



TFF Pharmaceuticals Reports Third Quarter Results and Provides Business Update

December 9, 2019

Company initiates Phase 1 clinical trial of Voriconazole Inhalation Powder, to treat invasive pulmonary aspergillosis (IPA)

Successfully completes \$24 million initial public offering of common stock

AUSTIN, Texas--(BUSINESS WIRE)--Dec. 9, 2019-- 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 announced its third quarter 2019 financial results and provided a corporate update on recent significant events.

"This has been a time of important milestones and accomplishments for TFF Pharmaceuticals," said Glenn Mattes, President and CEO of TFF Pharmaceuticals. "We are very pleased to report that we recently initiated and began dosing subjects in the Phase 1 clinical trial of our Voriconazole Inhalation Powder, to treat the severe and life-threatening disease of Invasive Pulmonary Aspergillosis, or IPA. This unique formulation of Voriconazole, which is considered to be the most effective antifungal drug for treating IPA, directly targets the site of the fungal infection in the lung and has the potential to be the first dry powder inhaled fungicide on the market."

"We also successfully completed our IPO on the Nasdaq Stock Market," continued Mr. Mattes. "We believe this will provide TFF with the funds for the development of our two initial product candidates, Voriconazole Inhalation Powder and Tac-Lac Inhalation Powder, through the completion of their proposed clinical studies, as well as additional product development."

Recent Clinical and Corporate Highlights

Initiated Phase 1 clinical trial: On November 25, we initiated a Phase 1 clinical trial of Voriconazole Inhalation Powder and began dosing individuals. This is the Company's next-generation, direct-to-lung, inhaled dry powder version of Voriconazole for treating Invasive Pulmonary Aspergillosis.

This randomized, double-blind, placebo-controlled study will be conducted at a site in Canada for purposes of evaluating, under a U.S. IND and Canadian CTA, the safety, tolerability and pharmacokinetic profile of Voriconazole Inhalation Powder in 64 healthy subjects.

Completed \$24 Million Initial Public Offering: In October, the Company closed its initial public offering of 4.8 million shares of common stock, including the exercise by the underwriter of an overallotment option, at a public offering price of \$5.00 per share. TFF Pharmaceuticals began trading under the ticker symbol "TFFP" on October 25, 2019 on the Nasdaq Capital Market. Net proceeds to the Company were approximately \$22.3 million after deducting underwriting discounts, commissions and other offering expenses.

Third Quarter Financial Results

Cash Position: As of September 30, 2019, TFF Pharmaceuticals reported cash and cash equivalents of \$10.6 million, which does not give effect to the Company's receipt of approximately \$22.3 million of net proceeds from its initial public offering in the fourth quarter.

Research and Development (R&D) expenses: R&D expenses for the third quarter of 2019 were \$2.6 million, compared to \$140,167 for the same period in 2018.

General & Administrative (G&A) expenses: G&A expenses for the third quarter of 2019 were \$300,640, compared to \$465,919 for the same period in 2018.

Net Loss: TFF Pharmaceuticals reported a net loss for the third quarter of 2019 of \$2.8 million, compared to a net loss of \$585,215 for the same period in 2018.

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 Tac-Lac Inhalation Powder. The Company plans to add to this pipeline by collaborating with large pharmaceutical partners. The TFF Platform is protected by 39 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 version of Voriconazole 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) 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 Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission on December 9, 2019. 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.
CONDENSED STATEMENTS OF OPERATIONS
UNAUDITED

	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	January 24, 2018 to September 30, 2018	January 1, 2018 to January 23, 2018 (Predecessor)
Operating expenses					
Research and development	\$ 2,563,528	\$ 140,167	\$ 5,554,046	\$ 759,355	\$ *
General and administrative	300,640	465,919	1,721,691	2,243,788	*
Total operating expenses	<u>2,864,168</u>	<u>606,086</u>	<u>7,275,737</u>	<u>3,003,143</u>	*
Loss from operations	(2,864,168)	(606,086)	(7,275,737)	(3,003,143)	*
Other income					*
Interest income	25,865	20,871	67,699	33,268	*
Total other income	<u>25,865</u>	<u>20,871</u>	<u>67,699</u>	<u>33,268</u>	*
Net loss	(2,838,303)	(585,215)	(7,208,038)	(2,969,875)	*
Preferred stock dividend	(258,635)	(219,498)	(768,876)	(505,516)	*
Net loss applicable to common stock	<u>\$ (3,096,938)</u>	<u>\$ (804,713)</u>	<u>\$ (7,976,914)</u>	<u>\$ (3,475,391)</u>	\$ *
Net loss applicable to common stock per share, basic and diluted	<u>\$ (0.70)</u>	<u>\$ (0.18)</u>	<u>\$ (1.81)</u>	<u>\$ (0.79)</u>	
Weighted average common shares outstanding, basic and diluted	<u>4,400,000</u>	<u>4,400,000</u>	<u>4,400,000</u>	<u>4,400,000</u>	

