Cano**

*Chief Operating Officer & Vice President, Business Development*

- 20 years of corporate development experience
- Previously served in senior business development roles at Aqua Pharmaceuticals, Duchesnay USA, Inc. and Noven 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.**

*Chief Scientific Officer*

- Professor Emeritus in Pharmacoengineering & Molecular Pharmaceutics at UNC Chapel Hill
- Founder of three pharmaceutical companies; author of multiple texts on inhalation and pharmaceutical process engineering



## Board of Directors

### Glenn Mattes

President, Chief Executive Officer and Director

### Aaron Fletcher, Ph.D.

Chairman of the Board

### Robert S. Mills

Director

### Stephen Rocamboli

Director

### Harlan Weisman, M.D.

Director

### Randy Thurman

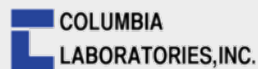
Director

### Malcolm Fairbairn

Director

### Brandi Roberts

Director



## Scientific Advisory Board

### David N. Cornfield, M.D

Professor of Pulmonary Medicine, Stanford University

### Prof. David Denning, FRCP, FRCPPath, 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

# TFF Pipeline – Building value through internal programs













	Category	Platform Formulation	Indication	Development Stage (& Partners)				Recent and Anticipated Milestones
				Pre-clinical	Phase 1	Phase 2	Phase 3	
Internal	<b>TFF VORI</b> <sup>1</sup>	Inhaled Voriconazole (Antifungal)	Invasive Pulmonary Aspergillosis (IPA)					<ul style="list-style-type: none"> <li>Final data from reactive airway study (4Q'21)</li> <li>End of Phase 1 meeting requested with FDA (4Q'21)</li> <li>Initiated Phase 2 study (~ year-end 2021)</li> <li>Interim Analysis (3Q'22)</li> </ul>
	<b>TFF TAC</b> <sup>2</sup>	Inhaled Tacrolimus (Immunosuppressant)	Prophylaxis of organ rejection in lung transplant					<ul style="list-style-type: none"> <li>Six-month tox. and Phase 1 SAD completed (1H'21)</li> <li>Final data from Phase 1 (3Q'21)</li> <li>Initiated Phase 2 study (~ year-end 2021)</li> <li>Interim Analysis (3Q'22)</li> </ul>
	<b>TFF NICLO</b> <sup>3</sup>	Inhaled Niclosamide (Antiviral)	COVID-19 and other viral infections					 <ul style="list-style-type: none"> <li>CTA Submitted (3Q'21)</li> <li>Phase 1 first dosing (4Q'21)</li> <li>Phase 1 completed (1Q'22)</li> </ul>
	<b>AUG-3387</b>	Inhaled mAb	COVID-19					 <ul style="list-style-type: none"> <li>Animal efficacy studies completed (3Q'21)</li> <li>Toxicology initiated (1Q'21)</li> <li>Phase 1 first doing (TBD)</li> </ul>

<sup>1</sup> Pursuing Orphan Drug Designation (ODD)

<sup>2</sup> Granted ODD

<sup>3</sup> Reformulation work ongoing for oral and inhaled-based delivery

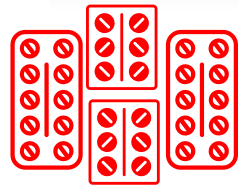
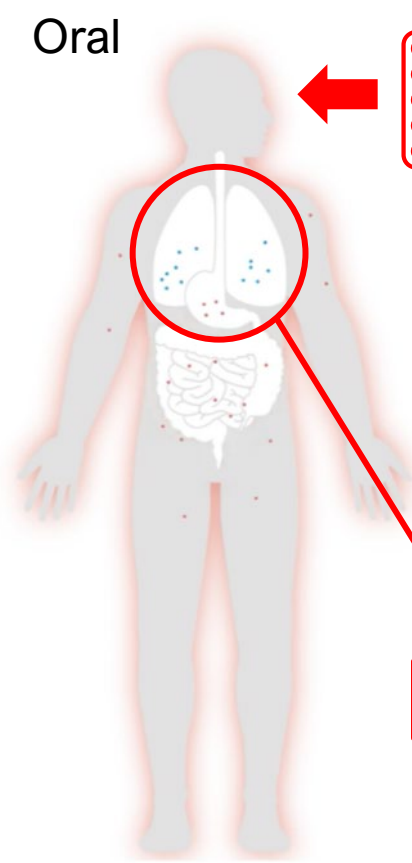
# TFF External Pipeline – Leveraging the TFF platform

