

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): June 23, 2023

TFF PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-39102

(Commission File Number)

82-4344737

(I.R.S. Employer
Identification Number)

1751 River Run, Suite 400
Fort Worth, Texas 76107

(Address of principal executive offices)

(817) 438-6168

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions.

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock: Par value \$.001	TFFP	Nasdaq Global Market

Item 8.01 Other Events.

On June 23, 2023, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, awarded TFF Pharmaceuticals, Inc. ("Company") a Direct to Phase II Small Business Innovation Research ("SBIR") grant of approximately \$2.97 million to continue development of a novel, pan-flu multivariant mucosal vaccine using the Company's Thin Film Freezing technology.

The purpose of the SBIR grant is to provide funding to support preclinical and IND enabling studies to advance the development of a shelf-stable dry powder formulation of a novel universal influenza virus vaccine, developed in the laboratory of Dr. Ted Ross at the Cleveland Clinic (previously of University of Georgia). Funding from the SBIR grant is expected to take place over three years.

SAFE HARBOR

This Form 8-K contains forward-looking statements regarding TFF Pharmaceuticals, Inc., including, the benefits of the Company's TFF platform and the Company's plans to conduct preclinical and IND enabling studies to advance the development of a shelf-stable dry powder formulation of a novel universal influenza virus vaccine. 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's preclinical and IND enabling studies of the dry powder formulation of the universal influenza vaccine may not be successful, (ii) the risk that the Company may not be able to successfully conclude clinical testing or obtain pre-market approval of the dry powder formulation of the universal influenza vaccine or any of its other dry powder product candidates, (iii) success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results, (iv) no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, (v) the Company has no current agreements or understandings with any large pharmaceutical companies for the development of a drug product incorporating the TFF Platform, (vi) the risk that the Company will not be able to conclude a long-term commercial agreement with any third-party, 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 May 11, 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TFF PHARMACEUTICALS, INC.

Dated: June 23, 2023

/s/ Kirk Coleman

Kirk Coleman,
Chief Financial Officer