UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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) March 7, 2023

FRESH TRACKS THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**000-21088**	**93-0948554**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

5777 Central Avenue
Suite 102
Boulder, CO 80301
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (720) 505-4755

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ 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 240.14a-12)
☐ 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))

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 $0.01 per share	**FRTX**	**The Nasdaq Stock Market LLC**

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. ☐

Item 7.01. Regulation FD Disclosure.

On March 7, 2023, Fresh Tracks Therapeutics, Inc. (the "Company" or "Fresh Tracks") issued a press release announcing positive topline results from the single ascending dose ("SAD") and multiple ascending dose ("MAD") parts of its Phase 1 clinical trial evaluating FRTX-02 in healthy subjects. A copy of the press release is attached as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01 and in Exhibit 99.1 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

Part 1, Phase 1 Clinical Trial Results for FRTX-02

On March 7, 2023, the Company announced positive topline results from the SAD and MAD parts of its Phase 1 clinical trial evaluating its product candidate FRTX-02 in healthy subjects. FRTX-02 is a potential first-in-class oral DYRK1A inhibitor under investigation for the treatment of autoimmune and inflammatory diseases. FRTX-02 is the first oral DYRK1A inhibitor to be tested in humans for autoimmune diseases.

Study Design

The Phase 1 clinical trial of FRTX-02 is a two-part, randomized, double-blinded, placebo-controlled study designed to evaluate the safety, tolerability, pharmacokinetics ("PK"), and pharmacodynamics ("PD") of FRTX-02 capsules in both healthy subjects and patients with atopic dermatitis ("AD"). Part 1A of the study was a SAD assessment, which enrolled a total of 56 healthy subjects across seven cohorts (single oral dose of 10 to 600 mg FRTX-02 or placebo). Part 1B of the study was a MAD assessment, which enrolled a total of 33 healthy subjects across three cohorts (75, 150 and 300 mg FRTX-02 or placebo, once-daily for 14 days). Part 2 of the study will compare once-daily oral doses of FRTX-02 to placebo in subjects with moderate-to-severe AD and include an exploratory evaluation of efficacy. Additional information on this clinical trial can be found on https://www.clinicaltrials.gov/ under identifier NCT05382819.

Safety

FRTX-02 was generally safe and well-tolerated in all seven SAD cohorts and in the 75 mg and 150 mg MAD cohorts, with no discontinuations due to Treatment-Emergent Adverse Events ("TEAEs"). No drug-related serious adverse events were reported. All but two TEAEs were classified as mild, with a single count of moderate back pain in the SAD cohort (assessed as unlikely related to treatment) and moderate headache in the MAD cohort (assessed as possibly related to treatment). No dose-dependent trend in the frequency or severity of TEAEs was observed. There were no electrocardiogram or lab findings of clinical relevance in any of the SAD cohorts and in the 75 mg and 150 mg MAD cohorts. In the 300 mg MAD cohort, QTc prolongation was observed in two subjects at Days 8 and 9, respectively. Both subjects were asymptomatic, and their QTc intervals returned to baseline levels and remained in the normal range after cessation of dosing. All subjects completed their scheduled study assessments.

Pharmacokinetics (PK)

A dose-proportional increase in exposure was observed through all SAD and MAD cohorts. PK data from the 75 mg and 150 mg MAD cohorts achieved maximum plasma concentrations (Cmax) and area under the concentration-time curve (AUC) values at or above the pharmacologically active exposure levels observed across multiple nonclinical autoimmune and inflammatory disease models. The PK data support once-daily oral dosing with FRTX-02. The time of maximum plasma FRTX-02 concentration (Tmax) occurred between 2.65 to 3.25 hours post-dose, and a plasma half-life of approximately 16.0 to 28.0 hours was observed at Day 14 in the 75 mg and 150 mg MAD cohorts, respectively. A minimal-to-moderate accumulation following once-daily oral administration of 75 mg and 150 mg FRTX-02 over 14 days was observed, and steady state plasma concentrations were attained before Day 14.