	Category	Platform Formulation	Indication	Development Stage (& Partners)			Recent and Anticipated Milestones
				Pre-clinical	Phase 1	Partner	
External	Vaccines	Inhaled and intranasal delivery	Influenza, Ebola, Marburg, COVID-19 and alphaviruses			 	<ul style="list-style-type: none"> <li>In vitro/ in vivo data; leading to first in human trials</li> </ul>
	Phage-based Biotherapeutic	Inhaled formulation of complex biologic	Antibiotic-resistant bacterial infections				<ul style="list-style-type: none"> <li>Feasibility complete</li> <li>Collaboration ongoing</li> </ul>
	Adv Chem/Bio Protection	Formulations for skin, eyes, lungs	Neutralizing countermeasures				<ul style="list-style-type: none"> <li>Project initiated and work is on-going</li> </ul>
	Undisclosed	Undisclosed	Undisclosed	Undisclosed			<ul style="list-style-type: none"> <li>Undisclosed</li> </ul>
	Undisclosed	Undisclosed	Undisclosed	Undisclosed			<ul style="list-style-type: none"> <li>Undisclosed</li> </ul>
	Undisclosed	Undisclosed	Undisclosed	Undisclosed			<ul style="list-style-type: none"> <li>Undisclosed</li> </ul>
	Vaccines and Therapeutics	Intranasal Delivery	Undisclosed	Undisclosed			<ul style="list-style-type: none"> <li>Undisclosed</li> </ul>
	Cannabis	Inhaled THC/CBD	Avoid vaping-based lung injury	(N/A)			<ul style="list-style-type: none"> <li>Market testing of TFF versions of cannabinoids potentially leading to commercial launch in 2022</li> </ul>

# Thin Film Freezing – Superior Pulmonary Drug Delivery

## The Problem

Oral



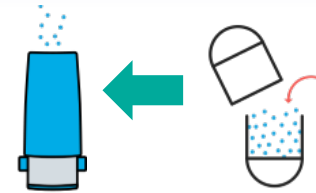
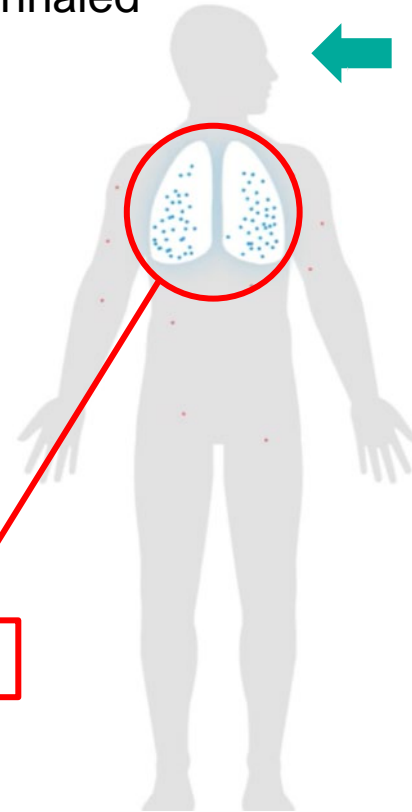
Typically, 10% of oral drugs reach their target and often contain bulking agents, fillers, and high dosages contributing to unwanted side effects.

- ↓ Low Efficacy
- ↑ Increase in adverse events

Drug in the lung = Efficacy

## Our Solution

Inhaled



Our TFF platform has shown the ability to deliver precise dosages to the site of action in increasing therapy response time and reducing side effects.

