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) November 10, 2022

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 2.02. Results of Operations and Financial Condition.

On November 10, 2022, Fresh Tracks Therapeutics, Inc. issued a press release reporting, among other things, its financial results for the three and nine months ended September 30, 2022. A copy of the press release is attached as Exhibit 99.1 to this Current Report.

The information in this Item 2.02, and Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by Fresh Tracks Therapeutics, Inc. on November 10, 2022

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 10, 2022

Fresh Tracks Therapeutics, Inc.

By: /s/ Robert B. Brown
Name: Robert B. Brown
Title: Chief Executive Officer

Fresh Tracks Therapeutics Reports Third Quarter 2022 Financial Results and Provides Corporate Update

Phase 1 study of FRTX-02 progressing well, with the SAD portion complete and MAD portion underway

Remain on track to report SAD and MAD topline results from the Phase 1 study of FRTX-02 by early 2023

Advancing the development of FRTX-10 through early preclinical stage studies

BOULDER, CO — **November 10, 2022** — Fresh Tracks Therapeutics, Inc. (the "Company" or "Fresh Tracks") (Nasdaq: FRTX), a clinical-stage pharmaceutical company striving to transform patient lives by developing innovative and differentiated prescription therapeutics for the treatment of autoimmune, inflammatory, and other debilitating diseases, today announced financial results for the third quarter ended September 30, 2022 and provided a corporate update.

"This year has been a transformational period for our company, as we executed a fundamental shift in strategy via the acquisition and development of a pipeline of new chemical entities targeting novel mechanisms of action for the treatment of a broad array of autoimmune and inflammatory diseases. To better align with our new strategic vision and plans, we recently rebranded the Company to Fresh Tracks Therapeutics," commented Robert Brown, Chief Executive Officer of Fresh Tracks. "This rebrand highlights our commitment to develop targeted, science-driven therapies, such as FRTX-02, our potential first-in-class oral DYRK1A inhibitor that is currently being evaluated in a Phase 1 clinical trial. We are pleased with the progress in this first-in-human study and remain on track to report topline results by early 2023."

Research and Development Highlights

FRTX-02*: a potential first-in-class DYRK1A inhibitor for the treatment of autoimmune and inflammatory diseases*

- Continue to progress the Phase 1 clinical trial of FRTX-02, which is a randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of FRTX-02 capsules in both healthy subjects and patients with atopic dermatitis ("AD"). Part 1A of the study is a single ascending dose ("SAD") assessment, which enrolled a total of 56 healthy volunteers at one study center across seven cohorts, each of which included six subjects receiving a single dose of FRTX-02 and two subjects receiving a placebo. Part 1B of the study is a multiple ascending dose ("MAD") assessment of FRTX-02 or placebo in healthy adult subjects. In the MAD assessment, up to 33 healthy volunteers are being enrolled across three cohorts, each of which includes nine subjects who receive FRTX-02 and two subjects who receive a placebo once daily for 14 days. After completing Part 1, the Company intends to initiate Part 2 of the study, which will compare FRTX-02 to placebo in patients with moderate-to-severe AD over 28 days of treatment and will include a preliminary assessment of efficacy. Additional information on this clinical trial can be found on www.clinicaltrials.gov under identifier NCT05382819.
    - Completed all SAD cohorts and initiated MAD part of the study in September 2022.
    - On track to report topline results from the SAD and MAD parts of the Phase 1 study by early 2023.
    - Progressing FRTX-02 nonclinical development program in parallel with the ongoing Phase 1 study.

FRTX-10*: a covalent Stimulator of Interferon Genes (STING) inhibitor candidate for the potential treatment of autoimmune, inflammatory, and rare genetic diseases*

- Preclinical development activities for FRTX-10 are underway.

