
**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) **May 10, 2023**

FRESH TRACKS THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-21088
(Commission File
Number)

93-0948554
(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 May 10, 2023, Fresh Tracks Therapeutics, Inc. issued a press release reporting, among other things, its financial results for the three months ended March 31, 2023 and provided a corporate update. 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 May 10, 2023

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: May 10, 2023

Fresh Tracks Therapeutics, Inc.

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



Fresh Tracks Therapeutics Reports First Quarter 2023 Financial Results and Provides Corporate Update

Reported positive topline results from SAD and MAD parts of Phase 1 study of lead DYRK1A inhibitor FRTX-02 in March 2023

Ongoing evaluation of strategic options to further develop FRTX-02 and maximize shareholder value

Strengthened balance sheet with aggregate net proceeds of \$6.6 million raised under an ATM program in March 2023

BOULDER, CO — **May 10, 2023** — 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 first quarter ended March 31, 2023 and provided a corporate update.

“We continue to be excited about our lead program, FRTX-02, which is a potential first-in-class DYRK1A inhibitor. During the first quarter, we reported topline data from Part 1 of a two-part Phase 1 study of FRTX-02 that showed its potential as a generally safe and well-tolerated, once-daily oral treatment for a broad range of autoimmune and inflammatory diseases,” commented Andrew Sklawer, President and Chief Executive Officer of Fresh Tracks. “Our current cash resources will support our operations as we continue to evaluate strategic options to progress the development of our novel pipeline, with the goal of maximizing shareholder value.”

Research and Development Highlights

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

- Announced in March 2023 positive topline results from Part 1 of a two-part 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 healthy subjects, including single and multiple ascending dose assessments of FRTX-02 or placebo in healthy adult subjects.
- 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.

FRTX-10: a covalent STING inhibitor for the potential treatment of autoimmune, inflammatory, and rare genetic diseases

- Continued to progress the preclinical IND-enabling development activities of FRTX-10.

Recent Corporate Highlights

Evaluation of Strategic Options

As previously announced in March 2023, the Company’s board of directors (“Board”) and executive management team have approved and are conducting 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, and/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 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.

Sales of Common Stock

In March 2023, the Company sold approximately 2.9 million shares of its common stock under an At-The-Market (ATM) program at a weighted-average price of approximately \$2.34 per share, for aggregate net proceeds of approximately \$6.6 million.

Sofpironium Bromide

In December 2022, the U.S. Food and Drug Administration (“FDA”) accepted the U.S. new drug application (“NDA”) submission by Botanix SB Inc. (“Botanix”) for sofipironium bromide gel, 15%. In April 2023, Botanix announced the successful completion of its FDA mid-cycle review for sofipironium bromide gel, 15%. The FDA communicated to Botanix that no significant issues were identified as part of the review process, including no major clinical safety issues or risk management issues, and that there are no complex regulatory issues that might warrant an advisory committee meeting discussion. Botanix has communicated that it believes FDA approval remains on track for September 2023. If FDA approval is received, Fresh Tracks will be due the next milestone payment (\$4.0 million if received before September 30th, less if received thereafter).

First Quarter 2023 Financial Results

The Company reported cash and cash equivalents of \$10.8 million as of March 31, 2023, compared to \$8.7 million as of December 31, 2022. The Company expects its cash and cash equivalents as of March 31, 2023 will be sufficient to fund its operations for at least the next 12 months.

Revenue was \$9 thousand for the first quarter of 2023, compared to \$92 thousand for the first quarter of 2022. Revenue in 2023 primarily consisted of contract revenue recognized for services provided under a transition services agreement with Botanix, while revenue in 2022 was driven by royalty revenue earned on a percentage of net sales of ECCLOCK® (sofipironium bromide gel, 5%) in Japan under a licensing agreement with Kaken Pharmaceutical Co., Ltd.

Research and development expenses were \$1.9 million for the first quarter of 2023, compared to \$6.0 million for the first quarter of 2022. The decrease in research and development expenses of \$4.1 million was driven primarily by lower clinical expenses of \$2.2 million related to sofipironium bromide, decreased costs of \$1.9 million related to our STING inhibitor program, and lower personnel and other unallocated expenses of \$0.2 million, partially offset by increased costs of \$0.2 million related to our DYRK1A inhibitor program.

General and administrative expenses were \$2.4 million for the first quarter of 2023, compared to \$3.5 million for the first quarter of 2022. The decrease of \$1.1 million was primarily related to decreased expenses in the 2023 period of \$0.6 million for legal and compliance fees, \$0.3 million for other expenses, and \$0.2 million for compensation-related expenses.

The Company’s net loss was \$4.3 million for the first quarter of 2023 compared to \$9.4 million for the first quarter of 2022.

No Quarterly Conference Call

In consideration of the Board and management team’s ongoing process of exploring and evaluating strategic options to progress the development of the Company’s novel pipeline, Fresh Tracks’ management has decided not to host a conference call to discuss its first quarter 2023 financial results. Additional details regarding the financial results for the first quarter 2023 and corporate update can be found in the Company’s Quarterly Report on Form 10-Q.

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 dual-specificity tyrosine phosphorylation regulated kinase 1A (DYRK1A) inhibitor that is currently being evaluated in a first-in-human Phase 1 clinical trial, FRTX-10, a novel, preclinical-stage oral Stimulator of Interferon Genes (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/or launched first-in-class products, some of which have achieved iconic status, including Cialis®, Taltz®, Gemzar®, Prozac®, Cymbalta®, Juvederm®, Pluvicto®, and sofipironium 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; the expected receipt of contingent payments and the timing thereof; 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," "imply," "induce," "regulate," "dampen," "target," "shift," "disrupt," "restore," "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 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 or delay 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 sofipironium 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.

Fresh Tracks Therapeutics, Inc.

Investor Contact:

Dan Ferry
LifeSci Advisors
(617) 430-7576
daniel@lifesciadvisors.com

Fresh Tracks Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2023	2022
Revenue		
Contract revenue	\$ 9	\$ —
Royalty revenue	—	92
Total revenue	9	92
Operating expenses:		
Research and development	1,936	6,013
General and administrative	2,414	3,486
Total operating expenses	4,350	9,499
Loss from operations	(4,341)	(9,407)
Other income	68	1
Interest expense	(3)	(4)
Net loss attributable to common stockholders	\$ (4,276)	\$ (9,410)
Net loss per common share attributable to common stockholders, basic and diluted	\$ (1.14)	\$ (3.55)
Weighted-average shares used to compute net loss per common share attributable to common stockholders, basic and diluted	3,756,613	2,652,828

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

	March 31, 2023	December 31, 2022
Cash and cash equivalents	\$ 10,764	\$ 8,680
Prepaid expenses and other current assets	1,049	1,403
Total assets	11,967	10,271
Total liabilities	2,101	3,077
Total stockholders' equity	9,866	7,194