- ↑ High Efficacy
- ↓ Decrease in adverse events



# TFF Brittle Matrix Process and Powders



DRUG/EXCIPIENT  
IN SOLUTION



RAPID-FREEZING ON  
A CRYOGENIC DRUM



SOLVENT REMOVAL  
BY LYOPHILIZATION

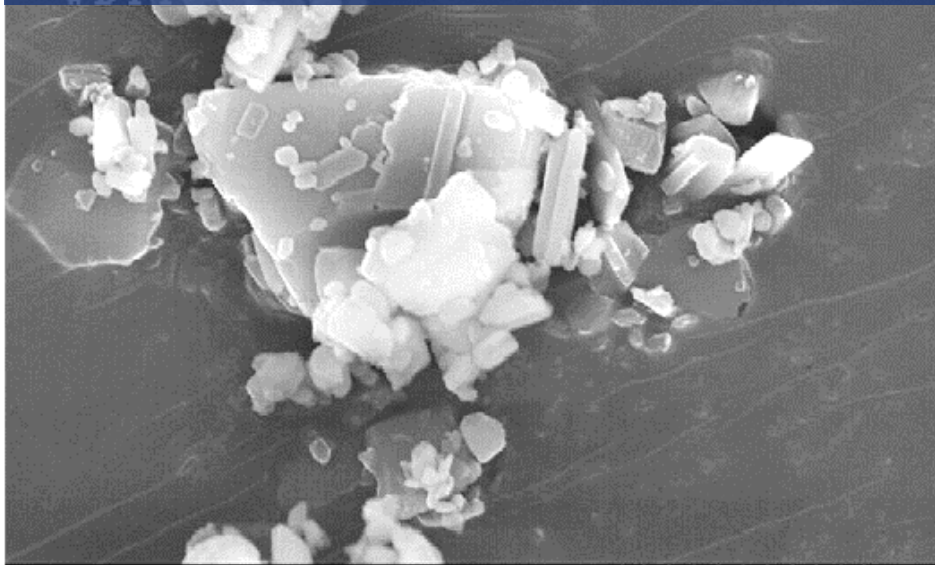


POWDER FILLING  
IN CAPSULE



COMMERCIALIZED  
PRODUCT

## Bulk Drug Material



15.0kV X5.00K 6.00µm



## Brittle Matrix Powders



10.0kV X5.00K 6.01µm

# TFF Platform Advantages

	Spray Drying	Spray Freeze Drying	Nano-Milling	TFF
<b>Potential To Prevent Molecular Damage</b>				
Thermal Degradation	X	✓	X	✓
Shear Stress	X	X	X	✓
Air/Water Denaturation	X	X	✓	✓
<b>Suitability For Dry Powder Inhalers</b>				
Technology Differentiators	<ul style="list-style-type: none"> <li>• Microparticles</li> <li>• Lower yield</li> <li>• Harder processing conditions</li> </ul>	<ul style="list-style-type: none"> <li>• Microparticles</li> <li>• Lower yield</li> <li>• Variable particle size (not suitable for DPI)</li> <li>• Cannot handle viscous solutions</li> </ul>	<ul style="list-style-type: none"> <li>• Microparticles</li> <li>• Can result in crystalline (insoluble in the lung)</li> <li>• Harsh processing conditions</li> </ul>	<ul style="list-style-type: none"> <li>• Nanoaggregate particles (better absorption)</li> <li>• Higher yield</li> <li>• Uniform particle size</li> <li>• Gentle processing (good for labile molecules)</li> </ul>

# A Revolutionary Technology Platform – Validated, Scalable, and IP-Protected

## Clinical validation of TFF Pharma's internal drug programs

- Voriconazole Inhalation Powder (VORI) – Phase 1 trial completed
  - Final data from reactive airway study in 4Q'21 (completed)
  - Pursuing ODD\*; Phase 2 trial initiated; Interim Analysis 2H 2022
- Tacrolimus Inhalation Powder (TAC) – Phase 1 trial completed
  - Phase 1 data in 3Q'21 (completed)
  - Granted ODD; Phase 2 trial initiated; Interim Analysis 2H 2022

## Industry-validated with robust BD activity

- Numerous finished formulations of small molecules & biologics; multiple R&D partnerships, and growing portfolio of opportunities

## Scalable, IP-protected platform

- Manufacturing drugs for clinical studies using GMP standards; strategic partnership with UT Austin for smaller-scale, BD work
- Strong IP portfolio: protection covering TFF process, multiple drug opportunities, and internal products

\* Orphan Drug Designation (ODD)



# GMP Manufacturing Readiness

- TFF partnered with CoreRx and IriSys to manufacture non-clinical 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.
- Working with Catalent to produce the Augmenta mAb, AUG-3387 and other biologics, some requiring aseptic fill and finish
- 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.
- Currently identifying equipment and vendors to encapsulate TFF powders at increased speed and scale to support increasing clinical supply needs and registration/early commercial requirements.

## Two-pronged Strategy For Leveraging TFF Formulations and Maximizing Value



# TFF Business Model

## In-house Development

Identify opportunities that address significant unmet medical need, and/or lower risk clinical pathway via 505(b)(2):

- TFF Voriconazole (VORI) for IPA/ABPA
- TFF Tacrolimus (TAC) for lung transplant as well as kidney, heart and liver
- TFF Niclosamide for COVID-19 and viral infections in first-in-human trials
- Augmenta/TFF mAb development for COVID-19

## 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. Potential licensing opportunities include:

- Academic vaccine partnerships – University of Georgia, Albert Einstein College of Medicine, University of Pennsylvania
- National priority biodefense vaccines and countermeasures – USAMRIID/GENEVA, DARPA, and LEIDOS
- Bacteriophage-based biotherapeutic – Felix Biotechnology
- Cannabis market opportunity – PLUS Products



