UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(mark one)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission File Number: 000-21088

FRESH TRACKS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**93-0948554**
(State or other jurisdiction of incorporation or organization)	(I.R.S. 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**

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, $0.01 par value per share	FRTX	The Nasdaq Stock Market LLC

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, based upon the closing sale price of the registrant 's common stock on June 30, 2022, as reported on The Nasdaq Capital Market, was $14.9 million. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 23, 2023, there were 5,906,475 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2023 annual meeting of stockholders (the "2023 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K ("Annual Report") where indicated.

FRESH TRACKS THERAPEUTICS, INC.
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RISK FACTORS SUMMARY

Our business, financial condition, and operating results may be affected by a number of factors, whether currently known or unknown. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, let alone combined with any of the others, could materially and adversely affect our business, financial condition, results of operations, and stock price. We have provided a summary of some of these risks below, with a more detailed explanation of those and other risks applicable to the Company in Part I, Item 1A. "Risk Factors" in this Annual Report.

- We will need to raise substantial additional financing to fund our operations, including to continue developing our lead development-stage program and the rest of our pipeline, which financing may not be available to us on favorable terms or at all.
- Our business depends on the successful continued financing, nonclinical and clinical development, regulatory approval, and commercialization of our pipeline assets.
- Clinical drug development for our pipeline assets is expensive, time-consuming, and uncertain. Any data resulting from our trials may not be favorable for further development.
- Our inability to regain and maintain compliance with continued listing requirements of The Nasdaq Stock Market LLC ("Nasdaq") could result in the delisting of our common stock.
- We have sponsored or supported and may sponsor or support future clinical trials for our product candidates outside the U.S., and the U.S. Food and Drug Administration ("FDA") and applicable foreign regulatory authorities may not accept data from such trials; in addition, we may not be allowed alone or with local country business partners to obtain regulatory approval for our product candidates without first conducting clinical trials in each of these other countries.
- We recently announced that we are exploring strategic options that could include a financing, sale or licensing of assets, acquisition, merger, business combination, and/or other strategic transaction or series of related transactions. There can be no assurance that this process will result in the pursuit or consummation of any potential transaction or strategy, or that any such potential transaction or strategy, if implemented, will provide sufficient funding to conduct certain additional research and development activities and/or initiate additional clinical trials of our product candidates.
- We rely and expect to continue to rely on third-party contractors for supply, manufacture, and distribution of preclinical or clinical supplies of any current or future product candidates.
- We may not be able to obtain, afford, maintain, enforce, or protect our intellectual property rights covering our product candidates and related technologies, that are of sufficient type, breadth, and term throughout the world.
- If we fail to comply with our obligations under our intellectual property and related license agreements, we could lose license rights that are important to our business. Additionally, these agreements may be subject to disagreement over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology, or other key aspects of product development and/or commercialization, or increase our financial or other obligations to our licensors.
- Our receipt of future payments from Botanix SB Inc. ("Botanix") is contingent on various factors outside of our control, including the successful development, regulatory approval, and commercialization of sofpironium bromide gel, 15%, by Botanix outside of Japan, the successful continued commercialization of sofpironium bromide gel, 5% ("ECCLOCK®") by Kaken Pharmaceutical Co., Ltd. ("Kaken") in Japan, and the sufficiency of funds to pay us and Bodor Laboratories, Inc. ("Bodor"), the licensor of this product.

PART I.

FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this Annual Report other than statements of historical fact, including statements 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, our strategy; future operations; future potential; future financial position; future liquidity; future revenue and payments of any type; 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 ("U.S."), Japan, South Korea, or any other country, or business development activities with other potential partners. 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," "looking forward," "promise," "provide," "commit," "best-in-class," "first-in-class," and similar expressions and their variants, are intended to identify forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors. Unless otherwise mentioned or unless the context requires otherwise, all references in this Annual Report to "Fresh Tracks," "Brickell Subsidiary," "Company," "we," "us," and "our," or similar references, refer to Fresh Tracks Therapeutics, Inc. and its consolidated subsidiaries.

We based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and business development activities, pipeline legal status, short-term and long-term business operations and objectives, employees, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in Part I, Item 1A, "Risk Factors" in this Annual Report and under a similar heading in any other periodic or current report we may file with the U.S. Securities and Exchange Commission (the "SEC") in the future. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge quickly and from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business and operations or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the future events and trends discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

You should read carefully the factors described in Part I, Item 1A, "Risk Factors" in this Annual Report to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are advised to consult any further disclosures we make on related subjects in our future public filings and on our website.

ITEM 1. BUSINESS

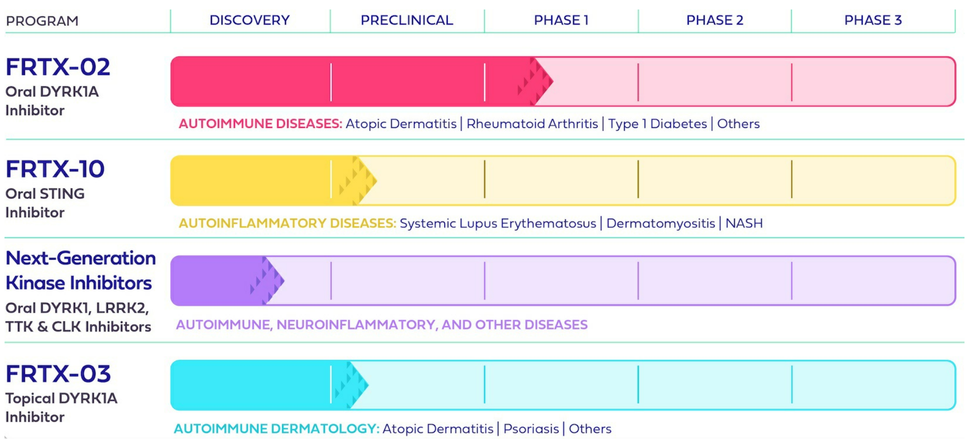
We are a clinical-stage pharmaceutical company striving to transform patient lives through the development of innovative and differentiated prescription therapeutics. Our pipeline aims to disrupt existing treatment paradigms and features several new chemical entities that inhibit novel targets with first-in-class potential for autoimmune, inflammatory, and other debilitating diseases. Our executive management team and board of directors (our "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 sofpironium bromide. Our 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.

On September 7, 2022, we changed our corporate entity name from Brickell Biotech, Inc. to Fresh Tracks Therapeutics, Inc. and updated our logo, website, and branding elements to reflect the new name. We also updated our product candidate names accordingly, for instance BBI-02 became FRTX-02 and BBI-10 became FRTX-10.

Exploration of Strategic Options

Our Board and executive management team are conducting a comprehensive process to explore and evaluate strategic options to progress the development of our 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 our Company. MTS Health Partners, LP has been retained as our exclusive financial advisor to assist in this review process.

The following image summarizes our current pipeline and corresponding development programs:



Research & Development Programs

FRTX-02: A Potential First-in-Class Oral DYRK1A Inhibitor for the Treatment of Autoimmune and Inflammatory Diseases

FRTX-02, a novel, potent, highly selective, and orally bioavailable potential first-in-class, small molecule DYRK1A inhibitor that aims to restore immune balance in patients whose immune systems have become dysregulated. We believe FRTX-02 has the potential to be a first-in-class therapy for the treatment of a wide array of debilitating autoimmune and inflammatory diseases.

FRTX-02 is our lead development-stage program and has demonstrated promising results in various preclinical models, including of atopic dermatitis (“AD”) and rheumatoid arthritis. In these models, FRTX-02 showed encouraging decreases in disease severity and reduction of pro-inflammatory cytokines compared to 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 immunosuppressive, which may lead to severe side effects, such as increased infection risk. Preclinical data have shown FRTX-02 to drive regulatory T-cell differentiation while dampening pro-inflammatory T_H17 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 inhibiting autoimmune disease and limiting chronic inflammation. The myeloid differentiation primary response 88 (“MyD88”) protein is normally 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 certain pro-inflammatory cytokines. Based on current understanding, this inhibition of the 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, as well as those currently being investigated, FRTX-02 may have the ability to target both the adaptive and innate immune imbalance simultaneously, potentially resulting in, or substantially achieving, restoration of immune homeostasis that, if proven, would represent a paradigm shift in the treatment of certain autoimmune and inflammatory diseases.

In May 2022, we initiated a first-in-human Phase 1 clinical trial for FRTX-02 (“FRTX-02-101”) in Canada, which marks the first time an oral DYRK1A inhibitor intended for patients with autoimmune diseases has been administered in humans. FRTX-02-101 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 AD. Parts 1A and 1B of the Phase 1 clinical trial were completed in the fourth quarter of 2022, and in March 2023, we reported positive topline results described in greater detail below. Part 2 of the study is planned to compare once-daily oral doses of FRTX-02 to placebo in subjects with moderate-to-severe AD and include an exploratory evaluation of efficacy. Part 2 is expected to enroll approximately 40 patients at up to 12 study centers.

FRTX-02 is covered by a composition of matter patent issued in the U.S., Japan, China, and other key countries through at least 2038, subject to patent term extensions and adjustments that may be available depending on how this early-stage asset is developed, as well as a pending Patent Cooperation Treaty (“PCT”) application, and other foreign and U.S. applications for FRTX-02, as of the date of this Annual Report.

FRTX-10: A covalent Stimulator of Interferon Genes (STING) inhibitor candidate for the Potential Treatment of Autoimmune, Inflammatory, and Rare Genetic Diseases

In February 2022, we acquired exclusive, worldwide rights to research, develop, and commercialize a portfolio of novel, preclinical-stage oral Stimulator of Interferon Genes (“STING”) inhibitors. STING is a well-known mediator of innate immune responses. Excessive signaling through STING is linked to numerous high unmet-need diseases, ranging from autoimmune disorders, such as systemic lupus erythematosus, to interferonopathies, which are a set of rare genetic conditions characterized by interferon overproduction and could have orphan drug potential.

STING is a key component of the cyclic GMP-AMP synthase (“cGAS”)-STING pathway, which plays an important role in the activation of innate immunity. cGAS acts as a DNA sensor, detecting DNA from sources such as invading bacteria, viruses, and cellular debris that can arise from aging and tissue damage. Upon DNA binding, cGAS produces the secondary messenger molecule cyclic GMP-AMP (“cGAMP”), which binds to STING. STING then undergoes the post-translational modification called palmitoylation, a step essential to the activation of STING. Activated STING then in turn activates the recruitment of kinases that phosphorylate IRF3 and IκBα. Phosphorylated IRF3 leads to activation of the type I interferon response, while phosphorylated IκBα activates NFκB and increases the secretion of pro-inflammatory cytokines such as IL-6 and TNFα, resulting in inflammation. While the innate immune response is an important defense mechanism, a dysregulated type I interferon response and overproduction of pro-inflammatory cytokines also represents a driving cause of multiple autoimmune and inflammatory diseases. As such, targeting the cGAS-STING pathway through STING inhibition may be a novel approach to treating these diseases.

FRTX-10, our lead early-stage STING inhibitor candidate, is a novel, potent, and orally bioavailable covalent STING inhibitor that specifically targets the palmitoylation site of STING. This allows it to inhibit both wild-type STING and gain-of-function mutants without competing with cGAMP binding, thus deactivating downstream signaling through IRF3 and IκBα and ultimately suppressing inflammation. FRTX-10 has exhibited strong proof-of mechanism and a promising profile in initial pharmacokinetics, toxicology, and safety pharmacology studies. In addition, *in vitro* studies show that FRTX-10 more potently blocks the STING pathway compared to other known STING palmitoylation inhibitors, and that mice treated with FRTX-10 *in vivo* demonstrate significant decreases in production of key pro-inflammatory cytokines following stimulation of STING.

For FRTX-10, as of the date of this Annual Report, we currently have two pending PCT applications and pending applications in the U.S., Japan, Europe, and other key countries. We possess an exclusive license directed to a library of compounds targeting/inhibiting STING, pharmaceutical compositions containing the same, and methods of their use, which are being evaluated.

Next-Generation Kinase Inhibitors: A Cutting-Edge Platform with the Potential to Produce Treatments for Autoimmune, Inflammatory, and Other Debilitating Diseases

In August 2021, we acquired exclusive global rights to a cutting-edge platform of next-generation kinase inhibitors. This library of new chemical entities includes next-generation DYRK1 inhibitors, as well as other molecules that specifically inhibit Leucine-Rich Repeat Kinase 2 (“LRRK2”), CDC2-like kinase (“CLK”), and TTK protein kinase (“TTK”), also known as Monopolar spindle 1 (Mps1) 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.

Compounds from the next-generation kinase inhibitor platform are covered by U.S. and foreign composition of matter patent applications, as well as other applications, that are currently pending in global prosecution.

Topline Results of FRTX-02 (Phase 1 Part A and B) Clinical Trial

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, and pharmacodynamics of FRTX-02 capsules in both healthy subjects and patients with AD. Part 1A of the study was a single ascending dose ("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 multiple ascending dose ("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 is planned to compare once-daily oral doses of FRTX-02 to placebo in subjects with moderate-to-severe AD and include an exploratory evaluation of efficacy.

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.

Competition

Our industry is highly competitive and subject to rapid and significant change. While we believe that our team's extensive pharmaceutical development and commercialization experience, scientific knowledge, and global industry relationships provide us with competitive advantages, we face competition from other pharmaceutical and biotechnology companies, specialty pharmaceutical companies, generic drug companies, over-the-counter companies, academic institutions, government agencies, and research institutions.

Many of our competitors have significantly greater financial, technical, and human resources than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our success will be based in part on our ability to identify, develop, and manage a patented portfolio of product candidates that are safer and/or more effective than competing products.

Intellectual Property

Our success depends in large part upon our ability to secure proprietary protection for our products and technologies, including those in development, and to operate without infringing the proprietary rights of others. We seek to avoid the latter by monitoring patents and publications that may affect our business, and to the extent we identify such threats, evaluate and take appropriate courses of action.

Patents extend for varying periods according to the date of patent filing or grant, applicable laws allowing for patent term extension, and the legal term of patents in various countries where patent protection is obtained. The actual protection afforded by a patent can vary from country to country and depends on the type of patent, the scope of its coverage, and the availability of legal remedies in the country.

We also intend to use regulatory exclusivity (also called data package exclusivity), or depending on eligibility, orphan drug designation, as a means of acquiring intellectual property protections that are separate and distinct to patents as appropriate for eligible pipeline candidates. These kinds of rights involve being given exclusivity for varying periods of time depending on the country to incentivize innovators who invest significant funds in and conduct clinical trials to produce necessary data to demonstrate a drug is safe and effective for its intended use(s) and, as such, the data package in a new drug application ("NDA") for the FDA (or similar regulatory filings in other countries) should receive some degree of protection even if no patent is available, or exclusivity given to produce a treatment for a disease that otherwise would not realistically be invested in without such incentive. In addition, there are other forms of intellectual property protection we may seek worldwide, including but not limited to trademarks, copyrights, trade secrets, pediatric exclusivity and the like, where available and appropriate for our business interests.

We further protect our proprietary information by requiring our directors, officers, employees, consultants, contractors, and other advisors to execute nondisclosure and assignment of invention agreements upon commencement of their respective employment or engagement. Agreements with our employees also prevent them from bringing the proprietary rights of third parties to our company without adequate permission to do so. In addition, we require confidentiality or service agreements from third parties that receive our confidential information or materials.

We aim to take advantage of a broad range of the intellectual property rights that are available to us and believe that this comprehensive approach will provide us with proprietary exclusive positions for our product candidates, where available.

Strategic, Licensing, and Other Arrangements

License and Development Agreement with Voronoi

In August 2021, we entered into a license and development agreement (the "Voronoi License Agreement") with Voronoi Inc. ("Voronoi"), pursuant to which we acquired exclusive, worldwide rights to research, develop, and commercialize FRTX-02 and other next-generation kinase inhibitors. In accordance with the terms of the

Voronoi License Agreement, in exchange for the licensed rights, we made a one-time payment of $2.5 million in cash and issued $2.0 million, or 62,597 shares, of our common stock to Voronoi.

With respect to FRTX-02, the Voronoi License Agreement provides that we will make payments to Voronoi of up to $211.0 million in the aggregate contingent upon achievement of specified development, regulatory, and commercial milestones. With respect to the compounds arising from the next-generation kinase inhibitor platform, we will make payments to Voronoi of up to $107.5 million in the aggregate contingent upon achievement of specified development, regulatory, and commercial milestones. Further, the Voronoi License Agreement provides that we will pay Voronoi tiered royalty payments ranging from low-single digits up to 10% of net sales of products arising from the DYRK1A inhibitor programs and next-generation kinase inhibitor platform. All of the contingent payments and royalties are payable in cash in U.S. Dollars, except for $1.0 million of the development and regulatory milestone payments, which amount is payable in equivalent shares of our common stock. Under the terms of the Voronoi License Agreement, we are responsible for, and bear the future costs of, all development and commercialization activities, including patenting, related to all the licensed compounds. During the years ended December 31, 2022 and 2021 and through the date of this Annual Report, we did not make any payments or recorded any liabilities related to the specified development, regulatory, and commercial milestones or royalties on net sales pursuant to the Voronoi License Agreement.

Exclusive License and Development Agreement with Carna

In February 2022, we entered into an exclusive license agreement (the "Carna License Agreement") with Carna Biosciences, Inc. ("Carna"), pursuant to which we acquired exclusive, worldwide rights to research, develop, and commercialize Carna's portfolio of novel STING inhibitors. In accordance with the terms of the Carna License Agreement, in exchange for the licensed rights, we made a one-time cash payment of $2.0 million.