Pharmacodynamics (PD)

As part of an exploratory PD assessment, *ex vivo* lipopolysaccharide (LPS)-stimulated cytokine assays were conducted. FRTX-02 demonstrated a reduction in disease-relevant proinflammatory cytokines in whole blood, suggesting initial support for the FRTX-02 mechanism of action. Mean percent cytokine reduction from baseline after

14 days of once-daily 75 mg or 150 mg FRTX-02 treatment versus placebo were in the range of approximately 66% to 20% for IFNγ, IL-23, IL-10, IL-6, and TNFα. Additionally, maximum individual subject cytokine reductions from baseline were shown to be >90% for IFNγ, >50% for IL-23, IL-10 and TNFα, and approximately 40% for IL-6.

Business Update

On March 7, 2023, the Company provided the following business update:

As of March 1, 2023, the Company had cash and cash equivalents of approximately $5.3 million. The Company's Board of Directors and executive management have approved a comprehensive process to explore and evaluate strategic options to progress the development of its novel pipeline of potential treatments for autoimmune, inflammatory and other diseases. Potential strategic options to be explored or evaluated as part of this process may include, but are not limited to, a financing, sale or licensing of assets, acquisition, merger, business combination, and/or other strategic transaction or series of related transactions involving the Company. To continue developing FRTX-02 and the rest of its pipeline, the Company needs to raise additional funds.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press release issued by Fresh Tracks Therapeutics, Inc. on March 7, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Cautionary Note Regarding Forward-Looking Statements

Any statements made in this document and its attachment relating to future financial, business, and/or research and development, investigational, preclinical or clinical performance and potential, conditions, plans, prospects, impacts, shifts, trends, progress, or strategies and other such matters, including without limitation, Fresh Tracks' strategy; future operations; future potential; future financial position; future liquidity; future revenue; territorial focus; projected expenses; results of operations; the anticipated timing, scope, design, results, possible impact of, and/or reporting of data of ongoing and future nonclinical and clinical trials involving FRTX-02 and any other products; intellectual property rights, including the acquisition, validity, term, and enforceability of such; the expected timing and/or results of regulatory submissions and approvals; and prospects for treatment of patients and commercializing (and competing with) any product candidates for any disease by Fresh Tracks or third parties, or research and/or licensing collaborations with, or actions of, its partners, including in the United States, Japan, South Korea, or any other country, are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. In addition, when or if used in this document and its attachment, the words "may," "could," "should," "might," "show," "topline," "positive," "announce," "anticipate," "advance," "reflect," "believe," "estimate," "expect," "intend," "plan," "predict," "potential," "will," evaluate," "advance," "excited," "aim," "strive," "help," "progress," "meet," "support," "select," "initiate," "look forward," "promise," "provide," "commit," "best-in-class," "first-in-class," "standard-of-care," "on track," "opportunity," "disrupt," "reduce," "restore," "demonstrate," "suggest," "attenuate," "reinforce," "imply," "induce," "attain," "regulate," "dampen," "inhibit," "target," "shift," and similar expressions and their variants, as they relate to Fresh Tracks or any of Fresh Tracks' investigational products, partners, or third parties, may identify forward-looking statements. Fresh Tracks cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time, often quickly, and in unanticipated ways. Important factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including without limitation, research results and data that do not meet targets; study limitations, including small sample sizes and the enrollment of only healthy patients; data variability; expectations or regulatory approval requirements; ability to obtain adequate financing for (i) product development, (ii) clinical trials, (iii) regulatory submission(s), and (iv) any future commercialization; ability to acquire, maintain, and enforce global intellectual property rights; potential delays or alterations in (i) product development, (ii) trials of any type, and (iii) regulatory submission and reviews; changes in law or policy; litigation; regulatory agency actions; feedback, or requests; supply chain disruptions; unanticipated demands on cash resources; interruptions, disruption, or inability by Fresh Tracks, its partners, or third parties to obtain or supply (i) research material, (ii) raw materials, and/or (iii) product anywhere, or secure essential services, in the world; the outcome of and reaction to Fresh Tracks' current and planned preclinical and clinical trials across its portfolio of assets and for the SAD/MAD portion of the Phase 1 study on FRTX-02; the inability of third parties to achieve the regulatory and sales-based events under Fresh Tracks' agreements with them, or their lack of funds, resulting in Fresh Tracks not receiving additional or full payments due from them, especially related to the sale and assignment of Fresh Tracks' ownership of sofpironium bromide; and other risks associated with (i) developing and obtaining regulatory approval for, and

commercializing, product candidates, (ii) raising additional capital, and (iii) maintaining compliance with Nasdaq listing requirements.