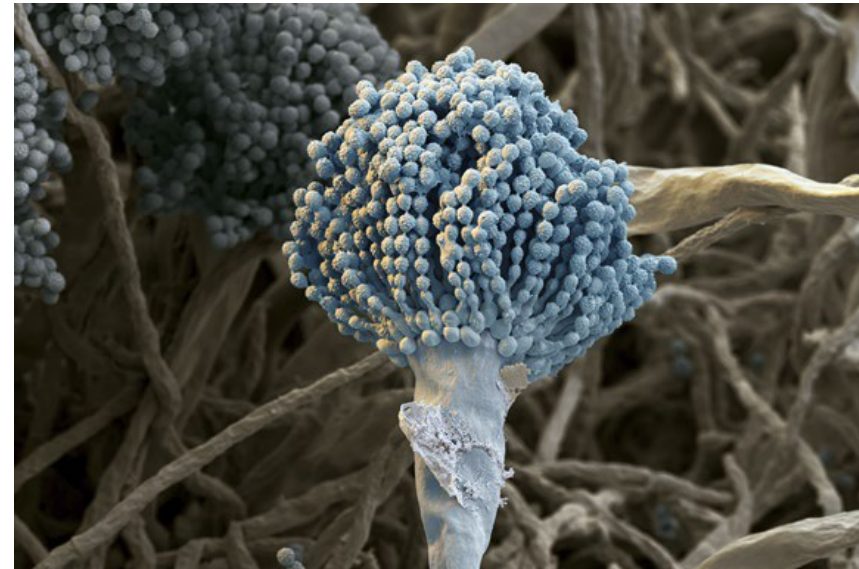
# Voriconazole Inhalation Powder (TFF VORI)

## Target Indications:

Invasive Pulmonary Aspergillosis (IPA)

Allergic Bronchopulmonary Aspergillosis (ABPA)

- IV/Oral voriconazole indication and side effects
- TFF VORI preclinical and clinical data highlights
- Clinical development plan and near-term data readouts
- Market opportunity



# TFF VORI Program (Inhaled Voriconazole)

## IV/oral voriconazole

### Approved Indication:

Treatment of patients 12 years or older with invasive aspergillosis

### Side Effects:

- Hepatic toxicity, including clinical hepatitis, cholestasis and fulminant hepatic failure, including fatalities \*
- Visual disturbances, including optic neuritis and papilledema \*

### Alternatives:

Oral and IV amphotericin, echinocandins, azoles



## TFF VORI

### Targeted indication:

Acute and chronic treatment of adults and pediatric patients 2 years-of-age and older with invasive pulmonary aspergillosis (IPA) and allergic bronchopulmonary aspergillosis (ABPA) and prophylaxis of IPA

### Preclinical POC data:

- 3X better survival vs. amphotericin in IPA

### Phase 1 data:

- 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

**Clinical development strategy: expand treatable patient population with improved safety profile, while lowering clinical development risk by focusing on pulmonary infections only**

# TFF VORI Preclinical and Clinical Data To Date

## Preclinical Data

- 13-week tox supportive of clinical approach
- 26-week tox study under way to support registration

## Phase 1 Clinical Data

- SAD/MAD Completed with doses up to 80 mg BID for 7 days
- No Clinically Significant Adverse Events

## Phase 2 Clinical Trial

- 80 mg dose selected for Phase 2

## Published Clinical Data with Inhaled Voriconazole

- Nebulized VORI efficacious at 40 mg BID

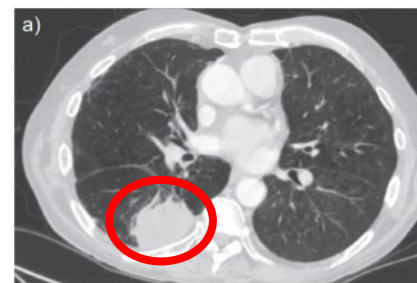
Remarkably efficient inhaled antifungal monotherapy for invasive pulmonary aspergillosis

*To the Editors:*

Voriconazole is a broad-spectrum antifungal agent that is effective against moulds such as *Aspergillus fumigatus*. It inhibits the cytochrome P450-dependent 14- $\alpha$ -lanosterol demethylase, preventing the conversion of lanosterol to ergosterol. This results in the accumulation of toxic methylsterols in the fungal wall and the inhibition of fungal growth [1]. Voriconazole is available as an intravenous infusion solution containing a cyclo-

protein. By that time, the patient had developed polyneuropathy and progressive increases in liver enzyme levels. Consequently, antifungal treatment was halted, which normalised liver enzymes but was also associated with a worsened clinical condition and elevated C-reactive protein and leukocytes. Therefore, in July 2010, the patient started monotherapy with inhaled voriconazole at an initial total dose of 40 mg *t.i.d.* that was reduced to 40 mg *b.i.d.* after 2 weeks and was