The Carna License Agreement provides that we will make success-based payments to Carna of up to $258.0 million in the aggregate contingent upon achievement of specified development, regulatory, and commercial milestones. Further, the Carna License Agreement provides that we will pay Carna tiered royalty payments ranging from mid-single digits up to 10% of net sales. All of the contingent payments and royalties are payable in cash in U.S. Dollars. Under the terms of the Carna License Agreement, we are responsible for, and bear the future costs of, all development and commercialization activities, including patenting, related to all the licensed compounds. During the years ended December 31, 2022 and 2021 and through the date of this Annual Report, we did not make any payments or recorded any liabilities related to the specified development, regulatory, and commercial milestones or royalties on net sales pursuant to the Carna License Agreement.

Agreements with Botanix

Asset Purchase Agreement with Botanix

On May 3, 2022 (the "Effective Date"), we and Brickell Subsidiary, Inc. ("Brickell Subsidiary") entered into an asset purchase agreement with Botanix and Botanix Pharmaceuticals Limited (the "Asset Purchase Agreement"), pursuant to which Botanix acquired and assumed control of all rights, title, and interests to assets primarily related to the proprietary compound sofpironium bromide that were owned and/or licensed by us or Brickell Subsidiary (the "Assets"). Prior to the sale of the Assets, we had previously entered into a License Agreement with Bodor, dated December 15, 2012 (last amended in February 2020) that provided us with a worldwide exclusive license to develop, manufacture, market, sell, and sublicense products containing sofpironium bromide through which the Assets were developed (the "Amended and Restated License Agreement"). As a result of the Asset Purchase Agreement, Botanix is now responsible for all further research, development, and commercialization of sofpironium bromide globally and replaced us as the exclusive licensee under the Amended and Restated License Agreement.

In accordance with the sublicense rights provided to us under the Amended and Restated License Agreement, we also had previously entered into a License, Development, and Commercialization Agreement with Kaken, dated as of March 31, 2015 (as amended in May 2018, the “Kaken Agreement”), under which we granted to Kaken an exclusive right to develop, manufacture, and commercialize the sofpironium bromide compound in Japan and certain other Asian countries (the “Territory”). In exchange for the sublicense, we were entitled to receive aggregate payments of up to $10.0 million upon the achievement of specified development milestones, which were earned and received in 2017 and 2018, and up to $19.0 million upon the achievement of sales-based milestones, as well as tiered royalties based on a percentage of net sales of licensed products in the Territory. In September 2020, Kaken received regulatory approval in Japan to manufacture and market ECCLOCK for the treatment of primary axillary hyperhidrosis, and as a result, we began recognizing royalty revenue earned on a percentage of net sales of ECCLOCK in Japan. Pursuant to the Asset Purchase Agreement, the Kaken Agreement was assigned to Botanix, which replaced us as the exclusive sub-licensor to Kaken.

We determined that the development of and ultimate sale and assignment of rights to the Assets is an output of our ordinary activities and Botanix is a customer as it relates to the sale of the Assets and related activities.

In accordance with the terms of the Asset Purchase Agreement, in exchange for the Assets, we (i) received an upfront payment at closing in the amount of $3.0 million, (ii) were reimbursed for certain recent development expenditures in advancement of the Assets, (iii) received a milestone payment of $2.0 million upon the acceptance by the FDA in December 2022 of the filing of an NDA for sofpironium bromide gel, 15%, and (iv) will receive a contingent milestone payment of $4.0 million if marketing approval in the U.S. for sofpironium bromide gel, 15%, is received on or before September 30, 2023, or $2.5 million if such marketing approval is received after September 30, 2023 but on or before February 17, 2024. Botanix submitted an NDA for sofpironium bromide gel, 15%, to the FDA in September 2022, which was accepted by the FDA in December 2022. Under the Asset Purchase Agreement, we also are eligible to receive additional success-based regulatory and sales milestone payments of up to $168.0 million. Further, we will receive tiered earnout payments ranging from high-single digits to mid-teen digits on net sales of sofpironium bromide gel (the “Earnout Payments”).

The Asset Purchase Agreement also provides that Botanix will pay to us a portion of the sales-based milestone payments and royalties that Botanix receives from Kaken under the assigned Kaken Agreement (together, the “Sublicense Income”). Sublicense Income represents our estimate of payments that will be earned by us in the applicable period from sales-based milestone payments and royalties Botanix will receive from Kaken to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Royalties vary based on net sales that are impacted by a wide variety of market and other factors. We have recorded a contract asset equal to the amount of revenue recognized related to the Sublicense Income, less the amount of payments received from or due by Botanix in relation to the Sublicense Income.

All other consideration due under the Asset Purchase Agreement is contingent upon certain regulatory approvals and future sales subsequent to such regulatory approvals, or is based upon future sales that we determined are not yet probable due to such revenues being highly susceptible to factors outside of our influence and uncertainty about the amount of such consideration that will not be resolved for an extended period of time. Therefore, we determined that such variable consideration amounts are fully constrained as of December 31, 2022, and, as such, did not recognize such amounts as contract revenue.

Transition Services Agreement with Botanix

In connection with the sale of the Assets, on the Effective Date, we and Botanix entered into a transition services agreement (the “TSA”) whereby we are providing consulting services as an independent contractor to Botanix in support of and through filing and potential approval of the U.S. NDA for sofpironium bromide gel, 15%. In accordance with the terms of the TSA, in exchange for providing these services, (i) prior to the acceptance of the filing by the FDA of such NDA in December 2022, we received from Botanix a fixed monthly amount of $71 thousand, and (ii) after the acceptance of the filing in December 2022, we will receive from Botanix, a variable amount based upon actual hours worked, in each case plus related fees and expenses of our advisors (plus a 5% administrative fee) and our out-of-pocket expenses.

Contract Revenue under the Botanix Agreements

During the year ended December 31, 2022, we recorded contract revenue of $6.9 million, of which $5.0 million related to upfront and milestones achieved under the Asset Purchase Agreement. For additional information regarding contract revenue described above, see Note 3. "*Strategic Agreements*" of the notes to our consolidated financial statements included in this Annual Report.

Agreements with Bodor

In connection with the sale of the Assets, on the Effective Date, we, Brickell Subsidiary, and Bodor entered into an agreement (the "Rights Agreement") to clarify that we and Brickell Subsidiary have the power and authority under the Amended and Restated License Agreement to enter into the Asset Purchase Agreement and the TSA, and that Botanix would assume the Amended and Restated License Agreement pursuant to the Asset Purchase Agreement. The Rights Agreement includes a general release of claims and no admission of liability between the parties. Pursuant to such Rights Agreement, as subsequently amended on November 10, 2022, we have agreed to pay Bodor (i) 20% of the amount of each payment due to us from Botanix for upfront and milestone payments, subject to deductions, credits, or offsets applied under the Asset Purchase Agreement, as well as (ii) certain tiered payments, set as a percentage ranging from mid-single digits to mid-teen digits, of the amount of each of the applicable Earnout Payments due to us from Botanix after deductions, credits, or offsets applied under the Asset Purchase Agreement.

Pursuant to the terms of the Asset Purchase Agreement, we retained our obligation under the Amended and Restated License Agreement to issue $1.0 million in shares of our common stock to Bodor upon the FDA's acceptance of an NDA filing for sofpironium bromide gel, 15%. On November 10, 2022, we entered into an Acknowledgment and Agreement Related to Asset Purchase Agreement and Amended and Restated License Agreement (the "Acknowledgment") with Brickell Subsidiary, Botanix, Botanix Pharmaceuticals Limited, and Bodor. Pursuant to the Acknowledgment, we paid $1.0 million in cash to Bodor in full satisfaction of this obligation to issue shares upon the FDA's acceptance of the NDA.

During the year ended December 31, 2022, $1.9 million was incurred and reported as general and administrative expenses in the consolidated statements of operations associated with achieved milestones related to sofpironium bromide gel, 15%. For additional information regarding obligations due to Bodor described above, see Note 3. "*Strategic Agreements*" of the notes to our consolidated financial statements included in this Annual Report.

Manufacturing and Supply

We currently contract with third parties for the manufacture of drug substances and drug products for use in nonclinical and clinical studies, and would expect to do so for any potential future commercial supply, and we intend to continue to do so in the future. To our knowledge, all of our clinical drug substance and drug product manufacturing activities are in compliance with current good manufacturing practice ("cGMP") and other applicable laws. We have assembled a team of experienced employees and consultants to provide the necessary technical, quality, and regulatory oversight over the contract manufacturing organizations ("CMOs") with which we contract. We rely on third-party cGMP manufacturers for scale-up and process development work and to produce sufficient quantities of development product candidates for use in nonclinical and clinical studies.

Government Regulation

FDA Drug Approval Process

In the U.S., prescription human drugs are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, advertising, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products, which apply to our pipeline of products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, corporate integrity agreements, and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves nonclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. In addition, other tests on the chemistry, manufacturing, and controls ("CMC") of producing the drug and its various formulations to establish the shelf life, stability, storage conditions, and quality parameters and specifications must be conducted, submitted, and approved by the FDA.

Satisfaction of FDA pre-market approval requirements typically takes many years at significant cost and the actual time required may vary substantially based on the type, complexity, and novelty of the product or disease. Nonclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the nonclinical tests must comply with federal regulations and requirements, including current good laboratory practice ("GLP") regulation. The results of nonclinical testing are submitted to the FDA as part of an IND along with other information, including information about product CMC described above and a proposed clinical trial protocol. Long-term nonclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the IND is considered in effect, and the clinical trial proposed in the IND may begin.

Clinical trials involve the initial administration of the IND to healthy subjects or patients, with subsequent trials involving patients with the disease or disorder for which the investigational drug is being studied to treat, all under the supervision of qualified physician investigator(s). Clinical trials must be conducted (1) in compliance with federal and state regulations; (2) in compliance with current good clinical practice ("cGCP") regulations, an international standard (as adopted by FDA) meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; and (3) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated as well as the actual primary and secondary endpoints of the study to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial participants. The study protocol and informed consent information for patients in clinical trials must also be submitted to a local or central institutional review board ("IRB") (outside the U.S., these are called Ethics Committees) for approval and oversight. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or in rarer cases early phases may be skipped depending on the amount and quality of data that exists. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess pharmacological actions, metabolism, pharmacokinetics, adverse effects associated with administration of the investigational drug and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients with the targeted disease or disorder, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled prospective Phase 3 clinical trials with statistically significant results to demonstrate the efficacy of the drug by comparing a treatment arm against a control (placebo or best supportive care) arm. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in limited instances for FDA registration where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of an effect on mortality, irreversible morbidity, or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically impossible or ethically problematic.

After completion of required clinical testing, applicable law requires that an NDA be prepared and submitted to the FDA. FDA approval of an NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all nonclinical, clinical, and other testing and a compilation of data relating to the product's efficacy, safety, quality, and manufacturing. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and sponsor under an approved NDA are also subject to annual product and establishment user fees. These fees are typically increased annually. Payment of a user fee is not expected to be required for filing of an initial NDA, because FDA guidance waives, or reduces, user fees for, among other things, a small business applicant submitting its first NDA.

The FDA has 60 calendar days from its receipt of an NDA submission to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed with Congress to certain performance goals in the review of NDAs. Priority review can be applied to drugs that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. In addition, the FDA provides an accelerated approval mechanism applied to investigational drugs for serious or life-threatening diseases. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA also may refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee, typically a panel that includes independent clinicians and other experts in the targeted disease, for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more of the sponsor's clinical sites to assure compliance with cGCPs. Additionally, the FDA will generally inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve an investigational product unless compliance with cGMP is satisfactory and the NDA contains data sufficient to support the labeled shelf life and to demonstrate that the drug can be manufactured reliably in a stable, controlled manner.

After the FDA evaluates the NDA and potentially the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information required.

An approval letter authorizes commercial marketing of the drug in the U.S. with specific prescribing information for specific indications and may contain certain post-marketing requirements, including additional surveillance of how the drug is used. The approval letter may contain safety information that limits the ability of the drug to be marketed (e.g., black box warning) or contains contraindications, warnings, and/or precautions that limit the potential of the drug's desirability (these are standard for most approved drugs). As another potential condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") for drugs that are effective but also have potentially significant safety concerns. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. As stated, product approval may require post-approval testing and surveillance to monitor the drug's safety or efficacy, which could be substantial. Once granted, product approvals may be withdrawn if compliance by the drug's sponsor with regulatory standards is not maintained or problems are identified following initial marketing and/or manufacturing by the sponsor or in how the drug is being used in the marketplace.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. Also, an NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates, in part, the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, social media, off-label promotion, formulary and reimbursement presentations, product sampling, sales force activities including dissemination of peer-reviewed journal articles, marketing items and detailing practices with prescribers, healthcare practitioner interactions, industry-sponsored scientific and educational activities, other promotional activities involving the internet and to certain other press, publicity and media communications initiated by us, while other parts of the government regulate, among other things, against false claims, foreign corrupt practices, trade sanctions, and anti-kickbacks. States often impose strict legal requirements and prohibitions on a variety of post-approval drug marketing practices. We may market drugs holding an approved NDA only for the permitted indications and in accordance with the provisions of the approved labeling.

Adverse event reporting, pharmacovigilance, and submission of periodic reports are required of the NDA holder following FDA approval of that NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, the aforementioned REMS, and/or surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product, especially in the U.S. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMPs or risk being sanctioned by the FDA from supplying the drugs they manufacture or facing partial or complete product recalls. Regulatory authorities may withdraw product approvals or request such product recalls if a company fails to comply with applicable regulatory standards, if we encounter problems following initial marketing and supply, or if previously unrecognized problems with the drug being prescribed subsequently are discovered.

The Hatch-Waxman Act

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each eligible patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application ("ANDA"). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, nonclinical or clinical studies to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug and may be required to be switched to from the original listed drug by certain laws or insurance and formulary practices, which can affect the profitability of the original listed drug adversely.

To proceed forward, the ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify either that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant also may elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA will not be approved until all the listed patents, if valid, claiming the referenced product expire.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then commence a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 calendar days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of (i) 30 months; (ii) expiration of the patent; (iii) settlement of the lawsuit; or (iv) a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product expires.

Regulatory Exclusivity

Upon NDA approval of a new chemical entity ("NCE"), which is a drug that contains no active molecule that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity in the

U.S. during which the FDA cannot receive any ANDA seeking approval of a generic version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA for a generic drug that includes the change. Other countries may, and do, have different periods for regulatory exclusivity.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification and, thus, no ANDA may be filed before the expiration of the exclusivity period.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent term extension in the U.S. The allowable patent term extension is calculated as half of the drug's testing phase, the time between IND application and NDA submission, and all of the review phase, the time between NDA submission and approval, up to a maximum of five years. Only one patent may be extended for a regulatory review period for any product. If more than one application for extension of the same patent is filed, the certificate of extension of patent term, if appropriate, will be issued based upon the first filed application for extension. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the U.S. Patent and Trademark Office ("USPTO") must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

It is premature to know what, and if any, patent term extension that may be allowed in the U.S. would be at this time, or which patent an extension may be triggered from.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, including when a clinical trial is initiated (often on www.clintrials.gov); information for certain Company studies can be accessed at this website. Information related to the product, patient population, phase, type and scope of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration process. Sponsors are obligated also to discuss the results of their clinical trials after completion and industry trade association ethics guidelines require publication of both favorable and unfavorable study results, which can affect the potential market for a drug. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress and intent of development programs.

Regulation Outside of the U.S.

In addition to regulations in the U.S., we will be subject to regulations of other countries governing any clinical trials and commercial sales and distribution of our product candidates, as well as the extent, scope, and enforceability of intellectual property rights associated with the product candidate introduced in these other countries. Whether or not we obtain FDA approval for a product, we, or our local partners, must obtain approval by the comparable regulatory authorities of countries outside of the U.S. before it can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union, before we may market products in those countries or areas. Certain countries outside of the U.S. have a process similar to the FDA's that requires the submission of a clinical trial application ("CTA"), much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval. In some cases, once the investigational drug is approved by a regulatory agency in certain established markets, like the FDA in the U.S., other countries will allow a sponsor to rely on that other country's approval and extend it, with the same terms and conditions, in the foreign country and this may accelerate the introduction of the drug in foreign markets, where applicable (often called a free sales certificate ("FSC"), or also a certificate of pharmaceutical products, process).

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders, or diabetes and is optional for those medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 calendar days of receiving the applications and assessments report, each member state must decide whether to recognize the national marketing authorization of a different member state.

Anti-Kickback, False Claims Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws in the U.S. have been applied to restrict or prohibit certain marketing practices in the pharmaceutical industry. These laws include, among others, anti-kickback statutes, false claims statutes and other statutes pertaining to healthcare fraud and abuse, and anticorruption. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce, or in return for, purchasing, leasing, ordering, or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The Patient Protection and Affordable Care Act, as amended ("PPACA"), amended the intent element of the federal anti-kickback statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Federal false claims laws prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, also may violate federal false claims laws. Additionally, PPACA amended the federal healthcare program anti-kickback statute such that a violation of that statute can serve as a basis for liability under certain federal false claims laws.

The majority of U.S. states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order or receive a reimbursable item or service from a particular supplier, and the healthcare fraud and false statements statutes, which prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations, or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items, or services.

Violations of these federal healthcare fraud and abuse laws are punishable in the U.S. by imprisonment, criminal fines, civil monetary penalties, and exclusion from participation in federal healthcare programs.