Further information on the factors and risks that could cause actual results to differ from any forward-looking statements are contained in Fresh Tracks' filings with the United States Securities and Exchange Commission, which are available at https://www.sec.gov (or at https://www.frtx.com). The forward-looking statements represent the estimates of Fresh Tracks as of the date hereof only. Fresh Tracks specifically disclaims any duty or obligation to update forward-looking statements.

SIGNATURES

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

Date: March 7, 2023

Fresh Tracks Therapeutics, Inc.

By: /s/ Andrew D. Sklawer
Name: Andrew D. Sklawer
Title: President and Chief Executive Officer

Fresh Tracks Therapeutics Announces Positive Topline Results from Single and Multiple Ascending Dose Parts of Phase 1 Study of Oral DYRK1A Inhibitor FRTX-02

FRTX-02 was generally safe and well tolerated within the potential therapeutic dose range, meeting the study's primary objectives

Plasma concentrations within the potential therapeutic dose range were consistent with efficacious exposure levels established in nonclinical disease models and support once-daily oral dosing

Reduction in disease-relevant cytokines was observed in exploratory ex-vivo LPS-stimulated whole blood pharmacodynamic assays

Topline results support the continued development of FRTX-02 as a potential first-in-class, once-daily oral treatment for atopic dermatitis and/or other autoimmune diseases

Evaluating strategic options to further develop FRTX-02 and maximize shareholder value

BOULDER, CO — **March 7, 2023** — Fresh Tracks Therapeutics, Inc. ("Fresh Tracks" or the "Company") (Nasdaq: FRTX), a clinical-stage pharmaceutical company aiming to disrupt existing treatment paradigms by developing innovative and differentiated prescription therapeutics for the treatment of autoimmune, inflammatory, and other debilitating diseases, today announced positive topline results from the single ascending dose ("SAD") and multiple ascending dose ("MAD") parts of its Phase 1 clinical trial evaluating FRTX-02 in healthy subjects. FRTX-02 is a potent, highly selective, and orally bioavailable potential first-in-class DYRK1A inhibitor that aims to restore immune balance by modulating both adaptive and innate immune responses in patients with autoimmune and inflammatory diseases. In parallel, the Company's Board of Directors approved a comprehensive process to explore and evaluate strategic options to progress the development of its novel pipeline to maximize shareholder value.

"The results from Part 1 of the first-in-human Phase 1 study demonstrate the potential of FRTX-02 as a generally safe and well-tolerated, once-daily oral treatment for a broad range of autoimmune and inflammatory diseases," commented Andy Sklawer, President and Chief Executive Officer of Fresh Tracks. "This clinical trial marks the first time an oral DYRK1A inhibitor intended for patients with autoimmune diseases has entered the clinic, and these topline SAD and MAD data reinforce our enthusiasm for the continued development of FRTX-02 as a potential first-in-class therapy. However, to fully unlock the potential of the Company's pipeline considering our current capital resources, we have determined it is prudent for us to initiate a comprehensive review of strategic options with the goal of maximizing shareholder value as we look to advance the clinical development of FRTX-02 and progress our earlier-stage assets."

Dr. Bernard Khor, MD, PhD, Principal Investigator and Assistant Member at the Benaroya Research Institute for Translational Medicine and Affiliated Assistant Professor at the University of Washington, added, "I am encouraged by the results from the FRTX-02 Phase 1 SAD and MAD clinical study. These safety, pharmacokinetics ("PK") and exploratory pharmacodynamics ("PD") data expand our understanding of DYRK1A's potential as a promising, novel target with potential clinical utility that could have disease modifying effects in autoimmunity and inflammation. Furthermore, the results from this trial mark an important step forward for inhibition of the historically undruggable DYRK1A target and highlight the potential of FRTX-02 as a first-in-class, once-daily oral autoimmune therapy. I look forward to participating in the continued development of FRTX-02."