*Hilberg et al. European Resp. Journal 2012 Jul;40(1):271-3*



# TFF VORI Outlook

## 2021/2022 inflection points and catalytic events

- 13-week toxicology study complete (2Q'21)
- Final data from reactive airway study (4Q'21)
- Initiated Phase 2 study (1Q'22)
- Interim Analysis (2H'22)

## Market opportunity and payor access\*

- Antifungal sales topped \$4B<sup>1</sup>. However, an inhaled voriconazole for IPA and ABPA and unmet medical needs could achieve blockbuster status
- Market: IPA\* - 40K US annually representing >\$300MM<sup>4</sup> opportunity
- Once TFF VORI demonstrates a safety advantage, payer respondents said they would be covered no matter the cost\*

## TFF VORI revenue forecast\*

- \$300MM in potential peak sales worldwide
- Assuming acute IPA penetration of 18%; at risk penetration 2%

# Tacrolimus Inhalation Powder (TFF TAC)

## Target Indication:

Prophylaxis of organ rejection in patients receiving lung transplants

- IV/oral tacrolimus indication and side effects
- TFF TAC preclinical and clinical data highlights
- Clinical development plan and near-term data readouts
- Substantial market opportunity





# TFF TAC Program (Inhaled Tacrolimus)

## IV/oral Tacrolimus

### Approved Indication:

Prophylaxis of organ rejection in patients receiving allogeneic liver, kidney, lung or heart transplants

### Side effects:

Development of lymphoma and other malignancies, serious infections, polyoma virus infections, cytomegalovirus infections, new onset diabetes, nephrotoxicity, neurotoxicity\*

### Alternatives:

Oral and IV immunosuppressants



## TFF TAC

### Targeted Indication:

Prophylaxis of organ rejection in patients receiving lung transplants

### Preclinical POC Data:

Rat lung transplant, asthma, peer-reviewed

### Clinical Safety Data:

- Successfully completed single and multiple ascending dosing of four cohorts of healthy subjects in Phase 1 trial
- Well tolerated with no reports of clinically significant drug-associated adverse events
- Single dose provides substantial systemic blood levels that approach levels associated with effective immunosuppression in heart, lung, kidney and liver transplant patients.

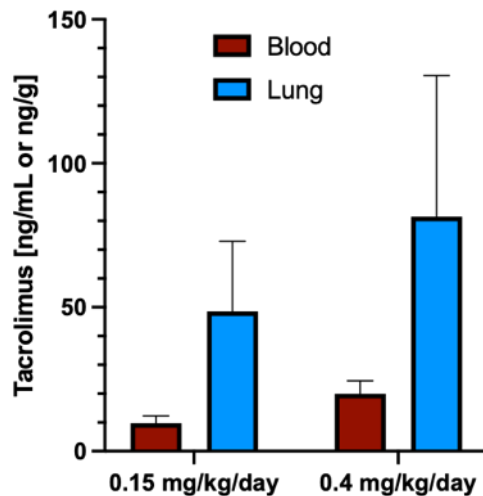
**Clinical development strategy:** To differentiate inhaled tacrolimus based primarily upon improved safety and fewer drug-drug interactions compared to oral tacrolimus

# TFF TAC Preclinical and Clinical Data To-Date

## Preclinical Data

- 26-week tox complete
- NOAEL established
- 3-4-fold higher lung exposure than blood

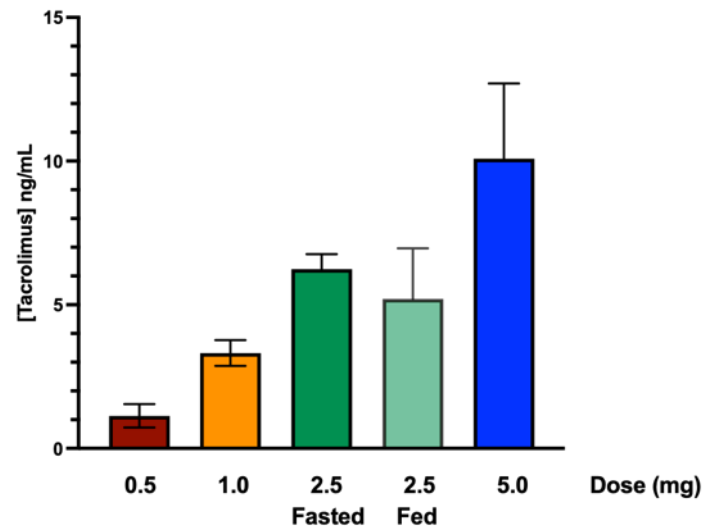
**Toxicology Study**  
Terminal Conc. Assessment