Other Federal and State Regulatory Requirements

Under the Open Payments Rule, the Centers for Medicare & Medicaid Services requires certain manufacturers of prescription drugs to annually collect and report information on payments or transfers of value to certain healthcare professionals, including physicians, and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties. Other countries require similar reporting, including France and Belgium, if the product is approved and marketed there. In addition, several states now require prescription drug companies to report expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners and entities in these states. Other states prohibit various other marketing-related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and marketing codes. Several additional states are considering similar proposals. Some of the state laws are broader in scope than federal laws. Compliance with these laws is difficult and time-consuming, and companies that do not comply with these state laws face civil or other penalties.

Coverage and Reimbursement

Sales of our product candidates, if approved, by us or any potential commercial partners will depend, in part, on the extent to which such products will be covered by third-party payors, such as government healthcare programs, commercial insurance, and managed healthcare organizations. These third-party payors are increasingly limiting coverage or reducing reimbursements for medical products and services. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of any products for which we receive regulatory approval for commercial sale will therefore depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care plans, private health insurers, and other organizations.

The process for determining whether a third-party payor will provide coverage for a drug typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce a physician’s willingness to prescribe our products once approved and have a material adverse effect on our sales, results of operations, and financial condition. Moreover, a third-party payor’s decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate.

In addition, the U.S. government, state legislatures, and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of drugs, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

Employees

As of December 31, 2022, we had 13 full-time employees, of which six were dedicated to research and development activities. From time to time, we retain independent contractors. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages, and we consider our relations with our employees to be excellent.

Corporate History

Vical Incorporated ("Vical") was incorporated in Delaware in 1987. On August 31, 2019, the Delaware corporation formerly known as "Vical Incorporated" completed a reverse merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger and Reorganization, dated June 2, 2019, as further amended on August 20, 2019 and August 30, 2019, by and among Vical, Brickell Biotech, Inc. ("Private Brickell") and Victory Subsidiary, Inc. ("Merger Sub"), pursuant to which Merger Sub merged with and into Private Brickell, with Private Brickell surviving the merger as a wholly-owned subsidiary of Vical (the "Merger"). Additionally, on August 31, 2019, immediately after the completion of the Merger, the Company changed its name from "Vical Incorporated" to "Brickell Biotech, Inc." On September 7, 2022, Brickell Biotech, Inc.'s name was changed to Fresh Tracks Therapeutics, Inc.

Corporate Information

Our corporate headquarters are in Boulder, Colorado, where we occupy facilities totaling approximately 3,000 square feet under a lease agreement that expires in December 2025 and provides us an early termination option. We use our current facilities primarily for research and development and general and administrative personnel.

This Annual Report contains references to our trademarks and trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork, and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

Information about our Executive Officers

The following table sets forth information concerning our executive officers.

Name	Age	Title
Andrew D. Sklawer	39	President and Chief Executive Officer
Albert N. Marchio, II	70	Chief Financial Officer
Deepak Chadha	53	Chief Research and Development Officer and Chief Operating Officer
David McAvoy	60	General Counsel, Chief Compliance Officer, and Secretary

Andrew D. Sklawer, President, Chief Executive Officer, and Co-Founder

Mr. Sklawer co-founded the Company and was appointed President and Chief Executive Officer in January 2023. Previously, Mr. Sklawer served as the Company's Chief Operating Officer from 2009 until his appointment as President and Chief Operating Officer in May 2022. Prior to 2009, Mr. Sklawer served as the Head of Operations at Concordia Pharmaceuticals, Inc., an oncology drug development company that was acquired by Kadmon Corporation in 2011. Prior to joining Concordia, Mr. Sklawer held various positions at Verid, Inc., a developer of security technology prior to its acquisition by EMC Corporation. Mr. Sklawer holds a B.A. in marketing from the University of Florida and earned his M.B.A. from the University of Miami. Mr. Sklawer currently serves as a board member for StartUp FIU, a Florida International University platform that supports researchers, inventors, innovators, and entrepreneurs to conceive, launch, and scale solutions, is a member of the Advisory Committee of Advancing Innovation in Dermatology Accelerator Fund, and is a board member of the Colorado BioScience Association.

Albert N. Marchio, II, Chief Financial Officer

Mr. Marchio has been with Danforth Advisors since May 2019, providing financial consulting services on a project/interim basis for public (CytomX Therapeutics (CTMX)) and various private life sciences companies. Previously, Mr. Marchio served in various finance and accounting roles at Edge Therapeutics, Inc. (now known as PDS Biotechnology Corporation), a clinical-stage biopharmaceutical company, including Chief Accounting and Administrative Officer from October 2016 to November 2018, Interim Chief Financial Officer from March 2017 to October 2017, Chief Accounting and Operations Officer from March 2014 to October 2016, and Chief Financial Officer from December 2011 through March 2014. Mr. Marchio was a Managing Operating Partner with Three Fields Capital, a multi-strategy healthcare-focused investment firm, and provided consulting services to life science companies through Rockabye Valley Consulting from January 2009 to May 2013. Previously, Mr. Marchio served as the Executive Vice President, Chief Financial Officer of Informed Medical Communications from February 2008 to October 2009, and as the Vice President, Treasurer of MedPointe Pharmaceuticals from 2006 to January 2008. He began his career in life sciences as the Vice President, Treasurer of Alpharma, Inc. from 1992 to 2005. Mr. Marchio holds a B.A. in Economics from Muhlenberg College, an M.B.A. in Professional Accounting from Rutgers Graduate School of Business, and a Post-M.B.A. Certificate in Taxation from Bernard Baruch College of the City University of New York.

Deepak Chadha, Chief Research and Development Officer and Chief Operating Officer

Mr. Chadha joined the Company in 2016 and served as its Chief Regulatory, Pre-clinical, and Quality Compliance Officer until his appointment as Chief Research and Development Officer in 2018. He also was appointed Chief Operating Officer in September 2022. Mr. Chadha served from 2014 to 2016 as Vice President, Global Regulatory Affairs at Suneva Medical, Inc. ("Suneva"), a medical technology company that develops, manufactures, and commercializes aesthetic products for the dermatology, plastic, and cosmetic surgery markets. During his time at Suneva, Mr. Chadha led the regulatory approval for BELLAFILL® dermal filler for acne scar correction and supported the company's commercial products life cycle management. Prior to joining

Suneva, Mr. Chadha worked at Allergan plc (f.k.a. KYTHERA Biopharmaceuticals, Inc.) from 2007 to 2014, where Mr. Chadha led the development of their product, KYBELLA®, from an early clinical phase to an NDA stage, and also supported the ex-U.S. regulatory activities. Mr. Chadha also served as Vice President of Global Regulatory Affairs at Allergan Medical (f.k.a. Inamed Corporation) from 2004 to 2007, where he assisted in building the organization's Global Regulatory Affairs department and was involved with the approval for JUVEDERM®, Bioenterics®, LAP-BAND®, and Silicone gel-filled breast implants. Mr. Chadha holds a B.S. in pharmaceutical sciences from Berhampur University in Orissa, India, an M.S. in pharmaceutics from Hamdard University in New Delhi, India, and an M.B.A. in international business from California State University, Dominguez Hills.

David McAvoy, General Counsel, Chief Compliance Officer, and Secretary

Mr. McAvoy joined the Company in 2019 and has served since then as its General Counsel and Chief Compliance Officer. He also was appointed Secretary in May 2022. He previously served as General Counsel, Vice President, and Chief Compliance Officer for Endocyte, Inc., a publicly traded nuclear medicine and oncology biotech company that was subsequently acquired by Novartis AG, from 2017 to 2018. Prior to joining Endocyte, Inc., Mr. McAvoy was at Eli Lilly and Company for 27 years serving in various leadership positions, including as General Counsel of Lilly Emerging Markets and in an executive management business role running strategic alliances for the food animal production group at Eli Lilly and Company's former Elanco Animal Health subsidiary. While at Eli Lilly and Company, Mr. McAvoy was lead counsel for and helped launch several blockbuster medicines, including Prozac® for depression, Gemzar® for pancreatic and lung cancers, and ReoPro®, one of the first interventional cardiology agents. Mr. McAvoy earned a J.D. and M.S. in environmental science from Indiana University and a B.A. in political science from the University of Notre Dame. He serves on the board of directors for The Villages of Indiana, Inc., championing families for abandoned and abused children.

ITEM 1A. RISK FACTORS

Our business, financial condition, and operating results may be affected by a number of factors, whether currently known or unknown, including but not limited to those described below. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, alone or combined with any of the other factors, could materially and adversely affect our business, financial condition, results of operations, and stock price. The following information should be read in conjunction with Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and related notes in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report.

Risks Related to Our Business Operations

Our business depends on the successful continued financing, nonclinical and clinical development, regulatory approval, and commercialization of our pipeline assets.

The successful development, regulatory approval, and commercialization of our pipeline assets will require significant additional financing and depend on a number of factors, including but not limited to the following:

- timely and successful initiation and completion of clinical trials for our product candidate portfolio, which may be significantly costlier than we currently anticipate and/or produce results that do not achieve the endpoints of the trials, or which are ultimately deemed not to be clinically meaningful;

- our ability to receive regulatory approval for our clinical trials;

- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our and their contractual obligations and with all regulatory and legal requirements applicable to them and to our pipeline assets;
- ability of third parties with which we contract to manufacture consistently adequate clinical trial supplies for development of our pipeline assets, to remain in good standing with regulatory agencies and to develop, validate, and maintain or supervise commercially viable manufacturing processes that are compliant with FDA-regulated current good manufacturing practice ("cGMP") and other applicable legal requirements, to hire and retain a sufficient and qualified workforce, and to manage their own supply chain(s) to comply with their contractual obligations to us;
- a continued acceptable safety and tolerability profile during clinical development of our pipeline assets;
- acceptance by physicians, insurers and payors, and patients of the quality, benefits, safety, and efficacy of our pipeline assets, if and where approved, including relative to alternative and competing treatments and the next best standard of care;
- existence of a regulatory, pricing and reimbursement, and legal environment conducive to the success of our pipeline assets;
- ability to price our pipeline assets to recover our development costs and generate a satisfactory profit margin;
- the ability of third parties to whom we have sold assets or rights to assets to successfully commercialize those assets, including sofpironium bromide, and the resulting impact on our potential future revenue;
- our ability and our partners' ability to establish, maintain, and enforce intellectual property rights in and to our pipeline assets, including but not limited to patents, regulatory exclusivity rights, trademarks, copyrights, and licenses;
- our ability to raise capital to commercialize and advance our pipeline assets, which will be limited if our common stock price does not appreciate; and
- the extent to which Botanix is successful in meeting its contract obligations to its licensor and completing the development and commercial launch of sofpironium bromide outside of Japan.

If we do not achieve one or more of these factors, many of which are beyond our reasonable control, in a timely manner or at all, we could experience significant delays, an inability to fund our operations and research and development, or an inability to obtain regulatory approvals or commercialize our pipeline assets. Our Board and executive management team are conducting a comprehensive process to explore and evaluate strategic options to progress the development of our 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 our Company. To continue developing FRTX-02 and the rest of our pipeline, we need to raise additional funds. If such financing or a strategic partnership is not forthcoming in a timely manner, we will be unable to conduct certain additional research and development activities.

Even if regulatory approvals are obtained, we may never be able to successfully commercialize our pipeline assets, especially if we attempt to do so without a partner. Accordingly, we cannot assure that we will be able to launch a product candidate in any market or, if we do, that we will be able to generate sufficient revenue from the sale of such product candidate, or any other asset, to continue our business.

Clinical drug development for our pipeline assets is expensive, time-consuming, and uncertain. Any data resulting from our trials may not be favorable for further development.

Clinical development for our pipeline assets is expensive, time-consuming, difficult to design and implement, and its outcome is inherently uncertain. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization, and of those that are approved, many do not cover their costs of development or ever generate a profit. In addition, we, any partner with which we currently or may in the future collaborate, the FDA, a local or central institutional review board, or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, extend, require modifications, or add additional requirements to or terminate our clinical trials at any time.

Our pipeline assets primarily target autoimmune and inflammatory diseases, and it is still too early in clinical development to know whether they will progress past Phase 1 clinical trials, including but not limited to our lead asset FRTX-02, which just completed Part 1 of a two-part Phase 1 trial. Any data resulting from our trials may not be favorable for further development, either due to the results themselves or because funding to continue additional development based on these results is not forthcoming. In the case of FRTX-02, further investigation on whether the 150 mg dose that has been identified in Part 1 of the Phase 1 trial is safe and effective in a targeted disease population, such as AD, remains to be proven, and additional financing will be necessary to further evaluate QTc interval prolongation as part of continued testing.

Major public health issues, and specifically the pandemic and related impacts caused by the ongoing spread of COVID-19 and COVID-19 variants, including in terms of constraints on supply chains and human resource availability and significant disruption of global financial and distribution markets, could have an adverse impact on our financial condition and results of operations and other aspects of our business and that of our suppliers, contractors, and business partners.

The extent to which COVID-19 impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted. Materials required for any future research and development activities, including clinical trials, study monitoring, and data analysis, may be paused or delayed due to changes in hospital or university policies, federal, state, or local regulations, prioritization of hospital resources toward pandemic efforts, worker and supplier patterns, or other reasons related to, or as a consequence of, the pandemic.

We also intend to rely on third parties, such as contract laboratories, contract research organizations, medical institutions, and clinical investigators to conduct any future studies and clinical trials for our pipeline assets. If these third parties themselves are adversely impacted by restrictions or disruptions resulting from the COVID-19 pandemic, we will likely experience delays, and/or realize additional costs.

The spread of COVID-19 and its variants, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, negative supply chain impacts, and worker unavailability, may have a material economic effect on our business. While the potential economic impact brought by, and the duration of, the pandemic may be difficult to assess or predict, it has already caused, and may result in further, significant disruption of global financial and distribution markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression, or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock.

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors, and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a risk evaluation and mitigation strategy, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of an approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population or their caregivers to try new therapies and of physicians to prescribe these therapies;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- patients’ willingness to pay for these therapies in the absence of such coverage and adequate reimbursement;
- the effectiveness of sales and marketing efforts;
- support from key opinion leaders and patient advocacy groups;
- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

If any of our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

We face significant competition in our industry, and our pipeline assets, if approved, may not be able to compete effectively or achieve significant market penetration.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition, less effective patent terms, and a strong emphasis on developing newer, fast-to-market proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing, and marketing of healthcare products competitive with those that we are developing. We face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies, and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, regulatory expertise, clinical trial expertise, intellectual property portfolios, more international reach, experience in obtaining patents and regulatory approvals for product candidates and other resources than us. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces, and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts.

To compete successfully, we will have to provide an attractive and cost-effective alternative to existing and new therapies. Such competition could lead to reduced market share and contribute to downward pressure on the pricing of future products, which could harm our business, financial condition, operating results, and prospects.

If clinical research organizations ("CROs") and other third parties do not meet our requirements or otherwise conduct any future clinical trials for our pipeline assets as required or are unable to staff or supply any such trials, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our pipeline assets at all or in the time frames currently planned for.

We have in the past relied, and expect to continue to rely, on third-party CROs to conduct and oversee any future clinical trials for pipeline assets and other aspects of product development. We also have relied on various medical institutions, clinical investigators, and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and good clinical practice ("GCP") requirements, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties have played a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We have relied heavily on these parties for the execution of our clinical trials and preclinical studies and controlled only certain aspects of their activities. We and our CROs and other third-party contractors were required to comply with GCP and current good laboratory practice ("GLP") requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP requirements, or reveal noncompliance from an audit or inspection, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our future clinical or preclinical trials comply with applicable GCP and GLP requirements, or that our CROs and other third-party contractors are otherwise compliant with applicable laws despite their contractual assurances to us. In addition, clinical trials generally must be conducted with product produced under cGMP regulations. Our failure, or the failure of our CROs and other third-party contractors, to comply with these regulations and policies, or to obtain supply of key items in sufficient quantities, in a timely manner or at all, may require us to extend or repeat any future clinical trials, which would delay or halt the regulatory approval process, or could cause us to fail to meet certain contractual obligations, including but not limited to milestone commitments, with licensors of our portfolio assets like Voronoi and Carna.

If any of our CROs or clinical trial sites terminate their involvement in any future clinical trial for any reason, including but not limited to impacts caused by the COVID-19 pandemic, we may not be able to enter into arrangements with alternative CROs or clinical trial sites, or do so on commercially reasonable terms, and in a satisfactory timeframe. If our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients enrolled in any future clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for past and any future clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

If we do not achieve our projected development goals in the timeframes we announce and expect, our business and strategies may be adversely affected and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory, other product development, and commercial goals, as well as achievement of certain contractual milestones by us and our partners. These goals may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings, as well as product launch. From time to time, we may publicly announce the expected timing of some of these goals. All of these goals are and will be based on numerous assumptions. The actual timing of these goals can vary dramatically compared to our estimates, in some cases for reasons beyond our control or that cannot be anticipated. If we do not meet these goals as publicly announced, or at all, our business and strategies may be adversely affected and, as a result, our stock price may decline.

Our receipt of future payments from Botanix is contingent on various factors outside of our control, including the successful development, regulatory approval, and commercialization of sofpironium bromide gel, 15%, by Botanix outside of Japan, the successful continued commercialization of ECCLOCK by Kaken in Japan, and the sufficiency of funds by both entities to pay us and Bodor, the licensor of this product.