Study Design

The Phase 1 clinical trial of FRTX-02 is a two-part, randomized, double-blinded, placebo-controlled study designed to evaluate the safety, tolerability, PK, and PD of FRTX-02 capsules in both healthy subjects and

patients with atopic dermatitis ("AD"). Part 1A of the study was a SAD assessment, which enrolled a total of 56 healthy subjects across seven cohorts (single oral dose of 10 to 600 mg FRTX-02 or placebo). Part 1B of the study was a MAD assessment, which enrolled a total of 33 healthy subjects across three cohorts (75, 150 and 300 mg FRTX-02 or placebo, once-daily for 14 days). With Part 1 of the Phase 1 clinical trial completed, the Company intends to progress to Part 2 of the study, which will compare once-daily oral doses of FRTX-02 to placebo in subjects with moderate-to-severe AD and will include an exploratory evaluation of efficacy. Additional information on this clinical trial can be found on https://www.clinicaltrials.gov/ under identifier NCT05382819.

Safety

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Exploration of Strategic Options

In parallel with announcing the topline results from Part 1 of the Phase 1 study of FRTX-02, the Company's Board and executive management team have approved a comprehensive process to explore and evaluate strategic options to progress the development of its novel pipeline of potential treatments for autoimmune, inflammatory and other diseases with the goal of maximizing shareholder value. Potential strategic options to be explored or evaluated as part of this process may include, but are not limited to, a financing, sale or licensing of assets, acquisition, merger, business combination, or other strategic transaction or series of related transactions involving the Company. Fresh Tracks does not expect to disclose developments with respect to this process until the evaluation of strategic options has been completed or until the Board of Directors has concluded disclosure is appropriate or legally required. MTS Health Partners, LP has been retained as the Company's exclusive financial advisor to assist in this review process.

About FRTX-02

FRTX-02 is a potent, highly selective, and orally bioavailable potential first-in-class dual specificity tyrosine-phosphorylation-regulated kinase 1A (DYRK1A) inhibitor that currently is being evaluated in a first-in-human Phase 1 clinical trial and has shown promising results in various preclinical models, including of AD and rheumatoid arthritis. In these preclinical models, decreases in disease severity and reduction of pro-inflammatory cytokines were reported compared to certain current standard-of-care agents,

such as janus kinase (JAK) inhibitors and anti-tumor necrosis factor (TNF) biologics. Notably, many current therapies for autoimmune disorders are broadly immunosuppressant, which may lead to severe side effects, such as increased infection risk. Preclinical data suggest that FRTX-02 may drive regulatory T-cell differentiation while dampening pro-inflammatory T-helper-cells and MyD88/IRAK4-related signaling pathways. Regulatory T cells serve to maintain tolerance and keep the autoreactive, pro-inflammatory T cells in check, thus decreasing the likelihood of autoimmune disease and limiting chronic inflammation. The MyD88 protein normally is spliced into a long form and a short form. The long form of MyD88 drives inflammation via pathways related to IRAK4, a protein kinase involved in signaling immune responses from toll-like receptors, while the short form of MyD88 limits IRAK4 phosphorylation and its respective downstream signaling pathway. DYRK1A inhibition shifts the balance to produce more MyD88 short form, which leads to deactivation of the downstream release of several pro-inflammatory cytokines. Based on current understanding, inhibition of this release of excess cytokines can be achieved by re-establishing the role of MyD88 short form as a negative regulator of this pathway. Unlike many existing therapies for autoimmune diseases, as well as the majority of those currently being investigated, FRTX-02 may have the ability to target both adaptive and innate immune imbalances simultaneously, resulting in potential restoration of immune homeostasis that, if proven, could represent a paradigm shift in the treatment of certain autoimmune and inflammatory diseases.