TFF PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS

	As of September 30, 2019	As of December 31, 2018
Assets		
Current Assets		
Cash and cash equivalents	\$ 10,550,569	\$ 10,261,671
Prepaid assets and other current assets	20,297	12,065
Total Current Assets	<u>10,570,866</u>	<u>10,273,736</u>
Deferred offering costs	461,893	127,768
Total Assets	<u>\$ 11,032,759</u>	<u>\$ 10,401,504</u>
Liabilities and Stockholders' Deficit		
Current Liabilities		
Accounts payable	\$ 691,105	\$ 428,645
Accrued dividends payable	1,497,226	728,350
Total Liabilities	<u>2,188,331</u>	<u>1,156,995</u>
Commitments and Contingencies (Note 4)		
Series A Preferred Stock		
Series A Preferred Stock, \$0.001 par value, 10,000,000 shares authorized; 8,930,000 shares issued and outstanding as of September 30, 2019 and 5,662,000 shares issued and outstanding as of December 31, 2018, respectively (Liquidation Preference of \$23,822,226)	19,684,197	12,485,971
Stockholders' Deficit:		
Common stock, \$0.001 par value, 45,000,000 shares authorized; 4,000,000 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	4,000	4,000
Additional paid-in capital	206,455	596,724

Accumulated deficit	(11,050,224)	(3,842,186)
Total Stockholders' Deficit	(10,839,769)	(3,241,462)
Total Liabilities, Series A Preferred Stock and Stockholders' Deficit	\$ 11,032,759	\$ 10,401,504

TFF PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
UNAUDITED

	For the Nine Months Ended September 30, 2019	January 24, 2018 to September 30, 2018	January 1, 2018 to January 23, 2018 (Predecessor)
Cash Flows from Operating Activities			
Net loss	\$ (7,208,038)	\$ (2,969,875)	—
Adjustment to reconcile net loss to net cash used in operating activities:			
Stock based compensation	378,607	1,235,946	—
Changes in operating assets and liabilities:			
Prepaid assets	(261,204)	(36,305)	—
Accounts payable	181,307	426,845	(1,833)
Net Cash Used in Operating Activities	<u>(6,909,328)</u>	<u>(1,343,389)</u>	<u>(1,833)</u>
Cash Flows from Investing Activities			
Net Cash Used in Investing Activities	<u>—</u>	<u>—</u>	<u>—</u>
Cash Flows from Financing Activities			
Net Transfers from parent	—	(6,542)	(1,833)
Proceeds from issuance of preferred stock	7,198,226	12,485,971	—
Net Cash Provided by Financing Activities	<u>7,198,226</u>	<u>12,479,429</u>	<u>(1,833)</u>
Net Increase in Cash and Cash Equivalents	288,898	11,136,040	—
Cash and Cash Equivalents – beginning of period	<u>10,261,671</u>	<u>—</u>	<u>—</u>
Cash and Cash Equivalents – end of period	<u>\$ 10,550,569</u>	<u>\$ 11,136,040</u>	<u>—</u>
Supplemental disclosure of non-cash investing and financing activities:			
Common stock issued to former parent for acquired assets	\$ —	\$ 4,000	—
Accrued offering costs	\$ 81,153	\$ 60,890	—
Accrued dividend	\$ 768,876	\$ 505,516	—

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Source: TFF Pharmaceuticals, Inc.

Company Contacts:

Glenn Mattes
President and CEO
TFF Pharmaceuticals, Inc
gmattes@tffpharma.com
737-802-1973

Kirk Coleman
Chief Financial Officer
TFF Pharmaceuticals, Inc.
kcoleman@tffpharma.com
817-989-6358

Investor Relations and Media Contact:

Paul Sagan
LaVoieHealthScience
psagan@lavoiehealthscience.com
617-953-4779