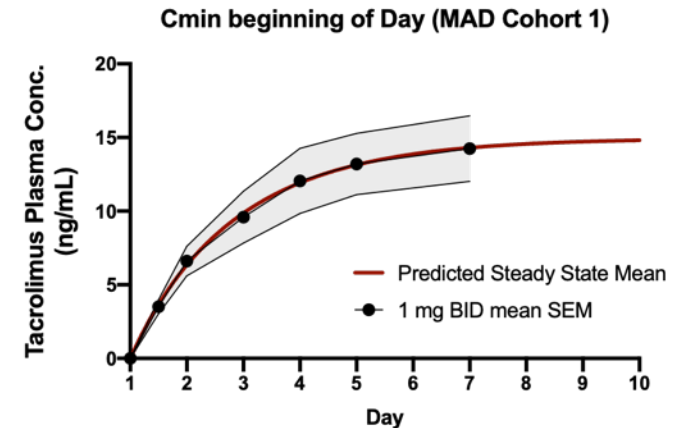
## Phase 1 Clinical Data

- SAD doses of 0.5, 1.0, 2.5, and 5.0 mg
- No food effect observed (2.5 mg cohort)
- MAD doses of 0.5 and 1.0 mg BID and 1.5 mg QD
- MAD dosing accumulates to therapeutic levels

**SAD 12 Hr Trough Levels**



**Tacrolimus Plasma Exposure  $C_{min}$  through Day 7 (TFF-T1-001)**



# TFF TAC Outlook

## 2021/2022 inflection points and catalytic events

- Six-month toxicology study completed (1Q'21)
- Phase 1 SAD dosing completed (2Q'21)
- Phase 1 MAD dosing complete, final data (3Q'21)
- Phase 2 initiated (1Q'22)
- Interim Analysis (2H'22)

## Market opportunity and payor access\*

- Total transplant addressable market: >\$1B<sup>5</sup>
- Once TFF TAC demonstrates a safety advantage, payer respondents said they would be covered no matter the cost\*\*

## TFF TAC revenue forecast\*

- \$400MM worldwide for first indication
- Assuming 27% penetration
- Global forecast including heart, liver, and kidney transplant exceeds \$1 billion

# 2021 Clinical Catalysts: Including NICLO and AUGMENTA

✓ Q1

TAC: 6-month tox completed, Phase 1 SAD dosing complete  
NICLO: Pre-IND submission, oral tox study start

✓ Q2

VORI: 13-week tox complete; release of Phase I data  
NICLO: Inhaled tox study start, oral tox complete

✓ Q3

VORI: 26-week tox study initiated  
TAC: Phase 1b topline data  
AUGMENTA: Preclinical efficacy data  
NICLO: CTA filing completed

✓ Q4

VORI: results from Phase 1b reactive airway study;  
AUGMENTA: Animal studies complete; formulation finalized  
NICLO: Phase 1 dosing initiated

# 2022 Expected Clinical Catalysts

✓ Q1	VORI: Phase 2 – initiation TAC: Phase 2 – initiation Niclo: Phase 1 – Completion of Phase 1 Aug: CMC – engineering run complete, Initiation of tox study (TBD)
Q2	VORI: Phase 2 – study ongoing TAC: Phase 2 – study ongoing Niclo: IND filing for Phase 2 start* Aug: GMP mAb Drug Substance Manufacturing complete (TBD)
Q3	VORI: Phase 2 – study ongoing, Interim Analysis TAC: Phase 2 – study ongoing, Interim Analysis Niclo: Phase 2 – initiation* Aug: Phase 1 – initiation (TBD)
Q4	VORI: Phase 2 – study complete TAC: Phase 2 – study complete Niclo: Phase 2 – study ongoing* Aug: Phase 1 – study complete (TBD)



# Business Development - The Power of the TFF Platform

## Under Consideration for Potential Development by TFF

### Vaccines

**Reformulation and development of new vaccines eliminating need for cold chain supply requirements**

Ongoing discussions with multiple global pharma companies to test their proprietary compounds using the TFF technology platform

### New Chemical Entities (NCEs)

Open MTAs with multiple pharma partners formulating new product opportunities in both small and large molecules

### Partnerships focused on Platforms

**mRNA**  
**sRNA**  
**Macrophage**  
**mAbs**  
**Peptides**  
**Peptoids**

### Government/ Academic Partnerships

**CRADA** agreements with **USAMRIID** to formulate dry powder neutralizing antibodies against national priority biodefense threats  
**LEIDOS/DARPA** contract

R&D collaborations with the **University of Georgia, Albert Einstein College of Medicine, and Upenn** on biologics development