Our receipt of future regulatory and sales milestone payments, as well as earnout payments, from Botanix is contingent on the successful development, regulatory approval, and commercialization of sofpironium bromide gel, 15%, which in turn depends on a number of factors, including but not limited to the following:

- whether Botanix is required to conduct additional clinical trials to support the NDA review by the FDA for sofpironium bromide;
- whether Kaken is able to execute successfully, in a timely, compliant, and efficient manner, certain active pharmaceutical ingredient (“API”)-related activities (chemistry, manufacturing, and controls) that Botanix is reliant on in connection with the FDA’s review in the U.S.;
- whether Kaken is able to satisfy its requirement to provide Botanix with certain key regulatory information that will be used during the NDA review by the FDA for sofpironium bromide;
- if approved, the ability to manufacture consistently adequate commercial supplies of sofpironium bromide, to remain in good standing with regulatory agencies and to develop, validate, and maintain or supervise commercially viable manufacturing processes that are compliant with FDA-regulated cGMPs and other applicable legal requirements, and to manage supply chain(s);
- a continued acceptable safety and tolerability profile following any commercial approval of sofpironium bromide;
- ability to obtain favorable labeling for sofpironium bromide through regulators that allows for successful commercialization, given the drug may be marketed only to the extent approved by these regulatory authorities (unlike with most other industries);
- acceptance by physicians, insurers and payors, and patients of the quality, benefits, safety, and efficacy of sofpironium bromide, if and where approved, including relative to alternative and competing treatments and the next best standard of care;

- existence of a pricing, insurance coverage and reimbursement environment conducive to the success of sofpironium bromide; and
- level of competition, including from other products earlier to market and from generic competition upon expiration of patent protection.

Although the FDA has accepted the filing of an NDA for sofpironium bromide gel, 15% by Botanix, there can be no assurance that the necessary regulatory approvals will be received. If approval is denied or delayed, we may not receive any of the payments from Botanix provided for in the Asset Purchase Agreement. Even if regulatory approvals are obtained, sofpironium bromide gel, 15%, may not be successfully commercialized and may not generate sufficient revenue for us to receive any such payments.

In addition, certain of the payments that would be due to us from Botanix would be triggered by milestones that do not involve receipt of funds by Botanix, and therefore our receipt of such payments would depend on Botanix's sufficiency of funds to pay us.

While we assigned the Kaken Agreement to Botanix in May 2022, we remain eligible to receive a portion of future regulatory and sales milestone payments and tiered earnout payments based on a percentage of net sales of ECCLOCK pursuant to the terms of the Asset Purchase Agreement. Kaken has final decision-making authority for the overall regulatory, development, and commercialization strategy for sofpironium bromide, market access activities, pricing and reimbursement activities, promotion, distribution, packaging, sales, and safety and pharmacovigilance in Japan and certain other Asian countries. As a result, Kaken substantially controls commercialization of ECCLOCK in Japan and may make decisions regarding commercialization that may reduce or eliminate the royalties and other payments due to us. We will not receive additional milestone or other payments from Botanix related to Kaken's sales if Kaken does not continue to be successful in its development, regulatory, or commercial activities, if the approval is withdrawn for any reason, or if Kaken is unable to maintain an adequate price for ECCLOCK in Japan.

We currently have no marketing capabilities or sales organization, and we contract medical support. If we are unable to generate adequate financing, establish sales, marketing, and medical capabilities on our own or through third parties, or are delayed in establishing these capabilities, we will be unable to successfully develop and commercialize our product candidates, if approved, or generate meaningful product revenue.

We currently have no marketing capabilities or sales organization and limited cash runway. To develop and commercialize our product candidates, if approved, we must continue to obtain additional financing, build our marketing, sales, medical, distribution, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing any of these. We currently contract for medical support to advise on our clinical programs and will need to continue doing this or at some point hire a medical organization to progress advanced phase development and commercialization of our product candidates. As a company, we have no prior experience in the commercial launch, marketing, sale, and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to fund costs and expenses of a sales organization and its activities, hire, retain, and incentivize qualified individuals, generate sufficient sales leads, or contract for a sales force and in either case, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team so they operate in an effective and compliant way. Any failure or delay in the development of our internal (or external contracted-for) sales, marketing, distribution, and pricing/reimbursement/access capabilities would impact adversely the commercialization of these products. In addition, we may need more than one approved and marketed product to sustain employing an internal sales force.

We may choose to collaborate with third parties in various countries, including the U.S., that have direct sales forces, commercial and regulatory capacities, and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We may not have sufficient financial resources to enter into and pay for such arrangements, and/or we may not be able to find adequate business partners. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our current or future product candidates. The inability to commercialize successfully our product candidates, either on our own or through collaborations or partnerships with one or more third parties, would harm our business, financial condition, operating results, and prospects.

Our business and operations would suffer in the event of system failures, illegal stock trading or manipulation by external parties, cyber-attacks, or a deficiency in or exploitation of our cyber-security.

We rely on cloud-based software to provide the functionality necessary to operate our company, utilizing what is known as “software as a service” (“SaaS”). SaaS allows users like us to connect to and use cloud-based applications over the Internet, such as email, calendaring, and office tools. SaaS provides us with a complete software solution that we purchase on a subscription basis from a cloud service provider. Despite our efforts to protect confidential and sensitive information from unauthorized disclosure across all our platforms, and similar efforts by our cloud service provider(s) and our other third-party contractors, consultants, and vendors, whether information technology (“IT”) providers or otherwise, including but not limited to our CROs, law firms, accountants, and even the government regulators who we rely on to advance our business, this information, and the systems used to store and transmit it, are vulnerable to damage from computer viruses, unauthorized access, computer hacking or breaches, natural disasters, epidemics and pandemics, terrorism, war, labor unrest, and telecommunication and electrical failures. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, or other illegal acts, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Other emerging threats we face include: phishing, account takeover attacks, data breach or theft (no matter where the data are stored), loss of control, especially in SaaS applications, over which users have access to what data and level of access, new malware, zero-day threats, and threats within our own organization. In addition, and probably exacerbated by the COVID-19 pandemic and increased remote working arrangements, malicious cyber actors may increase malware and ransom campaigns and phishing emails targeting teleworkers as well as company systems, preying on the uncertainties surrounding COVID-19 or other world trends and events, which exposes us to additional cybersecurity risks, or may try to illegally obtain inside information to manipulate our stock price. If such an event were to occur and cause interruptions in our operations, or substantial manipulation of our stock price, it could result in a material disruption of our development programs and our business operations. In addition, since we sponsor clinical trials, any breach that compromises patient data and identities, thereby causing a breach of privacy, could generate significant reputational damage and legal liabilities and costs to recover and repair, including affecting trust in us to recruit for future clinical trials. For example, the loss or theft of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts, stock manipulation, and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability or suffer from stock price volatility or decline, and the further development and commercialization of our products and product candidates could be delayed.

We may be adversely affected by natural disasters and other catastrophic events and by man-made problems such as war or terrorism or labor disruptions that could disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate office is located in Boulder, Colorado, near a major flood and blizzard zone and in an area prone to wildfires. If a disaster, power outage, or other event occurred that prevented us from using all or a significant portion of our office, that damaged critical infrastructure, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a period of time. Our contract manufacturers’ and suppliers’ facilities are located in multiple locations where other natural disasters or similar events, such as tornadoes, earthquakes, storms, fires, explosions or large-scale accidents or power outages, could severely disrupt our operations, could expose us to liability and could have a material adverse effect on our business, financial condition, operating results, and prospects. All of the aforementioned risks may be further increased if we do not implement an adequate disaster recovery plan or our partners' or manufacturers' disaster recovery plans prove to be inadequate.

Risks Related to Our Liquidity, Financial Matters, and Our Common Stock

We will need to raise substantial additional financing to fund our operations, including to continue developing our lead development-stage program and the rest of our pipeline, which financing may not be available to us on favorable terms or at all.

We will require substantial additional funds to develop and, if successful, commercialize our product candidates. Our future capital requirements will depend upon a number of factors, including but not limited to: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to obtain sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; compliance with our material contracts including the licensing agreements for our autoimmune and inflammatory portfolio; the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance for such product candidates; and overall stock market conditions, global business trends, our stock price performance, and our ability to generate funding under these and other conditions.

Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests or inhibit our ability to achieve our business objectives. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our stockholders' ownership interests in our company will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us in one or more countries.

Our ability to raise additional funds is uncertain and is limited given our small market capitalization and current stock price. Due to the SEC's "baby shelf rules," which prohibit companies with a public float of less than $75 million from issuing securities under a shelf registration statement in excess of one-third of such company's public float in a 12-month period, we are only able to issue a limited number of shares which aggregate to no more than one-third of our public float using our shelf registration statement at this time. Even if sufficient funding is available, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

Our Board and executive management team are conducting a comprehensive process to explore and evaluate strategic options to progress the development of our 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 our Company. To continue developing FRTX-02 and the rest of our pipeline, we need to raise additional funds. If such financing or a strategic partnership is not forthcoming in a timely manner, we will be unable to conduct certain additional research and development activities.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due in part to the ongoing military conflict between Russia and Ukraine. Our business, financial condition, and results of operations may be materially adversely affected by the negative impact on the global economy and capital markets resulting from the conflict in Ukraine or other geopolitical tensions.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the military conflict between Russia and Ukraine. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine has led to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain disruptions. Russian military actions and the resulting sanctions could further adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds.

The extent and duration of the military action, sanctions, and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this Annual Report.

Our operating results and liquidity needs could be affected negatively by global market fluctuations and economic downturns.

Our operating results and liquidity could be affected negatively by global economic conditions generally, both in the U.S. and elsewhere around the world, including but not limited to that related to the ongoing COVID-19 pandemic, the Russian invasion of Ukraine and related sanctions, global IT threats, and rising interest rates. The market for discretionary pharmaceutical products, medical devices, and procedures may be particularly vulnerable to unfavorable economic or other conditions. Domestic and international equity and debt markets are experiencing and may in the future experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets remain volatile, or an economic recession, including as a result of the COVID-19 pandemic, the Russian invasion of Ukraine and related sanctions or other stimulus, our operating results and liquidity could be affected adversely by those factors in many ways, making it more difficult for us to raise funds, and our stock price may decline.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations, financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance and/or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. We are still in the process of moving our cash deposits held at SVB and in a U.S. Treasury money market mutual fund purchased through SVB to a new financial institution.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC, and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC, and Federal Reserve Board ("Government Insurers") will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations, including but not limited to our employee payroll obligations, could be significantly impaired (and delayed) by factors that affect us, the financial institutions with which we have relationships, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, the loss of uninsured deposits, disruptions or instability in the financial services industry or financial markets, inability or refusal by Government Insurers to provide additional protections, or concerns or negative expectations about the prospects for companies in the financial services industry.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our contractual counterparties, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a contractual counterparty may fail to make payments when due, default under their agreements with us, become insolvent, or declare bankruptcy. In addition, a contractual counterparty could be adversely affected by any of the liquidity or other risks that are described above or by the loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any contractual counterparty bankruptcy or insolvency, or the failure of any contractual counterparty to make payments when due, or any breach or default by a contractual counterparty, or the loss of any significant contractual counterparty relationship, could result in material losses to us and may have a material adverse impact on our business.

Our stock price and volume of shares traded have been and may continue to be highly volatile, and our common stock may continue to be illiquid.

The market price of our common stock has been subject to significant fluctuations. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile and subject to large daily price swings. In addition, there has been limited liquidity in the trading market for our securities, which may adversely affect stockholders. Some of the factors that may cause the market price of our common stock to continue to fluctuate include, but are not limited to:

- our need for additional potential financings to raise funds to further develop and commercialize our pipeline assets, which could result in significant additional share dilution;
- material developments in, or the conclusion of, any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- our ability to satisfy all listing requirements of The Nasdaq Capital Market and the impact that may result from any failure to address current and avoid future deficiencies;
- the entry into, or termination of, or breach by us or our partners of material agreements, including key commercial partner or licensing agreements;
- our ability to obtain timely regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- issues in manufacturing or the supply chain for our product candidates;

- the results of any future clinical trials of our pipeline assets;
- failure of our product candidates, if approved, to achieve commercial success;
- announcements of any dilutive equity financings;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships, or capital commitments;
- the introduction of technological innovations or new therapies or formulations that compete with our pipeline assets;
- lack of commercial success of competitive products or products treating the same or similar indications;
- failure to elicit meaningful stock analyst coverage and downgrades of our stock by analysts, or to obtain more institutional stockholders; and
- the loss of key employees and/or inability to recruit the necessary talent for new positions or to replace exiting employees.

Moreover, the stock markets in general have experienced substantial volatility in our industry, especially for microcap biotechnology companies, and such volatility has often been unrelated to the operating performance of individual companies or a certain industry segment, such as the ongoing reaction of global markets to the COVID-19 pandemic, the Russian invasion of Ukraine and related sanctions and other economic disruptions or concerns, including inflation and interest rate increases. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation and could expose us to liability or negatively impact our business, financial condition, operating results, and prospects.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our operations to date have been limited primarily to business planning, raising capital, developing and entering into strategic partnerships for our pipeline assets, identifying and in-licensing product candidates, entering into sale arrangements that involve our rights to assets and related intellectual property, conducting clinical trials, and other research and development activities. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Our revenue and profitability will depend on development funding for our product portfolio, the receipt of sales milestones and earnout payments under the Asset Purchase Agreement, our ability to satisfy the development and regulatory milestones under applicable in-license agreements, as well as our ability to do the same with regard to any potential future collaboration and license agreements, overall sales of any products, if approved, and our ability to maintain all of our product licenses. Any upfront, milestone, or earnout payments either owed by or to us may vary significantly from product to product, period to period, and country to country, and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict.

We are a "smaller reporting company" and the reduced disclosure and governance requirements applicable to smaller reporting companies may make our common stock less attractive to some investors.

We qualify as a "smaller reporting company" under Rule 12b-2 of the Exchange Act. As a smaller reporting company, we are entitled to rely on certain exemptions and reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements, in our SEC filings. These exemptions and decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock price may be more volatile.

Our inability to regain and maintain compliance with Nasdaq continued listing requirements could result in the delisting of our common stock.

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we must satisfy minimum financial, governance, and other requirements. On August 19, 2022, we received a notice (the "Notice") from the Listing Qualifications Department of Nasdaq stating that the departure of Dennison T. Veru from the Board resulted in noncompliance with the independent director and audit committee requirements set forth in Nasdaq Listing Rule 5605. More specifically, the Board currently is not comprised of a majority of "independent directors" within the meaning of Nasdaq Listing Rule 5605(a)(2), and the Board's Audit Committee does not have at least three members, each of whom is independent and meets the criteria for independence set forth in Rule 10A-3(b)(1) under the Securities Exchange Act of 1934, as amended (the "Exchange Act'"), as required by Nasdaq Listing Rule 5605(c)(2)(A). Currently, the Board has two independent members and two non-independent members, and the Audit Committee consists of the two independent members.

The Notice states that, consistent with Nasdaq Listing Rules 5605(b)(1)(A) and 5605(c)(4), Nasdaq will provide us with a cure period in order to regain compliance (i) until the earlier of our next annual shareholders' meeting or July 28, 2023, or (ii) if the next annual shareholders' meeting is held before January 24, 2023, then we must evidence compliance no later than January 24, 2023.

However, there can be no assurance that we will be able to regain compliance with Nasdaq's listing standards. If our common stock is delisted from Nasdaq and we are unable to list our common stock on another national securities exchange, we expect our common stock would be quoted on an over-the-counter market. If this were to occur, we and our stockholders could face significant material adverse consequences, including limited availability of market quotations for our common stock; substantially decreased trading in our common stock; decreased market liquidity of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws; an adverse effect on our ability to issue additional securities or obtain additional financing in the future on acceptable terms, if at all; potential loss of confidence by investors, suppliers, partners, and employees and fewer business development opportunities; and limited news and analyst coverage. Additionally, the market price of our common stock may decline further, and stockholders may lose some or all of their investment.

Even if we are not delisted, the perception among investors that we are at a heightened risk of delisting could negatively affect the market price and trading volume of our common stock, or our ability to raise capital.

We do not anticipate paying any dividends in the foreseeable future.

Our current expectation is that we will retain any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our shares will be your sole source of gain, if any, for the foreseeable future.

Our ability to use our net operating loss carryforwards and other tax assets to offset future taxable income may be subject to certain limitations.

As of December 31, 2022, we had approximately $454.5 million of federal and $444.4 million of state net operating loss ("NOL") carryforwards available to offset future taxable income, of which $210.3 million will carryforward indefinitely and the remainder will expire in varying amounts beginning in 2023 for federal and state purposes if unused. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. Under the U.S. Tax Cuts and Jobs Acts, U.S. federal NOLs incurred in 2018 and later years may be carried forward indefinitely, but our ability to utilize such U.S. federal NOLs to offset taxable income is limited to 80% of the current-year taxable income. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986 and corresponding provisions of state law, if a corporation undergoes an "ownership change" (which is generally defined as a greater than 50 percentage points change (by value) in its equity ownership over a rolling three-year period), the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not determined whether we have experienced Section 382 ownership changes in the past and if a portion of our NOLs is therefore subject to an annual limitation under Section 382. Therefore, we cannot provide any assurance that a change in ownership within the meaning of the Internal Revenue Code of 1986 and corresponding provisions of state law has not occurred in the past, and there is a risk that changes in ownership could have occurred. We may experience ownership changes as a result of subsequent changes in our stock ownership, as a result of offerings of our stock or subsequent shifts in our stock ownership, some of which may be outside of our control. In that case, the ability to use NOL carryforwards to offset future taxable income will be limited following any such ownership change and could be eliminated. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance on our financial statements.