About Fresh Tracks Therapeutics

Fresh Tracks Therapeutics is a clinical-stage pharmaceutical company striving to transform patient lives through the development of innovative and differentiated prescription therapeutics. The Company's pipeline aims to disrupt existing treatment paradigms and features several new chemical entities that inhibit novel targets with first-in-class potential for autoimmune, inflammatory, and other debilitating diseases. This includes FRTX-02, a potent, highly selective, and orally bioavailable potential first-in-class DYRK1A inhibitor that currently is being evaluated in a first-in-human Phase 1 clinical trial, FRTX-10, a novel, preclinical-stage oral STING inhibitor, and a platform of next-generation DYRK, LRRK2, TTK, and CLK inhibitors. Fresh Tracks' executive management team and Board have a proven track record of leadership across early-stage research, product development, and global commercialization, having served in leadership roles at large global pharmaceutical and biotech companies that successfully developed and launched first-in-class and/or iconic products, including Cialis®, Gemzar®, Prozac®, Cymbalta®, Juvederm®, Pluvicto®, and sofpironium bromide. The Company's strategy is to align this experience and clear vision to explore beyond the limitations of current therapies by identifying, pursuing, and developing next-generation therapeutics that can be groundbreaking in their ability to help millions of people struggling with autoimmune, inflammatory, and other debilitating diseases. For more information, visit https://www.frtx.com.

Cautionary Note Regarding Forward-Looking Statements

Any statements made in this press release relating to future financial, business, and/or research and development, investigational, preclinical or clinical performance and potential, conditions, plans, prospects, impacts, shifts, trends, progress, or strategies and other such matters, including without limitation, Fresh Tracks' strategy; future operations; future potential; future financial position; future liquidity; future revenue; territorial focus; projected expenses; results of operations; the anticipated timing, scope, design, results, possible impact of, and/or reporting of data of ongoing and future nonclinical and clinical trials involving FRTX-02 and any other products ; intellectual property rights, including the acquisition, validity, term, and enforceability of such; the expected timing and/or results of regulatory submissions and approvals; and prospects for treatment of patients and commercializing (and competing with) any product candidates for any disease by Fresh Tracks or third parties, or research and/or licensing collaborations with, or actions of, its partners, including in the United States, Japan, South Korea, or any other country, are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words "may," "could," "should," "might," "show," "topline," "positive," "announce," "anticipate," "advance," "reflect," "believe," "estimate," "expect," "intend," "plan," "predict," "potential," "will," evaluate," "advance," "excited," "aim," "strive," "help," "progress," "meet," "support," "select," "initiate," "look forward," "promise," "provide," "commit," "best-in-class," "first-in-class," "standard-of-care," "on track," "opportunity," "disrupt," "reduce," "restore," "demonstrate," "suggest," "attenuate," "reinforce," "imply," "induce," "attain," "regulate," "dampen," "inhibit," "target," "shift," and similar expressions and their variants, as they relate to Fresh Tracks or any of Fresh Tracks' investigational products, partners, or third parties, may identify forward-looking statements. Fresh Tracks cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time, often quickly, and in unanticipated ways. Important factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including without limitation, research results and data that do not meet targets;

study limitations, including small sample sizes and the enrollment of only healthy patients; data variability; expectations or regulatory approval requirements; ability to obtain adequate financing for (i) product development, (ii) clinical trials, (iii) regulatory submission(s), and (iv) any future commercialization; ability to acquire, maintain, and enforce global intellectual property rights; potential delays or alterations in (i) product development, (ii) trials of any type, and (iii) regulatory submission and reviews; changes in law or policy; litigation; regulatory agency actions; feedback, or requests; supply chain disruptions; unanticipated demands on cash resources; interruptions, disruption, or inability by Fresh Tracks, its partners, or third parties to obtain or supply (i) research material, (ii) raw materials, and/or (iii) product anywhere, or secure essential services, in the world; the outcome of and reaction to Fresh Tracks' current and planned preclinical and clinical trials across its portfolio of assets and for the SAD/MAD portion of this Phase 1 study on FRTX-02; the inability of third parties to achieve the regulatory and sales-based events under Fresh Tracks' agreements with them, or their lack of funds, resulting in Fresh Tracks not receiving additional or full payments due from them, especially related to the sale and assignment of Fresh Tracks' ownership of sofpironium bromide; and other risks associated with (i) developing and obtaining regulatory approval for, and commercializing, product candidates, (ii) raising additional capital, and (iii) maintaining compliance with Nasdaq listing requirements.

Further information on the factors and risks that could cause actual results to differ from any forward-looking statements are contained in Fresh Tracks' filings with the United States Securities and Exchange Commission, which are available at https://www.sec.gov (or at https://www.frtx.com). The forward-looking statements represent the estimates of Fresh Tracks as of the date hereof only. Fresh Tracks specifically disclaims any duty or obligation to update forward-looking statements.

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