### Botanicals

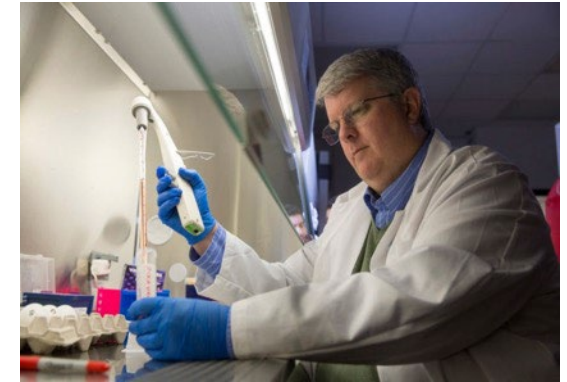
Thin Film Freezing technology can effectively convert these compounds into a dry powder inhalation form, which can result in a rapid onset of action, with peak blood levels in minutes and with very positive bioavailability and absorption attributes

# Disclosed Collaboration Partners



## ***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 institutions 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 using TFF technology, and Univ. of Georgia CVI will evaluate these formulated compounds to elicit broadly reactive immune responses and potentially provide longer-lasting protection against a wider variety of influenza viruses.



## ***Cooperative Research and Development Agreements (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***

- Lead by Dr. John Dye, USAMRIID's chief of viral immunology, one of the scientists responsible for the development of the Ebola vaccine, this 3-year collaboration between TFF and US Army will investigate Thin Film Freezing to formulate two different countermeasures, a monoclonal antibody against Alphaviruses and a vesicular stomatitis virus vaccine against Filoviruses.
- 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.



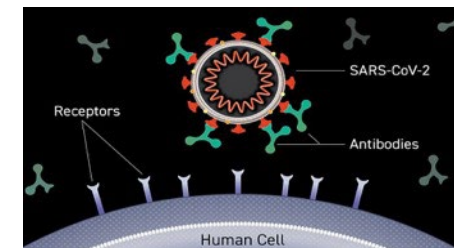
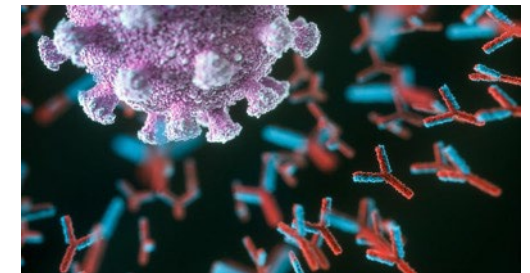
# Monoclonal Antibodies and Antivirals for COVID-19

## ***TFF Pharmaceuticals, UT Austin, and Union Therapeutics are reformulating niclosamide for inhaled delivery***

- Niclosamide (used since the 1960's) is more potent when compared with other drugs such as chloroquine, lopinavir and remdesivir, but it is poorly absorbable when delivered orally.
- TFF-developed inhaled formulation of niclosamide.

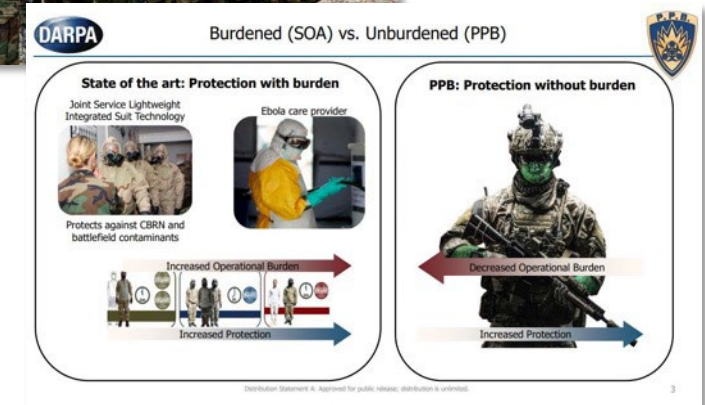
## ***Worldwide Joint Development Agreement for COVID-19 monoclonal antibody therapies with Augmenta Bioworks. Collaboration on first-of-its-kind uses of Thin Film Freezing technology applied to monoclonal antibodies (mAbs)***

- Joint Development Project to develop one or more commercial therapeutics based on, derived from, and/or incorporating Augmenta's human mAbs to potentially treat patients with COVID-19. AUG-3387 selected to move forward into human testing.
- 50-50 split of all expenses, and potential revenues and future cash payments.



## ***Thin Film Freezing platform to be used to rapidly neutralize chemical and biological threats at vulnerable tissue barriers to increase soldier protection and decrease operational burden under DARPA's Personalized Protective Biosystems (PPB) Program***

- Leidos subcontract overseen by DARPA to develop an integrated system that simultaneously reduces protective equipment needs while increasing protection for the individual against existing and future chemical and biological (CB) threats.
- TFF to formulate a series of countermeasures designed to neutralize chemical and biological agents at the site of vulnerable tissue barriers, including the skin, the eyes and the respiratory system.
- Successful PPB technologies could change how the military and public health communities perform in unpredictable threat environments.