Risks Related to Legal, Regulatory, and Compliance Matters

We or our partners may never obtain regulatory approval to commercialize any other product candidates, and any products approved for sale will be subject to continued regulatory review and compliance obligations and there could be further restrictions on post-approval activities, including commercialization efforts. In obtaining regulatory approval, the approved product label (aka package insert) will determine the extent of allowed promotional activities, and this label could be restrictive or prohibitory with regard to subject matter that may be necessary to maximize the commercial success of the products that are approved.

The research, testing, manufacturing, safety surveillance, efficacy, quality assurance and control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export, and reporting of safety and other post-market information related to our investigational drug products are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and foreign countries, and such regulations differ from country to country and frequently are revised.

Even after we or our partners achieve regulatory approval for a product candidate, if any, we or our partners will be subject to continued regulatory review and compliance obligations, including on how the product is commercialized. For example, with respect to our product candidates for the U.S., the FDA may impose significant restrictions on the approved indicated use(s) for which the product may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product or include in the approved label restrictions on the product and how it may be used or sold. Approved products also will be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, pharmacovigilance and adverse event reporting, storage, advertising, promotion, and recordkeeping for our product candidates. These requirements include submissions of safety and other post-marketing information and reports, registration, continued compliance with cGMP requirements and with the FDA's GCP requirements and GLP requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical and preclinical development, and for any clinical trials that we conduct post-approval, as well as continued compliance with the FDA's laws governing commercialization of the approved product, including but not limited to the FDA's Office of Prescription Drug Promotion's regulation of promotional activities and direct-to-consumer advertising, fraud and abuse, antikickback, product sampling, debarment, scientific speaker engagements and activities, formulary interactions as well as interactions with healthcare practitioners, including various conflict-of-interest reporting requirements for any healthcare practitioners we may use as consultants, and laws relating to the pricing of drug products, including federal "best price" regulations that if not met can prohibit us from participating in federal reimbursement programs like Medicare or Medicaid. To the extent that a product candidate is approved for sale in other countries, it may be subject to similar or more onerous (e.g., prohibition on direct-to-consumer advertising and price controls that do not exist in the U.S.) restrictions and requirements imposed by laws and government regulators, and even private institutions, in those countries.

In addition, manufacturers of drug and biologic products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we, our partners, or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the manufacturing, processing, distribution, or storage facility where, or processes by which, the product is made, a regulatory agency may impose restrictions on that product, us or our partners, including requesting that we or they initiate a product recall, or requiring notice to physicians or the public, withdrawal of the product from the market, or suspension of manufacturing.

If we, our partners, our product candidates, or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the sale, marketing, advertising, or manufacturing of the product, or amend, suspend, or withdraw product approvals, or revoke necessary licenses;

- mandate modifications to or prohibit promotional and other product-specific materials or require us or our partners to provide corrective information to healthcare practitioners and other customers and/or patients, or in our or their advertising and promotion;

- require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions, penalties for noncompliance and, in extreme cases, require an independent compliance monitor to oversee our activities;

- issue warning letters, bring enforcement actions, initiate surprise inspections, issue show cause notices or untitled letters describing alleged violations, which may be publicly available;

- commence criminal investigations and prosecutions;

- debar certain healthcare professionals;

- exclude us or our partners from participating in or being eligible for government reimbursement and formulary inclusion;

- initiate audits, inspections, accounting and civil investigations, or litigation;
- impose injunctions, suspensions, or revocations of necessary approvals or other licenses;
- impose other civil or criminal penalties;
- suspend or cancel any ongoing clinical trials;
- place restrictions on the kind of promotional activities that can be done;
- delay or refuse to approve pending applications or supplements to approved applications filed by us or our partners;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the U.S.;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- change or restrict product labeling; or
- seize or detain products or require us or our partners to initiate a product recall.

The regulations, policies, or guidance of the FDA and other applicable government agencies may change quickly, and new or additional statutes or government laws or regulations may be enacted, including at federal, state, and local levels, or case law may issue, which can differ by geography and could prevent or delay regulatory approval of product candidates or further restrict or regulate post-approval activities, including commercialization efforts. We cannot predict the likelihood, nature, or extent of adverse government regulations that may arise from future legislation or administrative action, or judicial outcomes based on litigation, either in the U.S. or abroad. If we or our partners are not able to achieve and maintain regulatory or other legal compliance, we or they may not be permitted to commercialize product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

We have sponsored or supported and may sponsor or support future clinical trials for our product candidates outside the U.S., and the FDA and applicable foreign regulatory authorities may not accept data from such trials; in addition, we may not be allowed alone or with local country business partners to obtain regulatory approval for our product candidates without first conducting clinical trials in each of these other countries.

We have sponsored or supported and may sponsor or support future clinical trials outside of the U.S., including our recently completed Part 1 of our Phase 1 clinical trial for FRTX-02 in Canada. Although the FDA or applicable foreign regulatory authorities may accept data from clinical trials conducted outside the U.S. or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authorities may be subject to certain conditions or exclusions. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U.S., the FDA will not approve the application on the basis of foreign data alone unless such data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authorities will accept data from trials conducted outside of the U.S. or the applicable home country. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our business plan.

We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability or similar causes of action as a result of the clinical testing (and use) of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and is manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority and notwithstanding that we comply with applicable laws on promotional activity. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse, or abuse associated with our product candidates could result in actual or perceived injury to a patient that may or may not be reversible or potentially even cause death. We cannot offer any assurance that we will not face product liability or other similar suits in the future or that we will be successful in defending them, nor can we assure that our insurance coverage will be sufficient to cover our liability under any such cases.

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, healthcare providers, pharmaceutical companies, or others selling or otherwise coming into contact with our product candidates, among others, and under some circumstances even government agencies. If we cannot successfully defend against product liability or similar claims, we will incur substantial liabilities, reputational harm, and possibly injunctions and punitive actions. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal or delay of recruitment or decreased enrollment rates of clinical trial participants;
- termination or increased government regulation of clinical trial sites or entire trial programs;
- the inability to commercialize, or restrictions on commercializing, our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market or labeling, marketing, or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management’s attention and other resources from our primary business;
- significant delay in product launch;
- debarment of our clinical trial investigators or other related healthcare practitioners working with our company;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance;
- withdrawal of reimbursement or formulary inclusion; or
- loss of revenue.

Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. Our insurance coverage may not be sufficient to cover all of our product liability-related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, restrictive, and narrow, and, in the future, we may not be able to maintain adequate insurance coverage at a reasonable cost, or through self-insurance, in sufficient amounts or upon adequate terms to protect us against losses due to product liability or other similar legal actions. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all and for all geographies in which we wish to launch. A successful product liability claim or series of claims brought against us could, if judgments exceed our insurance coverage, decrease our cash, expose us to liability and harm our business, financial condition, operating results, and prospects.

Healthcare reform measures, including price controls or restricted access, could hinder or prevent the commercial success of our product candidates.

The enactment of any new healthcare initiatives or pharmaceutical industry regulations could have significant impacts on our ability to advance the development of our product candidates and eventually to commercialize them, if at all. Specifically, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which shall take effect in 2023. Under the Inflation Reduction Act, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year and it only applies to drug products that have been approved for at least nine years and biologics that have been licensed for at least 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. Further, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The new law also caps Medicare out-of-pocket drug costs at an estimated $3,250 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates if approved or additional pricing pressures.

There are also calls to severely curtail or ban all direct-to-consumer advertising of pharmaceuticals or restrict activities by pharmaceutical sales representatives to have access to prescribers, which would limit our ability to market our product candidates. With regard to marketing directly to consumers and patients, the U.S. is in a minority of jurisdictions that even allow this kind of advertising, and its removal could limit the potential reach of a marketing campaign.

We are and may be subject to strict healthcare laws, regulation, and enforcement, and our failure to comply with those laws could expose us to liability or adversely affect our business, financial condition, operating results, and prospects.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights and privacy are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct business. The healthcare laws and regulations that may affect our ability to operate include: the Federal Food, Drug and Cosmetic Act, as amended; Title 21 of the Code of Federal Regulations Part 202 (21 CFR Part 202); the 21st Century Cures Act, the federal Anti-Kickback Statute; federal civil and criminal false claims laws and civil monetary penalty laws; the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act; the Prescription Drug Marketing Act (for sampling of drug product); the federal Best Price Act and Medicaid drug rebate program; the federal physician sunshine reporting requirements under the Affordable Care Act and state disclosure laws; the Foreign Corrupt Practices Act as it applies to activities both inside and outside of the U.S.; the federal Right-to-Try legislation; and state law equivalents of many of the above federal laws.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business and result in reputational damage. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including administrative, civil, and criminal penalties, damages, including punitive damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or corporate criminal liability, or the curtailment or restructuring of our operations, and injunctions, any of which could expose us to liability and could adversely affect our business, financial condition, operating results, and prospects.

Our employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs, and any partners with which we may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, officers, directors, independent contractors, principal investigators, other clinical trial staff, consultants, advisors, vendors, CROs, and any partners with which we may collaborate may engage in fraudulent or other illegal or unethical activity. Misconduct by these persons could include intentional, reckless, gross or negligent misconduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete, and accurate information to the FDA or foreign regulatory authorities; product sampling; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; anticorruption laws, anti-kickback and Medicare/Medicaid rules, debarment laws, promotional laws, securities laws, and/or laws that require the true, complete and accurate reporting of financial information or data, books, and records. If any such or similar actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative and punitive penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal or state healthcare programs, debarments, contractual damages, reputational harm, diminished profits and future earnings, injunctions, and curtailment or cessation of our operations, any of which could expose us to liability and adversely affect our business, financial condition, operating results, and prospects.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We incur significant legal, accounting, and other expenses to operate as a public company, including costs associated with public company reporting and other SEC requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and Nasdaq. These rules and regulations have, and are expected to continue to, increase our legal and financial compliance costs and to make some activities more time-consuming and costly. These rules and regulations may also make it expensive for us to operate our business.

Risks Related to Strategic Matters

We recently announced that we are exploring strategic options that could include a financing, sale or licensing of assets, acquisition, merger, business combination, and/or other strategic transaction or series of related transactions. There can be no assurance that this process will result in the pursuit or consummation of any potential transaction or strategy, or that any such potential transaction or strategy, if implemented, will provide sufficient funding to conduct certain additional research and development activities and/or initiate additional clinical trials of our product candidates.

We recently announced that we are exploring strategic options, which could include a financing, sale or licensing of assets, acquisition, merger, business combination, and/or other strategic transaction or series of related transactions, to progress the development of our novel pipeline of potential treatments for autoimmune, inflammatory, and other diseases. Our Board, with the assistance of outside advisors, is evaluating a wide range of strategies. This process, including any uncertainty created by this process, involves a number of risks which could impact our business and our stockholders, including the following:

- significant fluctuations in our stock price could occur in response to developments relating to the process or market speculation regarding any such developments;
- we may encounter difficulties in hiring, retaining and motivating key personnel during this process or as a result of uncertainties generated by this process or any developments or actions relating to it;
- we may incur substantial increases in general and administrative expense associated with increased legal fees and the need to retain and compensate third-party advisors; and
- we may experience difficulties in preserving the commercially sensitive information that may need to be disclosed to third parties during this process or in connection with an assessment of our strategic options.

The review process also requires significant time and attention from management, which could distract them from other tasks in operating our business or otherwise disrupt our business. Such disruptions could cause concern to our suppliers, strategic partners or other constituencies and may have a material impact on our business and operating results and volatility in our share price.

There can be no assurance that this process will result in the pursuit or consummation of any potential transaction or strategy, or that any such potential transaction or strategy, if implemented, will provide sufficient funding to conduct certain additional research and development activities and/or initiate additional clinical trials of our product candidates. Any outcome of this process would be dependent upon a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, regulatory approvals, and the availability of financing on reasonable terms. The occurrence of any one or more of the above risks could have a material adverse impact on our business, financial condition, results of operations and cash flows.

We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, or we may sell and assign our rights, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development or commercialization of any of our early-stage or licensed rights to product candidates, or sell and assign our rights, for a variety of reasons, including the appearance of new technologies that make our product obsolete or significantly impact the ability to commercialize the affected product successfully, competition from a competing product including entry of generics, supply chain considerations, intellectual property right impacts, ability to price or changes in or failure to comply with applicable regulatory requirements, inability or difficulty to generate financing to commercialize a product, market reaction to the market potential for any product asset, or constraints on obtaining additional financing and capital. To continue developing FRTX-02 and the rest of our pipeline, we need to raise additional funds. If such financing or a strategic partnership is not forthcoming in a timely manner, we will be unable to conduct certain additional research and development activities. If we terminate, exit, or assign a program in which we have invested significant resources, we either likely will not receive any return, or only a partial return, on our investment, and we may have missed an opportunity to have allocated those resources to potentially more productive uses.

Risks Related to Our Dependence on Third Parties

We expect to rely on our collaboration with third-party partners for the successful development and commercialization of our product candidates.

We expect to rely upon the efforts of third-party partners for the successful development and commercialization of our current and future product candidates. The clinical, regulatory, and commercial success of our product candidates may depend upon maintaining successful relationships with third-party partners which are subject to a number of significant risks, including the following:

- our partners' ability to execute their responsibilities in a timely, cost-efficient, and compliant manner and to maintain their supply chain systems and safeguard their IT operations and their and our data;
- reduced control over supply, delivery, and manufacturing schedules;
- price increases and product reliability;
- our ability to attract and retain the right partners;
- manufacturing deviations from internal or regulatory specifications;
- quality or integrity incidents;
- the failure of partners to perform their obligations for technical, market, legal, or other reasons;
- misappropriation of our current or future product candidates;
- ability of partners to comply with applicable laws or continue their own operations based on their unique situations; and
- other risks in potentially meeting our current and future product commercialization schedule or satisfying the requirements of our end-users.

We cannot assure that we will be able to establish or maintain third-party partner relationships to successfully develop and commercialize our product candidates.

We rely and expect to continue to rely on third-party contractors for supply, manufacture, and distribution of preclinical or clinical supplies of any current or future product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or internal capability to supply, store, manufacture, or distribute preclinical or clinical quantities of drug substances or products. Additionally, we have not entered into a long-term commercial supply agreement to provide us with such drug substances or products. As a result, our ability to develop our product candidates is dependent, in part, on our ability to obtain the APIs and other substances and materials used in our product candidates successfully from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing. If we fail to develop and maintain supply and other technical relationships with these third parties, or global conditions like the COVID-19 pandemic significantly and adversely impact such third parties, we may be unable to continue to develop our product candidates.

We do not have direct control over whether our contract suppliers and manufacturers will maintain current pricing terms, be willing (or able) to continue supplying us with APIs and finished products, or maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance, and qualified personnel. We are dependent on our contract suppliers and manufacturers for day-to-day compliance with applicable laws and cGMPs for production of both APIs and finished products. If the safety or quality of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for the affected product candidate successfully, and we may be held liable for injuries sustained as a result.

Additionally, any damage to, destruction of, or threats to our third-party manufacturers' or suppliers' facilities, equipment, or systems, even by force majeure or by criminal acts, may significantly impair our ability to have our product candidates manufactured on a timely basis. Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities and systems, will have access to and may misappropriate our trade secrets, clinical trial and other research data, or other proprietary information. In addition, the manufacturing facilities of certain of our suppliers may be located outside of the U.S. This may give rise to difficulties in importing our product candidates or their components into the U.S. or other countries, or otherwise protecting these assets.

Risks Related to Our Intellectual Property

We may not be able to obtain, afford, maintain, enforce, or protect our intellectual property rights covering our product candidates and related technologies that are of sufficient type, breadth, and term throughout the world.

Our success with respect to our autoimmune and inflammatory portfolio and other product candidates will depend, in part, on our ability to protect patent and other intellectual property protections in both the U.S. and other countries, to preserve our trade secrets, and to prevent third parties from infringing on our proprietary rights. Our ability to prevent unauthorized or infringing use of our autoimmune and inflammatory portfolio and other product candidates by third parties depends in substantial part on our ability to leverage valid and enforceable patents and other intellectual property rights around the world.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file, and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner in all the countries that may be desirable. It is also possible that we or our current licensors and licensees, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection by others on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, our competitors independently may develop equivalent knowledge, methods, and know-how or discover workarounds to our patents that would not constitute infringement. Our partners or licensees may inappropriately take or use our intellectual property and/or confidential information to infringe our patents or otherwise violate their contractual obligations to us related to protection of our intellectual property. Any of these outcomes could impair our ability to enforce the exclusivity of our patents effectively, which may have an adverse impact on our business, financial condition, operating results, and prospects.

Due to constantly shifting global legal standards relating to patentability, validity, enforceability, and claim scope of patents covering pharmaceutical inventions, our ability to protect patents in any jurisdiction is uncertain and involves complex legal and factual questions, especially across countries. Accordingly, rights under any applicable patents that apply to us may not cover our product candidates or may not provide us with sufficient protection for our product candidates to afford a sustainable commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. In addition, we cannot guarantee that any patents or other intellectual property rights will issue from any pending or future patent or other similar applications related to us. Even if patents or other intellectual property rights have issued or will issue, we cannot guarantee that the claims of these patents and other rights are or will be held valid or enforceable by the courts or other legal authorities, through injunction or otherwise, or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us in every country of commercial significance that we may target, or that a legislative or executive branch of government will not alter the rights and enforceability thereof at any time.