Next-Generation Kinase Inhibitors*: a cutting-edge platform with the potential to produce treatments for autoimmune, inflammatory, and other debilitating diseases*

- The Company is planning to identify and characterize both brain penetrant and non-brain penetrant new chemical entities from this next-generation kinase inhibitor platform that specifically inhibit LRRK2, TTK, and CLK kinases.

- A number of these drug candidates have the potential to penetrate the blood-brain barrier, presenting an opportunity to address neuroinflammatory conditions of high unmet need, such as Down Syndrome, Alzheimer's Disease, and Parkinson's Disease, while other peripherally acting novel LRRK2, TTK, and CLK kinase inhibitors could be developed in additional therapeutic areas within autoimmunity, inflammation, and oncology.

Recent Corporate Highlights

Scientific Advisory Board

In September 2022, Fresh Tracks announced the formation of a Scientific Advisory Board ("SAB") consisting of five renowned scientists and clinicians with deep experience across immunology and inflammation, including Drs. Kate Fitzgerald, Bernard Khor, Pui Lee, Peter Nigrovic, and Bridget Wagner. The SAB members are offering their expertise and guidance to the Company as it develops its novel pipeline of differentiated therapies for the treatment of autoimmune and inflammatory diseases, including FRTX-02, FRTX-10, and next-generation kinase inhibitor platform.

Sofpironium Bromide

In the second quarter of 2022, Fresh Tracks entered into an asset purchase agreement ("APA") with Botanix SB Inc. ("Botanix"). Under the terms of the APA, Botanix acquired and assumed control of rights, title, and interests to assets primarily related to the proprietary compound sofpironium bromide in exchange for an upfront fee, near-term regulatory milestone payments, and sales-based milestone payments, as well as tiered earnout payments on net sales of sofpironium bromide gel. In connection with the sale of sofpironium bromide, Fresh Tracks and Botanix entered into a transition services agreement ("TSA") whereby Fresh Tracks is providing consulting services to Botanix as an independent contractor in support of and through filing and potential approval of a U.S. new drug application ("NDA") for sofpironium bromide gel, 15%.

In September 2022, Botanix submitted an NDA for sofpironium bromide gel, 15% to the U.S. Food and Drug Administration ("FDA"). If the FDA accepts the NDA for filing, Fresh Tracks will receive a milestone payment of $2.0 million from Botanix. On November 10, 2022, Fresh Tracks paid its former licensor of sofpironium bromide $1.0 million in cash in lieu of issuing $1.0 million in shares of its common stock as originally provided for in the license agreement.

Third Quarter 2022 Financial Results

The Company reported cash and cash equivalents of $11.3 million as of September 30, 2022, compared to $26.9 million as of December 31, 2021. The Company expects its cash and cash equivalents as of September 30, 2022, combined with $6.0 million from expected near-term payments under the APA with Botanix, will be sufficient to fund its operations for at least the next 12 months.

Revenue was $0.5 million for the third quarter of 2022, compared to $0.1 million for the third quarter of 2021. Revenue for the three months ended September 30, 2022 consisted of contract revenue recognized under the APA and TSA with Botanix, while revenue for the three months ended September 30, 2021 was driven by royalty revenue earned on a percentage of net sales of ECCLOCK® (sofpironium bromide gel, 5%) in Japan under the Kaken agreement. Contract revenue for the three months ended September 30, 2022 consisted of fees for consulting services the Company provided to Botanix under the TSA of $0.4 million and sublicense income under the APA of $0.1 million.

Research and development expenses were $3.6 million for the third quarter of 2022, compared to $10.2 million for the third quarter of 2021, which decrease was driven primarily by lower clinical expenses related to sofpironium bromide, upfront license expense incurred in the third quarter of 2021 under the license agreement with Voronoi Inc., and lower regulatory and compliance fees, partially offset by increased clinical costs for FRTX-02. Throughout 2021, the Company was executing its U.S. Phase 3 pivotal clinical program for sofpironium bromide gel, 15%, which concluded in the fourth quarter of 2021. During the second quarter of 2022, the Company initiated its Phase 1 clinical trial for FRTX-02 and began incurring research and development expenses related to the clinical trial.