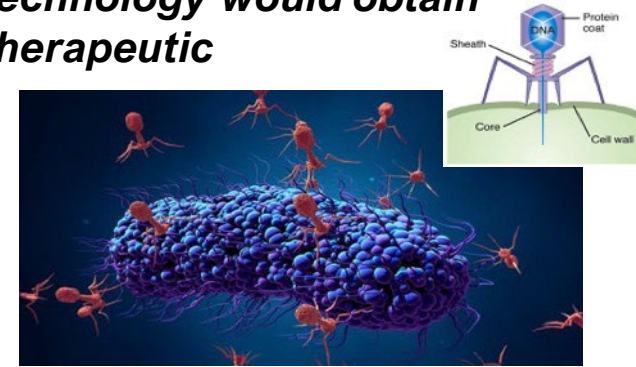




# Bacteriophage-based Biotherapeutic

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

- 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.
- TFF reformulation of these unique, complex biologics is a first-of-its-kind breakthrough for a potentially more effective and targeted delivery to the deep lung of patients.



## Opportunity in Cannabis Market

**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**

- TFF can generate dry power inhaled versions of cannabinoids with lung friendly ingredients.
- 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.
- Direct lung delivery as a powder leads to rapid onset of action; market testing underway.



# Collaborations

## ***Collaboration with Pfizer to evaluate the Thin Film Freezing technology with multiple proprietary drug candidates of Pfizer***

- TFF to formulate and perform feasibility testing on multiple Pfizer drug candidates utilizing TFF's proprietary thin film freezing technology
- Pfizer's proprietary drug candidates and the financial terms of the arrangement are undisclosed



## ***Collaborative Research Agreement (CRA) with Dr. Drew Weissman at the Perelman School of Medicine at the University of Pennsylvania***

- Led by Dr. Drew Weissman, the world-renowned leading mRNA expert and inventor of the Pfizer/BioNTech and Moderna COVID-19 vaccines, TFF and Dr. Weissman are testing UPenn's mRNA vaccines from a frozen liquid into a dry powder version utilizing TFF's thin-film freezing technology to evaluate the potency & immunogenicity of the TFF processed mRNA vaccines
- The TFF dry powder formulations of the mRNA-LNPs will be formulated and tested to improve stability, generate room temperature storage and explore new routes of administration, oral & nasal inhaled delivery
- Dr. Drew Weissman is a member of TFF's Scientific Advisory Board



**Perelman**  
School of Medicine  
UNIVERSITY of PENNSYLVANIA



# TFF Pharma – Catalent Collaboration Agreement

- *Catalent will introduce their customer base to TFF's proprietary and innovative Thin Film Freezing technology*
- *Catalent to provide CDMO services to any referred client that licenses and partners TFF technology*
- *Collaboration focused on development of dry powder formulations of therapies, specifically biologics, for inhalation to the lungs and nose and/or reconstitution for injection*



## **Focuses of agreement:**

- Generation, testing and manufacturing of dry powder formulations of biologics, including but not limited to:
  - mRNA, siRNA, ncRNA
  - monoclonal antibodies, antibody fragments, antibody conjugates, proteins, peptides
  - Phage, AAV, VLP, gene and cell therapies
- TFF and Catalent will share in revenues generated from future commercialized products from agreement

# Key Takeaways

*Revolutionary platform enabling inhalable drug delivery across the entire spectrum of pharmaceutical agents (small & large molecules, biologics, vaccines, mRNA), targeting multiple \$Billion-plus markets*



**Two proprietary, high commercial and lower risk clinical programs** (TFF VORI & TFF TAC) with significant near-term data readouts; both with accelerated 505(b)(2) regulatory pathway



**Growing business development** and partnering activity as industry increasingly recognizes the clinical and commercial potential of TFF technology



**Strong patent portfolio:** TFF process, drug opportunities, new IP development



**Cash:** \$26M as of 3/31/22; sufficient runway into 2023



**Proven management team,** with multiple successful exits



*Thank you!*

# ENDNOTES

1. Antifungal Market Growth-2013. Global Data Research Report <https://www.globaldata.com/> (last accessed February 15, 2019). TFF Pharmaceuticals Estimates Q1 2019
2. Growth of Global Immunosuppressant Market for Acute Rejection - 2013. Global Data Research Report <https://www.globaldata.com/> (last accessed January 10, 2019).
3. COPD Market Growth – 2017. Global Data Research Report <https://www.globaldata.com/> (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.
6. Severe Asthma Market Growth - 2015. Global Data Research Report [www.globaldata.com/](http://www.globaldata.com/) (last accessed February 20, 2019). TFF Pharmaceuticals Estimates Q1 2019