Competitors in the therapeutic areas of our strategic focus have created a substantial amount of prior art, including scientific publications, abstracts, posters, presentations, patents and patent applications, and other public disclosures, including on the Internet and various social media. Our ability to protect valid and enforceable patents and other intellectual property rights depends on whether the differences between our proprietary technology and the prior art allow our technology to be patentable over the prior art. We do not have outstanding issued patents covering all of the recent developments in our technology and are unsure of the patent protection that we will be successful in securing, if any. Even if the patents do issue successfully, third parties may design around or challenge the validity, enforceability, or scope of such issued patents or any other issued patents or intellectual property that apply to us, which may result in such patents and/or other intellectual property being narrowed, invalidated, or held unenforceable. If the breadth or strength of protection provided by the patents and other intellectual property we hold or pursue with respect to our product candidates is challenged, regardless of our future success, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize or finance, our product candidates.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent or duration as in the U.S., and many companies have encountered significant difficulties in acquiring, maintaining, protecting, defending, and especially enforcing such rights in foreign jurisdictions. If we encounter such difficulties in protecting, or are otherwise precluded from effectively protecting, our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed, especially internationally.

Patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally 20 years after it is filed, with patent term extensions granted in certain instances to compensate for part of the period in which the drug was under development and could not be commercialized while under the patent. Without patent protection for our product portfolio, we may be open to competition from generic versions of these assets. FRTX-02 is covered by a composition of matter patent issued in the U.S., Japan, China, and other key countries through at least 2038, subject to patent term extensions and adjustments that may be available depending on how this early-stage asset is developed, as well as a pending PCT application, and other foreign and U.S. applications for FRTX-02, as of the date of this Annual Report. We are evaluating the patent protection and strategy for the remainder of the assets in-licensed from Voronoi and Carna.

Proprietary trade secrets and unpatented know-how and confidential information are also important to our business. Although we have taken steps to protect our trade secrets, unpatented know-how, and confidential information by entering into confidentiality and nondisclosure agreements with third parties and intellectual property protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that binding agreements will not be breached or enforced by courts or other legal authorities, that we would have adequate remedies for any breach, including injunctive and other equitable relief, or that our trade secrets, unpatented know-how, and confidential information will not otherwise become known, be inadvertently disclosed by us or our agents and representatives, or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use, and if we and our agents or representatives inadvertently disclose trade secrets, unpatented know-how, and/or confidential information, we may not be allowed to retrieve the inadvertently disclosed trade secret, unpatented know-how, and/or confidential information and maintain the exclusivity we previously enjoyed.

We may not be able to protect our intellectual property rights meaningfully throughout the world.

Filing, prosecuting, and defending patents on our product candidates do not guarantee exclusivity. The requirements for patentability differ in certain countries, particularly developing countries, and can change over time in the same country. In addition, the laws of some other countries do not protect intellectual property rights to the same extent as laws in the U.S., especially when it comes to granting use and other kinds of patents and what kind of enforcement rights will be allowed, especially injunctive relief in a civil infringement proceeding. Consequently, we may not be able to prevent third parties from practicing our inventions in countries outside the U.S. and even in launching an identical version of our product notwithstanding our having a valid patent or other intellectual property rights in that country. Competitors may use our technologies in jurisdictions where we, or our licensors or licensees, have not obtained patent or other protections to develop their own products, or produce copy products, and further, may export otherwise infringing products to territories where we have patent and other protections but enforcement against infringing activities is inadequate or where we have no patents or other intellectual property rights. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from commercialization or other uses.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly in developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, and the judicial and government systems are often corrupt, apathetic, or ineffective, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our global patents and other rights at risk of being invalidated or interpreted narrowly and our global patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuit that we initiate or infringement action brought against us, and the damages or other remedies awarded, if any, may not be commercially meaningful when we are the plaintiff. When we are the defendant, we may be required to post large bonds to stay in the market while we defend ourselves from an infringement action.

In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, especially if the patent owner does not enforce or use its patents over a protracted period of time. In some cases, the courts will force compulsory licenses on the patent holder even when finding the patentholder's patents are valid if the court believes it is in the best interests of the country to have widespread access to an essential product covered by the patent. Further, there is no guarantee that any country will not adopt or impose compulsory licensing in the future. In these situations, the royalty the court requires to be paid by the license holder receiving the compulsory license may not be calculated at fair market value and can be inconsequential, thereby disaffecting the patentholder's business. In these countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could also materially diminish the value of those patents. This would limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license, especially in comparison to what we enjoy from enforcing our intellectual property rights in the U.S. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in both U.S. and foreign intellectual property laws, or changes to the policies in various government agencies in these countries, including but not limited to the patent office issuing patents and the health agency issuing pharmaceutical product approvals. For example, in Brazil, pharmaceutical patents require prior initial approval from the Brazilian health agency, ANVISA. Finally, many countries have large backlogs in patent prosecution, and in some countries in Latin America, it can take years, even decades, just to get a pharmaceutical patent application reviewed notwithstanding the merits of the application.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent and similar agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance, validation, and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction just for failure to know about and/or timely pay such fee. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees in prescribed time periods, and failure to properly legalize and submit formal documents in the format and style the country requires. If we or our licensors fail to maintain the patents and patent applications covering our product candidates for any reason, our competitors might be able to otherwise enter the market, which would have an adverse effect on our business, financial condition, operating results, and prospects.

In addition, countries continue to increase the fees that are charged to acquire, maintain, and enforce patents and other intellectual property rights, which may become prohibitive to initiate or continue paying in certain circumstances.

If we fail to comply with our obligations under our intellectual property and related license agreements, we could lose license rights that are important to our business. Additionally, these agreements may be subject to disagreement over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology, or other key aspects of product development and/or commercialization, or increase our financial or other obligations to our licensors.

We have entered into in-license arrangements with respect to all of our product candidates. These license agreements impose various diligence, milestone, royalty, insurance, reporting, and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate or modify the license, or trigger other more disadvantageous contract clauses, in which event we may not be able to finance, develop or market the affected product candidate. The loss of such rights could expose us to liability and could materially adversely affect our business, financial condition, operating results, and prospects.

Our commercial success depends on our ability to develop, manufacture, market, and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties and do this in one or more countries. We cannot assure that marketing and selling such product candidates and using such technologies will not infringe existing or future patents or other intellectual property rights. Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents and other intellectual property rights are issued, the risk increases that others may assert that our product candidates, technologies, or methods of delivery or use(s) infringe their patent or other intellectual property rights. Moreover, it is not always clear to industry participants, including us, which patents and other intellectual property rights cover various drugs, biologics, drug delivery systems and formulations, manufacturing processes, or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields across many countries, there may be a risk that third parties may allege they have patent or other rights encompassing our product candidates, technologies, or methods.

In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by our product candidates or proprietary technologies notwithstanding the patents we may possess. Because some patent applications in the U.S. and other countries may be maintained in confidence until the patents are issued, because patent applications in the U.S. and many foreign jurisdictions are typically not published until eighteen (18) months or some other time after filing, and because publications in the scientific literature or other public disclosures often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to our technology. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies, which may mean paying significant licensing fees or royalties, or the like. If another party has filed a U.S. patent application on inventions similar to ours, we or the licensor may have to participate in the U.S. in an interference proceeding to determine priority of invention.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing in the U.S. under Paragraph IV of the Hatch-Waxman Act or other countries' laws similar to the Hatch-Waxman Act. These lawsuits could claim that there are existing patent rights for such drug, and this type of litigation can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us are ultimately established as invalid. There is a risk that a court or other legal authority would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court or other legal authority will order us to pay the other party significant damages for having violated the other party's patents or intellectual property rights.

Because we rely on certain third-party licensors, licensees, and partners and will continue to do so in the future, around the world, if one of our licensors, licensees, or partners is sued for infringing a third party's intellectual property rights, this could expose us to liability, and our business, financial condition, operating results, and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we have agreed to indemnify certain third-party licensors, licensees, and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost-sharing agreements with some of our licensors, licensees, and partners that could require us to pay some of the costs of patent or other intellectual property rights litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than would be assumed just on the basis of our technology.

The occurrence of any of the foregoing could expose us to liability or adversely affect our business, financial condition, operating results, and prospects at any time.

General Risk Factors

Provisions of Delaware law and our restated certificate of incorporation and amended and restated bylaws may discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of Delaware law and our restated certificate of incorporation and amended and restated bylaws may discourage, delay, or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove members of our Board. These provisions include, but are not limited to:

- authorizing the issuance of “blank check” preferred stock without any need for action by stockholders;
- providing for a classified Board with staggered terms;
- requiring supermajority stockholder voting to effect certain amendments to our current certificate of incorporation and bylaws;
- eliminating the ability of stockholders to call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to our Board or for proposing matters that can be acted on by stockholders at stockholder meetings.

Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our Board, they would apply even if an offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it difficult for stockholders to replace members of our Board, which is responsible for appointing the members of our management.

If we fail to attract and retain management and other key personnel and directors, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceutical industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, regulatory and compliance, sales and marketing, business development, commercial and other personnel, and members of our Board. We are highly dependent on our management, scientific personnel, and directors. The loss of the services of any of these individuals could impede, delay, or prevent the successful development of our product pipeline, completion of our current or any future clinical trials, commercialization of our product candidates, or in-licensing or acquisition of new assets and could impact negatively our ability to implement successfully our business plan in a way that complies with all applicable laws. If we lose the services of any of these individuals, we might not be able to find suitable diverse replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain diverse qualified management and other key personnel or directors in the future due to the intense competition for qualified individuals among biotechnology, pharmaceutical, and other businesses. This risk is heightened recently for most employers by the global reaction to the emergence of the COVID-19 pandemic and its impact on worker availability and government regulation of workplace practices associated with public health and other factors.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters are in Boulder, Colorado, occupying approximately 3,000 square feet under a lease agreement that expires in December 2025 and provides us an early termination option. We use our current facilities primarily for research and development and general and administrative personnel. We believe that our existing facilities are adequate for our current needs.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our company, nor is any such litigation threatened as of the date of this filing.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II.

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "FRTX."

Holders

As of March 23, 2023, we had 119 registered holders of record of our common stock. A greater number of holders of our common stock are "street name" or beneficial holders, whose shares of record are held by banks, brokers, other financial institutions, and registered clearing agencies.

Stock Repurchases

There were no repurchases made by us or on our behalf, or by any "affiliated purchaser," of shares of our common stock during the year ended December 31, 2022.

Dividend Policy

We historically have not, and do not anticipate in the future, paying dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Subject to these limitations, any future determination as to the payment of cash dividends on our common stock will be at our Board's discretion and will depend on our financial condition, operating results, capital requirements, and other factors that our Board considers to be relevant.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

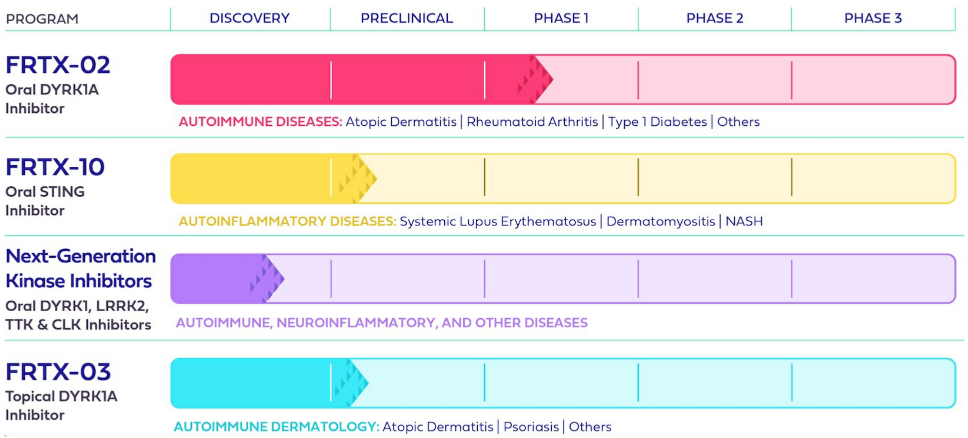
We are a clinical-stage pharmaceutical company striving to transform patient lives through the development of innovative and differentiated prescription therapeutics. Our pipeline aims to disrupt existing treatment paradigms and features several new chemical entities that inhibit novel targets with first-in-class potential for autoimmune, inflammatory, and other debilitating diseases. Our 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 sofpironium bromide. Our 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.

On September 7, 2022, we changed our corporate entity name from Brickell Biotech, Inc. to Fresh Tracks Therapeutics, Inc. and updated our logo, website, and branding elements to reflect the new name. We also updated our product candidate names accordingly, for instance BBI-02 became FRTX-02 and BBI-10 became FRTX-10.

Exploration of Strategic Options

Our Board and executive management team are conducting a comprehensive process to explore and evaluate strategic options to progress the development of our 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 our Company. MTS Health Partners, LP has been retained as our exclusive financial advisor to assist in this review process.

The following image summarizes our current pipeline and corresponding development programs:



Research & Development Programs

FRTX-02: A Potential First-in-Class Oral DYRK1A Inhibitor for the Treatment of Autoimmune and Inflammatory Diseases

FRTX-02, a novel, potent, highly selective, and orally bioavailable potential first-in-class, small molecule DYRK1A inhibitor that aims to restore immune balance in patients whose immune systems have become dysregulated. We believe FRTX-02 has the potential to be a first-in-class therapy for the treatment of a wide array of debilitating autoimmune and inflammatory diseases.

FRTX-02 is our lead development-stage program and has demonstrated promising results in various preclinical models, including of AD and rheumatoid arthritis. In these models, FRTX-02 showed encouraging decreases in disease severity and reduction of pro-inflammatory cytokines compared to 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 immunosuppressive, which may lead to severe side effects, such as increased infection risk. Preclinical data have shown FRTX-02 to drive regulatory T-cell differentiation while dampening pro-inflammatory T_H17 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 inhibiting autoimmune disease and limiting chronic inflammation. The MyD88protein is normally 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 certain pro-inflammatory cytokines. Based on current understanding, this inhibition of the 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, as well as those currently being investigated, FRTX-02 may have the ability to target both the adaptive and innate immune imbalance simultaneously, potentially resulting in, or substantially achieving, restoration of immune homeostasis that, if proven, would represent a paradigm shift in the treatment of certain autoimmune and inflammatory diseases.

In May 2022, we initiated a first-in-human Phase 1 clinical trial for FRTX-02 (FRTX-02-101) in Canada, which marks the first time an oral DYRK1A inhibitor intended for patients with autoimmune diseases has been administered in humans. FRTX-02-101 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 AD. Parts 1A and 1B of the Phase 1 clinical trial were completed in the fourth quarter of 2022, and in March 2023, we reported positive topline results described in greater detail below. Part 2 of the study is planned to compare once-daily oral doses of FRTX-02 to placebo in subjects with moderate-to-severe AD and include an exploratory evaluation of efficacy. Part 2 is expected to enroll approximately 40 patients at up to 12 study centers.

FRTX-02 is covered by a composition of matter patent issued in the U.S., Japan, China, and other key countries through at least 2038, subject to patent term extensions and adjustments that may be available depending on how this early-stage asset is developed, as well as a pending PCT application, and other foreign and U.S. applications for FRTX-02, as of the date of this Annual Report.

FRTX-10: A covalent Stimulator of Interferon Genes (STING) inhibitor candidate for the Potential Treatment of Autoimmune, Inflammatory, and Rare Genetic Diseases

In February 2022, we acquired exclusive, worldwide rights to research, develop, and commercialize a portfolio of novel, preclinical-stage oral STING inhibitors. STING is a well-known mediator of innate immune responses. Excessive signaling through STING is linked to numerous high unmet-need diseases, ranging from autoimmune disorders, such as systemic lupus erythematosus, to interferonopathies, which are a set of rare genetic conditions characterized by interferon overproduction and could have orphan drug potential.

STING is a key component of the cyclic GMP-AMP synthase (cGAS)-STING pathway, which plays an important role in the activation of innate immunity. cGAS acts as a DNA sensor, detecting DNA from sources such as invading bacteria, viruses, and cellular debris that can arise from aging and tissue damage. Upon DNA binding, cGAS produces the secondary messenger molecule cyclic GMP-AMP (cGAMP), which binds to STING. STING then undergoes the post-translational modification called palmitoylation, a step essential to the activation of STING. Activated STING then in turn activates the recruitment of kinases that phosphorylate IRF3 and IκBα. Phosphorylated IRF3 leads to activation of the type I interferon response, while phosphorylated IκBα activates NFκB and increases the secretion of pro-inflammatory cytokines such as IL-6 and TNFα, resulting in inflammation. While the innate immune response is an important defense mechanism, a dysregulated type I interferon response and overproduction of pro-inflammatory cytokines also represents a driving cause of multiple autoimmune and inflammatory diseases. As such, targeting the cGAS-STING pathway through STING inhibition may be a novel approach to treating these diseases.

FRTX-10, our lead early-stage STING inhibitor candidate, is a novel, potent, and orally bioavailable covalent STING inhibitor that specifically targets the palmitoylation site of STING. This allows it to inhibit both wild-type STING and gain-of-function mutants without competing with cGAMP binding, thus deactivating downstream signaling through IRF3 and IκBα and ultimately suppressing inflammation. FRTX-10 has exhibited strong proof-of mechanism and a promising profile in initial pharmacokinetics, toxicology, and safety pharmacology studies. In addition, *in vitro* studies show that FRTX-10 more potently blocks the STING pathway compared to other known STING palmitoylation inhibitors, and that mice treated with FRTX-10*in vivo* demonstrate significant decreases in production of key pro-inflammatory cytokines following stimulation of STING.

For FRTX-10, as of the date of this Annual Report, we currently have two pending PCT applications and pending applications in the U.S., Japan, Europe, and other key countries. We possess an exclusive license directed to a library of compounds targeting/inhibiting STING, pharmaceutical compositions containing the same, and methods of their use, which are being evaluated.