General and administrative expenses were $3.0 million for the third quarter of 2022, compared to $3.3 million for the third quarter of 2021. The decrease was primarily related to lower expenses incurred in the third quarter of 2022 associated with compensation and other administrative fees.

The Company's net loss was $6.0 million for the third quarter of 2022 compared to $13.3 million for the third quarter of 2021.

Conference Call and Webcast Information

Fresh Tracks' management will host a conference call today at 4:30 p.m. EDT to discuss the financial results and recent corporate developments. The dial-in number for the conference call is 1-877-407-3982 for domestic participants and 1-201-493-6780 for international participants, with Conference ID #: 13732536. A live webcast of the conference call can be accessed at (https://viavid.webcasts.com/starthere.jsp?ei=1566730&tp_key=49e1233eb2) or through the Investors section of Fresh Tracks' website at https://ir.frtx.com/events. A replay will be available on this website shortly after conclusion of the event for approximately 90 days.

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. Fresh Tracks' executive management team and board of directors 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/or launched first-in-class products, some of which have achieved iconic status, including Cialis®, Taltz®, 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 investigational, preclinical, or clinical performance, conditions, plans, prospects, trends, 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, progress, results, possible impact of, and/or reporting of data of ongoing and future nonclinical and clinical trials; 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 commercializing (and competing with) any product candidates of 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," "announce," "anticipate," "advancing," "reflect," "believe," "estimate," "expect," "intend," "plan," "predict," "potential," "will," evaluate," "advance," "excited," "aim," "strive," "help," "progress," "select," "initiate," "look forward," "promise," "provide," "commit," "best-in-class," "first-in-class," "on track," "opportunity," 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, expectations or regulatory approval requirements; ability to obtain adequate financing for product development, regulatory submissions, and any commercialization; ability to acquire, maintain and enforce intellectual property rights; potential delays or alterations in product development, trials of any type, and regulatory submission and reviews; changes in law or policy; litigation, regulatory agency actions, feedback, or requests; supply chain disruptions; unanticipated demands on cash resources; disruptions and negative effects related to the COVID-19 pandemic and the conflict in Ukraine; interruptions, disruption, or inability by Fresh Tracks, its partners or third parties to obtain or supply research material, raw materials, and/or product anywhere, or secure essential services, in the world; efforts to obtain and retain adequate pricing and adequate reimbursement and other insurance coverage for Fresh Tracks' future products; the outcome of and reaction to Fresh Tracks' current and planned preclinical and clinical trials across its portfolio of assets; 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; 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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Fresh Tracks Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue				
Contract revenue	$ 486	$ —	$ 4,801	$ —
Royalty revenue	—	132	92	300
Total revenue	486	132	4,893	300
Operating expenses:				
Research and development	3,560	10,222	11,438	25,112
General and administrative	3,002	3,269	10,396	9,127
Total operating expenses	6,562	13,491	21,834	34,239
Loss from operations	(6,076)	(13,359)	(16,941)	(33,939)
Other income	58	107	372	597
Interest expense	—	(1)	(6)	(65)
Net loss attributable to common stockholders	$ (6,018)	$ (13,253)	$ (16,575)	$ (33,407)
Net loss per common share attributable to common stockholders, basic and diluted	$ (2.07)	$ (7.15)	$ (6.05)	$ (21.19)
Weighted-average shares used to compute net loss per common share attributable to common stockholders, basic and diluted	2,906,000	1,852,851	2,738,954	1,576,869

Fresh Tracks Therapeutics, Inc.
Selected Financial Information
Condensed Consolidated Balance Sheet Data
(amounts in thousands)
(unaudited)

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 11,250	$ 26,884
Prepaid expenses and other current assets	3,021	2,716
Total assets	14,447	29,717
Total liabilities	3,224	4,810
Total stockholders' equity	11,223	24,907