Next-Generation Kinase Inhibitors: A Cutting-Edge Platform with the Potential to Produce Treatments for Autoimmune, Inflammatory, and Other Debilitating Diseases

In August 2021, we acquired exclusive global rights to a cutting-edge platform of next-generation kinase inhibitors. This library of new chemical entities includes next-generation DYRK1 inhibitors, as well as other molecules that specifically inhibit Leucine-Rich Repeat Kinase 2 (LRRK2), CDC2-like kinase (CLK), and TTK protein kinase (TTK), also known as Monopolar spindle 1 (Mps1) 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.

Compounds from the next-generation kinase inhibitor platform are covered by U.S. and foreign composition of matter patent applications, as well as other applications, that are currently pending in global prosecution.

Topline Results of FRTX-02 (Phase 1 Part A and B) Clinical Trial

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, and pharmacodynamics of FRTX-02 capsules in both healthy subjects and patients with 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 is planned to compare once-daily oral doses of FRTX-02 to placebo in subjects with moderate-to-severe AD and include an exploratory evaluation of efficacy.

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 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.

Strategic, Licensing, and Other Arrangements

License and Development Agreement with Voronoi

In August 2021, we entered into the Voronoi License Agreement with Voronoi, pursuant to which we acquired exclusive, worldwide rights to research, develop, and commercialize FRTX-02 and other next-generation kinase inhibitors. In accordance with the terms of the Voronoi License Agreement, in exchange for the licensed rights, we made a one-time payment of $2.5 million in cash and issued $2.0 million, or 62,597 shares, of our common stock to Voronoi, which was recorded as research and development expenses in the consolidated statements of operations during the year ended December 31, 2021.

With respect to FRTX-02, the Voronoi License Agreement provides that we will make payments to Voronoi of up to $211.0 million in the aggregate contingent upon achievement of specified development, regulatory, and commercial milestones. With respect to the compounds arising from the next-generation kinase inhibitor platform, we will make payments to Voronoi of up to $107.5 million in the aggregate contingent upon achievement of specified development, regulatory, and commercial milestones. Further, the Voronoi License Agreement provides that we will pay Voronoi tiered royalty payments ranging from low-single digits up to 10% of net sales of products arising from the DYRK1A inhibitor programs and next-generation kinase inhibitor platform. All of the contingent payments and royalties are payable in cash in U.S. Dollars, except for $1.0 million of the development and regulatory milestone payments, which amount is payable in equivalent shares of our common stock. Under the terms of the Voronoi License Agreement, we are responsible for, and bear the future costs of, all development and commercialization activities, including patenting, related to all the licensed compounds. During the years ended December 31, 2022 and 2021 and through the date of this Annual Report, we did not make any payments or recorded any liabilities related to the specified development, regulatory, and commercial milestones or royalties on net sales pursuant to the Voronoi License Agreement.

Exclusive License and Development Agreement with Carna

In February 2022, we entered into the Carna License Agreement with Carna, pursuant to which we acquired exclusive, worldwide rights to research, develop, and commercialize Carna's portfolio of novel STING inhibitors. In accordance with the terms of the Carna License Agreement, in exchange for the licensed rights, we made a one-time cash payment of $2.0 million, which was recorded as research and development expenses in the consolidated statements of operations during the year ended December 31, 2022.

The Carna License Agreement provides that we will make success-based payments to Carna of up to $258.0 million in the aggregate contingent upon achievement of specified development, regulatory, and commercial milestones. Further, the Carna License Agreement provides that we will pay Carna tiered royalty payments ranging from mid-single digits up to 10% of net sales. All of the contingent payments and royalties are payable in cash in U.S. Dollars. Under the terms of the Carna License Agreement, we are responsible for, and bear the future costs of, all development and commercialization activities, including patenting, related to all the licensed compounds. During the years ended December 31, 2022 and 2021 and through the date of this Annual Report, we did not make any payments or recorded any liabilities related to the specified development, regulatory, and commercial milestones or royalties on net sales pursuant to the Carna License Agreement.

Agreements with Botanix

Asset Purchase Agreement with Botanix

On the Effective Date, we and Brickell Subsidiary entered into the Asset Purchase Agreement, pursuant to which Botanix acquired and assumed control of all rights, title, and interests to assets primarily related to the Assets. Prior to the sale of the Assets, we had previously entered into the Amended and Restated License Agreement with Bodor that provided us with a worldwide exclusive license to develop, manufacture, market, sell, and sublicense products containing sofpironium bromide through which the Assets were developed. As a result of the Asset Purchase Agreement, Botanix is now responsible for all further research, development, and commercialization of sofpironium bromide globally and replaced us as the exclusive licensee under the Amended and Restated License Agreement.

In accordance with the sublicense rights provided to us under the Amended and Restated License Agreement, we also had previously entered into the Kaken Agreement, under which we granted to Kaken an exclusive right to develop, manufacture, and commercialize the sofpironium bromide compound in the Territory. In exchange for the sublicense, we were entitled to receive aggregate payments of up to $10.0 million upon the achievement of specified development milestones, which were earned and received in 2017 and 2018, and up to $19.0 million upon the achievement of sales-based milestones, as well as tiered royalties based on a percentage of net sales of licensed products in the Territory. In September 2020, Kaken received regulatory approval in Japan to manufacture and market ECCLOCK for the treatment of primary axillary hyperhidrosis, and as a result, we began recognizing royalty revenue earned on a percentage of net sales of ECCLOCK in Japan. Pursuant to the Asset Purchase Agreement, the Kaken Agreement was assigned to Botanix, which replaced us as the exclusive sub-licensor to Kaken. During the year ended December 31, 2022, prior to entering into the Asset Purchase Agreement, we recognized royalty revenue of $0.1 million under the Kaken Agreement. During the year ended December 31, 2021, we recognized royalty revenue of $0.4 million under the Kaken Agreement.

We determined that the development of and ultimate sale and assignment of rights to the Assets is an output of our ordinary activities and Botanix is a customer as it relates to the sale of the Assets and related activities.

In accordance with the terms of the Asset Purchase Agreement, in exchange for the Assets, we (i) received an upfront payment at closing in the amount of $3.0 million, (ii) were reimbursed for certain recent development expenditures in advancement of the Assets, (iii) received a milestone payment of $2.0 million upon the acceptance by the FDA in December 2022 of the filing of an NDA for sofpironium bromide gel, 15%, and (iv) will receive a contingent milestone payment of $4.0 million if marketing approval in the U.S. for sofpironium bromide gel, 15%, is received on or before September 30, 2023, or $2.5 million if such marketing approval is received after September 30, 2023 but on or before February 17, 2024. Botanix submitted an NDA for sofpironium bromide gel, 15%, to the FDA in September 2022, which was accepted by the FDA in December

2022. Under the Asset Purchase Agreement, we also are eligible to receive additional success-based regulatory and sales milestone payments of up to $168.0 million. Further, we will receive Earnout Payments on net sales of sofpironium bromide gel.

The Asset Purchase Agreement also provides that Botanix will pay to us Sublicense Income from a portion of the sales-based milestone payments and royalties that Botanix receives from Kaken under the assigned Kaken Agreement. Sublicense Income represents our estimate of payments that will be earned by us in the applicable period from sales-based milestone payments and royalties Botanix will receive from Kaken to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Royalties vary based on net sales that are impacted by a wide variety of market and other factors. We have recorded a contract asset equal to the amount of revenue recognized related to the Sublicense Income, less the amount of payments received from or due by Botanix in relation to the Sublicense Income.

All other consideration due under the Asset Purchase Agreement is contingent upon certain regulatory approvals and future sales subsequent to such regulatory approvals, or is based upon future sales that we determined are not yet probable due to such revenues being highly susceptible to factors outside of our influence and uncertainty about the amount of such consideration that will not be resolved for an extended period of time. Therefore, we determined that such variable consideration amounts are fully constrained as of December 31, 2022, and, as such, did not recognize such amounts as contract revenue.

Transition Services Agreement with Botanix

In connection with the sale of the Assets, on the Effective Date, we and Botanix entered into the TSA whereby we are providing consulting services as an independent contractor to Botanix in support of and through filing and potential approval of the U.S. NDA for sofpironium bromide gel, 15%. In accordance with the terms of the TSA, in exchange for providing these services (i) prior to the acceptance of the filing by the FDA of such NDA in December 2022, we received from Botanix a fixed monthly amount of $71 thousand, and (ii) after the acceptance of the filing in December 2022, we will receive from Botanix a variable amount based upon actual hours worked, in each case plus related fees and expenses of our advisors (plus a 5% administrative fee) and our out-of-pocket expenses.

Contract Revenue under the Botanix Agreements

We recognized the following as contract revenue during the year ended December 31, 2022 (in thousands):

	Year Ended December 31, 2022
Upfront consideration	$ 3,000
Milestone payment received upon acceptance by FDA of NDA filing	2,000
Consulting services provided under the TSA	794
Reimbursed development expenditures under the Asset Purchase Agreement	624
Sublicense Income	433
Total contract revenue	$ 6,851

Agreements with Bodor

In connection with the sale of the Assets, on the Effective Date, we, Brickell Subsidiary, and Bodor entered into the Rights Agreement to clarify that we and Brickell Subsidiary have the power and authority under the Amended and Restated License Agreement to enter into the Asset Purchase Agreement and the TSA, and that Botanix would assume the Amended and Restated License Agreement pursuant to the Asset Purchase Agreement. The Rights Agreement includes a general release of claims and no admission of liability between the parties. Pursuant to such Rights Agreement, as subsequently amended on November 10, 2022, we have agreed to pay Bodor (i) 20% of the amount of each payment due to us from Botanix for upfront and milestone payments, subject to deductions, credits, or offsets applied under the Asset Purchase Agreement, as well as (ii) certain tiered payments, set as a percentage ranging from mid-single digits to mid-teen digits, of the amount of each of the applicable Earnout Payments due to us from Botanix after deductions, credits, or offsets applied under the Asset Purchase Agreement.

Pursuant to the terms of the Asset Purchase Agreement, we retained our obligation under the Amended and Restated License Agreement to issue $1.0 million in shares of our common stock to Bodor upon the FDA's acceptance of an NDA filing for sofpironium bromide gel, 15%. On November 10, 2022, we entered into the Acknowledgment with Brickell Subsidiary, Botanix, Botanix Pharmaceuticals Limited, and Bodor. Pursuant to the Acknowledgment, we paid $1.0 million in cash to Bodor in full satisfaction of our obligation to issue shares upon the FDA's acceptance of the NDA. We determined to prepay this obligation in cash in order to avoid the substantial dilution to our stockholders that would have resulted if we had issued the shares of our common stock originally provided for in the Amended and Restated License Agreement.

During the year ended December 31, 2022, $1.9 million was incurred and reported as general and administrative expenses in the consolidated statements of operations associated with achieved milestones related to sofpironium bromide gel, 15%. Prior to December 31, 2022, no expenses associated with milestones had been incurred. Prior to the execution of the Rights Agreement, we paid Bodor immaterial amounts with respect to the royalties we received from Kaken for sales of ECCLOCK in Japan during those periods.

Reverse Stock Split

On June 30, 2022, our stockholders approved a reverse stock split of our outstanding common stock, which was effected at a split ratio of 1-for-45 on July 5, 2022, at which date each forty-five (45) shares of common stock issued and outstanding immediately prior to the reverse stock split were automatically reclassified, combined and converted into one (1) validly issued, fully paid, and non-assessable share of our common stock, subject to the treatment of fractional share interests.

All common stock shares, per-share amounts, and other related balances and computations presented in this Management's Discussion and Analysis of Financial Condition and Results of Operations give effect to the 1-for-45 reverse stock split of our outstanding shares of common stock that occurred on July 5, 2022.

Significant Financing Arrangements

This section sets forth our recent and ongoing financing arrangements, all of which involve our common stock.

Public Offerings of Common Stock and Warrants

In October 2021, we completed the sale of 672,521 shares of our common stock (the "October 2021 Offering"). The October 2021 Offering resulted in net proceeds of approximately $10.3 million, after deducting the underwriting discount and offering expenses payable by us.

In July 2021, we completed the sale of 288,530 shares of our common stock (the "July 2021 Offering"). The July 2021 Offering resulted in net proceeds of approximately $7.3 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

In October 2020, we completed the sale of 422,300 shares of our common stock, and, to certain investors, pre-funded warrants to purchase 40,663 shares of our common stock, and accompanying common stock warrants to purchase up to an aggregate of 462,979 shares of our common stock (the "October 2020 Offering"). The October 2020 Offering resulted in net proceeds of approximately $13.7 million to us after deducting underwriting commissions and discounts and other offering expenses payable by us of $1.3 million and excluding the proceeds from the exercise of the warrants. During the year ended December 31, 2021, 276,165 common warrants associated with the October 2020 Offering were exercised at a weighted-average exercise price of $32.40 per share, resulting in aggregate proceeds of approximately $8.9 million. No warrants associated with the October 2020 Offering were exercised during the year ended December 31, 2022.

In June 2020, we completed the sale of 328,669 shares of our common stock, and, to certain investors, pre-funded warrants to purchase 60,220 shares of our common stock, and accompanying common stock warrants to purchase up to an aggregate of 388,920 shares of our common stock (the "June 2020 Offering"). The June 2020 Offering resulted in approximately $18.7 million of net proceeds after deducting underwriting commissions and discounts and other offering expenses payable by us of $1.4 million and excluding the proceeds from the exercise of the warrants. During the year ended December 31, 2021, 388 common warrants associated with the June 2020 Offering were exercised at a weighted-average exercise price of $56.25 per share, resulting in aggregate proceeds of approximately $22 thousand. No warrants associated with the June 2020 Offering were exercised during the year ended December 31, 2022.

For additional information regarding the offerings described above, see Note 7. "*Capital Stock*" of the notes to our consolidated financial statements included in this Annual Report.

At Market Issuance Sales Agreements

In March 2021, we entered into an At Market Issuance Sales Agreement (the "2021 ATM Agreement") with Oppenheimer & Co. Inc. ("Oppenheimer") and William Blair & Company, L.L.C. ("William Blair") as our sales agents (the "Agents"). Pursuant to the terms of the 2021 ATM Agreement, we may sell from time to time through the Agents shares of our common stock having an aggregate offering price of up to $50.0 million. Such shares are issued pursuant to our shelf registration statement on Form S-3 (Registration No. 333-254037). Sales of shares are made by means of ordinary brokers' transactions on The Nasdaq Capital Market at market prices or as otherwise agreed by us and the Agents. Under the terms of the 2021 ATM Agreement, we may also sell the shares from time to time to an Agent as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the shares to an Agent as principal would be pursuant to the terms of a separate placement notice between us and such Agent. During the year ended December 31, 2022, we sold 354,381 shares of common stock under the 2021 ATM Agreement at a weighted-average price of $3.70 per share, for aggregate net proceeds of $1.3 million, after giving effect to a 3% commission to the Agents. During the year ended December 31, 2021, we sold 98,882 shares of common stock under the 2021 ATM Agreement at a weighted-average price of $40.04 per share, for aggregate net proceeds of $3.8 million, after giving effect to a 3% commission to the Agents. As of December 31, 2022, approximately $44.7 million of shares of common stock were remaining, but had not yet been sold under the 2021 ATM Agreement. Subsequent to December 31, 2022 and through March 30, 2023, we sold 2,887,535 shares of our common stock under the 2021 ATM Agreement at a weighted-average price of $2.34 per share, for aggregate net proceeds of approximately $6.6 million, resulting in approximately $38.0 million of shares of common stock remaining under the 2021 ATM Agreement.

In April 2020, we entered into an At Market Issuance Sales Agreement (the "2020 ATM Agreement" and, together with the 2021 ATM Agreement, the "ATM Agreements") with Oppenheimer as our sales agent. Pursuant to the terms of the 2020 ATM Agreement, we may sell from time to time through Oppenheimer shares of our common stock having an aggregate offering price of up to $8.0 million. Such shares are issued pursuant to our shelf registration statement on Form S-3 (Registration No. 333-236353). Sales of the shares are made by means of ordinary brokers' transactions on The Nasdaq Capital Market at market prices or as otherwise agreed by us and Oppenheimer. Under the terms of the 2020 ATM Agreement, we may also sell the shares from time to time to Oppenheimer as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the shares to Oppenheimer as principal would be pursuant to the terms of a separate placement notice between us and Oppenheimer. During the year ended December 31, 2022, no sales of common stock under the

2020 ATM Agreement occurred. During the year ended December 31, 2021, we sold 24,201 shares of our common stock under the 2020 ATM Agreement at a weighted-average price of $69.62 per share, for aggregate net proceeds of approximately $1.6 million, after giving effect to a 3% commission to Oppenheimer as agent. As of December 31, 2022, approximately $2.6 million of shares of common stock were remaining, but had not yet been sold under the 2020 ATM Agreement.

We are subject to the SEC's "baby shelf rules," which prohibit companies with a public float of less than $75 million from issuing securities under a shelf registration statement in excess of one-third of such company's public float in a 12-month period. These rules may limit future issuances of shares by us under the ATM Agreements or other common stock offerings.

Private Placement Offerings

In February 2020, we and Lincoln Park Capital Fund, LLC ("Lincoln Park") entered into (i) a securities purchase agreement (the "Securities Purchase Agreement"); (ii) a purchase agreement (the "Purchase Agreement"); and (iii) a registration rights agreement (the "Registration Rights Agreement"). Pursuant to the Securities Purchase Agreement, Lincoln Park purchased, and we sold, (i) an aggregate of 21,111 shares of common stock (the "Common Shares"); (ii) a warrant to initially purchase an aggregate of up to 13,476 shares of common stock at an exercise price of $0.45 per share (the "Series A Warrant"); and (iii) a warrant to initially purchase an aggregate of up to 34,588 shares of common stock at an exercise price of $52.20 per share (the "Series B Warrant" and, together with the Series A Warrant, the "Warrants"). The aggregate gross purchase price for the Common Shares and the Warrants was $2.0 million. No warrants associated with the Securities Purchase Agreement were exercised during the years ended December 31, 2022 or 2021.

Under the terms and subject to the conditions of the Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $28.0 million in the aggregate of shares of our common stock. In order to retain maximum flexibility to issue and sell up to the maximum of $28.0 million of our common stock under the Purchase Agreement, we sought and, at our annual meeting on April 19, 2021, received, stockholder approval for the sale and issuance of common stock in connection with the Purchase Agreement under Nasdaq Listing Rule 5635(d). Sales of common stock by us will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on August 14, 2020 (the "Commencement Date").

Following the Commencement Date, under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to 2,222 shares of our common stock on such business day (each, a "Regular Purchase"), provided, however, that (i) the Regular Purchase may be increased to up to 2,777 shares, provided that the closing sale price of the common stock is not below $3.00 on the purchase date; and (ii) the Regular Purchase may be increased to up to 3,333 shares, provided that the closing sale price of the common stock is not below $5.00 on the purchase date. In each case, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed $1,000,000. The purchase price per share for each such Regular Purchase will be based on prevailing market prices of common stock immediately preceding the time of sale. In addition to Regular Purchases, we may direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the Purchase Agreement. In all instances, we may not sell shares of our common stock to Lincoln Park under the Purchase Agreement if it would result in Lincoln Park beneficially owning more than 9.99% of the outstanding shares of our common stock. During the year ended December 31, 2022, no sales of common stock under the Purchase Agreement occurred. During the year ended December 31, 2021, we sold to Lincoln Park 28,893 shares under the Purchase Agreement at a weighted-average price of $36.61 per share, for aggregate net proceeds of $1.0 million. As of December 31, 2022, approximately $26.9 million of shares of common stock were remaining, but had not yet been sold under the Purchase Agreement.

On September 9, 2022, a registration statement was declared effective covering the resale of up to 1,750,000 additional shares of our common stock that we have reserved for issuance and sale to Lincoln Park under the Purchase Agreement (Registration Statement No. 333-267254).

We agreed with Lincoln Park that we will not enter into any "variable rate" transactions with any third party, subject to certain exceptions, for a period defined in the Purchase Agreement. We have the right to terminate the Purchase Agreement at any time, at no cost or penalty.

Financial Overview

Our operations to date have been limited to business planning, raising capital, developing and entering into strategic partnerships for our pipeline assets, identifying and in-licensing product candidates, conducting clinical trials, and other research and development activities.

To date, we have financed operations primarily through funds received from the sale of common stock and warrants, convertible preferred stock, debt and convertible notes, and payments received under license, collaboration, and other agreements. Other than through arrangements as they relate to sales of ECCLOCK in Japan, none of our product candidates has been approved for sale and we have not generated any product sales. Since inception, we have incurred operating losses. We recorded a net loss of $21.1 million and $39.5 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $166.5 million. We expect to continue incurring significant expenses and operating losses for at least the next several years as we:

- intend to complete a Phase 1 clinical trial, along with other nonclinical development activities, for FRTX-02, subject to any delays or limitations described below;
- conduct preclinical development activities for FRTX-10 and experimental characterization of the STING inhibitor library;
- engage in research to identify and characterize both brain penetrant and non-brain penetrant kinase inhibitors from the next-generation kinase inhibitor platform;
- advance research and development-related activities to develop and expand our product pipeline; and
- maintain, expand, and protect our intellectual property portfolio for all our assets.

We do not expect to generate significant revenue unless and until we successfully complete development of, obtain marketing approval for, and commercialize product candidates, either alone or in collaboration with third parties. We expect these activities may take several years and our success in these efforts is subject to significant uncertainty. We expect we will need to raise substantial additional capital prior to the regulatory approval and commercialization of any of our product candidates. Until such time, if ever, that we generate substantial product revenue, we expect to finance our operations through public or private equity or debt financings, collaborations or licenses, or other available financing transactions. However, we may be unable to raise additional funds through these or other means when needed.

Our Board and executive management team are conducting a comprehensive process to explore and evaluate strategic options to progress the development of our 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 our Company. To continue developing FRTX-02 and the rest of our pipeline, we need to raise additional funds. If such financing or a strategic partnership is not forthcoming in a timely manner, we will be unable to conduct certain additional research and development activities.

Key Components of Operations

Revenue

Revenue generally consists of revenue recognized under our strategic agreements for the development and commercialization of our product candidates. Our strategic agreements generally outline overall development plans and include payments we receive at signing, payments for the achievement of certain milestones, sublicense income, earnout payments on net product sales, and royalties on net product sales. For these activities and payments, we utilize judgment to assess the nature of the performance obligations to determine whether the performance obligations are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. Prior to entering into the Asset Purchase Agreement, we recognized royalty revenue earned on a percentage of net sales of ECCLOCK in Japan. Beginning in the second quarter of 2022, we began recognizing contract revenue pursuant to the terms of the Asset Purchase Agreement. After December 31, 2022, we expect to continue to recognize contract revenue associated with Sublicense Income related to royalties on applicable net sales of sofpironium bromide gel pursuant to the Asset Purchase Agreement, as such estimated sales become probable. Other than the contract revenue we may generate in connection with the Asset Purchase Agreement, we do not expect to generate any revenue from any product candidates that we developed or develop unless and until we obtain regulatory approval and commercialize our products or enter into other collaboration agreements with third parties.

Research and Development Expenses

Research and development expenses principally consist of payments to third parties known as clinical research organizations (CROs) and upfront in-licensing fees of development-stage assets. CROs help plan, organize, and conduct clinical and nonclinical studies under our direction. Personnel costs, including wages, benefits, and share-based compensation, related to our research and development staff in support of product development activities are also included, as well as costs incurred for supplies, clinical and nonclinical studies, consultants, and facility and related overhead costs.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, including wages, benefits, and share-based compensation, related to our executive, sales, marketing, finance, and human resources personnel, as well as professional fees, including legal, accounting, and sublicensing fees.

Other Income, Net

Other income, net consists primarily of interest income, interest expense, and various income or expense items of a non-recurring nature. We have earned interest income from money market funds and interest-bearing accounts. Our interest income varies each reporting period depending on our average cash balances during the period and market interest rates. We expect interest income to fluctuate in the future with changes in average cash balances and market interest rates.

Critical Accounting Estimates

We have prepared the consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). The preparation of these consolidated financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, and related disclosures at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. On an ongoing basis, management evaluates its critical estimates, including those related to revenue recognition and accrued research and development expenses. We base our estimates on our historical experience and on assumptions that we believe are reasonable; however, actual results may differ materially from these estimates under different assumptions or conditions.

For information on our significant accounting policies, please refer to Note 2 of the notes to our consolidated financial statements included elsewhere in this Annual Report.

Contract Revenue Recognition

Pursuant to the Asset Purchase Agreement, we have rights to receive from Botanix future milestone payments, sales-based payments, and sublicense income related to sales-based milestone payments and royalties earned by Botanix from Kaken under the Kaken Agreement (all of such payments, "Botanix Payments"). The payments under the Asset Purchase Agreement vary based on net sales and/or are contingent upon certain regulatory approvals. Therefore, we are required to estimate the Botanix Payments, which represent variable consideration, to be achieved and recognize revenue to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. We may use either the most likely amount or the expected value method in making such estimates based on the nature of the payment to be received and whether there is a wide range of outcomes or only two possible outcomes. For any milestone payments, we utilize the most likely amount method, which represents our best estimate of the single most likely outcome to be achieved. For any sales-based payments or other consideration where there are more than two possible outcomes, we utilize the expected value method, which represents the sum of probability-weighted amounts in a range of possible consideration amounts.

We base our estimates of variable consideration to be recognized as revenue using the applicable method described above on factors such as, but not limited to, required regulatory approvals, historical sales levels, market events and projections, and others as necessary. We update our estimates at each reporting period based on actual results and future expectations as necessary. Our estimates are subject to changes in net sales of sofpironium bromide and the occurrence of contingent events, such as regulatory approvals. Changes in net sales could occur due to various risks such as competitors entering the market, technology changes as to how hyperhidrosis is treated, and foreign exchange risk.

Research and Development

Research and development costs are charged to expense when incurred and consist of costs incurred for independent and collaboration research and development activities. The major components of research and development costs include formulation development, nonclinical studies, clinical studies, clinical manufacturing costs, in-licensing fees for development-stage assets, salaries and employee benefits, and allocations of various overhead and occupancy costs. Research costs typically consist of applied research, preclinical, and toxicology work. Pharmaceutical manufacturing development costs consist of product formulation, chemical analysis, and the transfer and scale-up of manufacturing at contract manufacturers. Assets acquired (or in-licensed) that are utilized in research and development that have no alternative future use are expensed as incurred. Milestone payments related to our acquired (or in-licensed) assets are recorded as research and development expenses when probable and reasonably estimable.

Costs for certain research and development activities, such as clinical trial expenses, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, and information provided to us by our vendor on their actual costs incurred or level of effort expended. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as prepaid expenses and other current assets or accrued expenses. As of December 31, 2022, related to clinical trials, we recorded

$0.4 million of accrued expenses and $0.3 million of prepaid expenses, which are reported in the consolidated balance sheet as components of accrued liabilities and prepaid expenses and other current assets, respectively.

We have entered into and may continue to enter into licensing or subscription arrangements to access and utilize certain technology. In each case, we evaluate if the license agreement results in the acquisition of an asset or a business. To date, none of our license agreements have been considered an acquisition of a business. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments made before product approval that do not meet the definition of a derivative, are immediately recognized as research and development expenses when they are paid or become payable, provided there is no alternative future use of the rights in other research and development projects.

Recent Accounting Pronouncements

Unless otherwise discussed elsewhere in this Annual Report, we believe that the impact of recently issued guidance, whether adopted or to be adopted in the future, is not expected to have a material impact on our consolidated financial statements upon adoption.

Results of Operations

Comparison of the Year Ended December 31, 2022 and 2021

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Revenue	$ 6,943	$ 404
Research and development expenses	(14,043)	(28,231)
General and administrative expenses	(14,434)	(12,417)
Other income, net	432	770
Net loss	$ (21,102)	$ (39,474)

Revenue

Revenue increased by $6.5 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. Revenue for the year ended December 31, 2022 primarily consisted of contract revenue recognized under the Asset Purchase Agreement and TSA with Botanix, while revenue for the year ended December 31, 2021 was driven by royalty revenue earned on a percentage of net sales of ECCLOCK in Japan under the Kaken Agreement.

Upon entering into the Asset Purchase Agreement on the Effective Date, we sold all rights, title, and interests to assets primarily related to sofpironium bromide that were owned and/or licensed by us, and therefore incurred no royalty revenue after the Effective Date. During the year ended December 31, 2022, we recognized contract revenue that was associated with the following: an upfront payment from Botanix of $3.0 million; a milestone payment of $2.0 million upon the FDA's acceptance of Botanix's NDA submission of sofpironium bromide gel, 15%; fees for consulting services we provided to Botanix under the TSA of $0.8 million; reimbursed development expenditures from Botanix under the Asset Purchase Agreement of $0.6 million; and Sublicense Income under the Asset Purchase Agreement of $0.4 million.

Research and Development Expenses

Below is a summary of our research and development expenses by period related to our programs:

	Year Ended December 31, 2022	Year Ended December 31, 2021	Change
	(in thousands)		
Direct program expenses related to			
Sofpironium bromide	$ 2,090	$ 18,647	$ (16,557)
DYRK1A inhibitor program (FRTX-02)	6,046	5,355	691
STING inhibitor program (FRTX-10)	2,162	—	2,162
Personnel and other unallocated expenses	3,745	4,229	(484)
Total research and development expenses	$ 14,043	$ 28,231	$ (14,188)

Research and development expenses decreased by $14.2 million for the year ended December 31, 2022, compared to the year ended December 31, 2021, driven primarily by lower clinical expenses of $16.6 million related to sofpironium bromide and lower personnel and other unallocated expenses of $0.5 million, partially offset by increased costs related to our STING inhibitor platform under the Carna License Agreement of $2.2 million and increased costs related to our DYRK1A inhibitor program of $0.7 million. Additional detail over our programs is as follows:

- *Sofpironium bromide.* In the fourth quarter of 2021, we completed our Phase 3 pivotal clinical program for sofpironium bromide gel, 15%. While we incurred $2.1 million in 2022 associated with our Phase 3 pivotal clinical program, we do not expect in the future to incur any additional research and development expenses related to sofpironium bromide subsequent to the Effective Date, when we sold the assets primarily related to sofpironium bromide that we previously owned and/or licensed to Botanix, which is responsible for all further research, development, and commercialization of sofpironium bromide.

- *DYRK1A inhibitor program.* In August 2021, we acquired exclusive, worldwide rights to research, develop, and commercialize FRTX-02. As a result, expenses in 2021 primarily related to upfront in-licensing fees of $5.4 million. In May 2022, we initiated a Phase 1 clinical trial in Canada for FRTX-02 and incurred $6.0 million in clinical trial expenses during the year ended December 31, 2022.

- *STING inhibitor program.* In February 2022, we acquired a portfolio of novel, potent, and orally available STING inhibitors that has broad potential in autoimmune, inflammatory, and rare genetic diseases, of which our primary product candidate is FRTX-10. To date, the expenses associated with our STING inhibitor program primarily relate to upfront in-licensing fees of $2.0 million.

- *Personnel and other unallocated expenses.* Personnel and other expenses include operating expenses related to research and development activities not specifically attributable to a specific program. Other expenses include travel, office supplies, license fees, and other miscellaneous expenses. These expenses vary over time depending on the development phase of the assets, the timing of acquisition or disposition of the assets, and other variables inherent in carrying out preclinical and clinical studies.

General and Administrative Expenses

General and administrative expenses increased by $2.0 million for the year ended December 31, 2022, compared to the year ended December 31, 2021. The increase was primarily related to $1.9 million in payments to Bodor under the Rights Agreement and higher expenses associated with legal and compliance fees of $0.4 million, partially offset by lower compensation-related expenses of $0.2 million and lower other general administrative expenses of $0.1 million.

Total Other Income, Net

Total other income, net decreased by $0.3 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. The decrease was primarily due to a gain on extinguishment of debt of approximately $0.4 million that resulted from the forgiveness of an outstanding loan that we received under the Paycheck Protection Program (the "PPP Loan") in June 2021.

Liquidity and Capital Resources

We have incurred significant operating losses and have an accumulated deficit as a result of ongoing efforts to in-license and develop our product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. For the years ended December 31, 2022 and 2021, we had a net loss of $21.1 million and $39.5 million, respectively. As of December 31, 2022, we had an accumulated deficit of $166.5 million. As of December 31, 2022, we had cash and cash equivalents of $8.7 million compared to $26.9 million as of December 31, 2021. Since inception, we have financed our operations primarily through funds received from the sale of common stock and warrants, convertible preferred stock, debt, and convertible notes, and payments received under license and other strategic agreements.

We believe that our cash and cash equivalents as of December 31, 2022, combined with $6.6 million in net proceeds received in March 2023 from sales of our common stock under the 2021 ATM Agreement, will be sufficient to fund our operations for at least the next 12 months. However, it is difficult to predict our spending for our product candidates prior to obtaining FDA approval. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control. We expect to continue to incur additional substantial losses in the foreseeable future as a result of our research and development activities. Our Board and executive management team are conducting a comprehensive process to explore and evaluate strategic options to progress the development of our 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 our Company. To continue developing FRTX-02 and the rest of our pipeline, we need to raise additional funds. If such financing or a strategic partnership is not forthcoming in a timely manner, we will be unable to conduct certain additional research and development activities. To the extent that additional funds are raised through the sale of equity, the issuance of securities will result in dilution to our stockholders.

Additionally, we are subject to the SEC's "baby shelf rules," which prohibit companies with a public float of less than $75 million from issuing securities under a shelf registration statement in excess of one-third of such company's public float in a 12-month period. These rules may limit our future issuances of shares under the ATM Agreements or other common stock offerings.

Cash Flows

Since inception, we have primarily used our available cash to fund expenditures related to product discovery and development activities. The following table sets forth a summary of cash flows for the periods presented:

	Year Ended December 31, 2022	Year Ended December 31, 2021
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (19,335)	$ (36,148)
Investing activities	(47)	(36)
Financing activities	1,178	32,953
Total	$ (18,204)	$ (3,231)

Operating Activities

Net cash used in operating activities of $19.3 million during the year ended December 31, 2022 decreased compared to $36.1 million during the year ended December 31, 2021, which was primarily attributable to a decrease in cash used to support our operating activities, including but not limited to, our clinical trials, research and development activities, and general working capital requirements. The $16.8 million decrease was impacted by the net effect of a decrease in net loss of $18.4 million, partially offset by a decrease in non-cash operating expenses of $1.7 million. Our non-cash operating activity during the year ended December 31, 2021 consisted of approximately $2.0 million in expense for the issuance of our common stock under the Voronoi License Agreement, net of a $0.4 million gain on extinguishment of the PPP Loan.

Investing Activities

Net cash used in investing activities during both years ended December 31, 2022 and 2021 was related to purchases of property and equipment.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2022 decreased by $31.8 million compared to the year ended December 31, 2021. The decrease primarily resulted from the following financing activities:

- net proceeds received during the year ended December 31, 2021 of $10.3 million from the sale of our common stock in the October 2021 Offering, $9.0 million from the exercise of warrants, and $7.3 million from the sale of our common stock in the July 2021 Offering, and

- lower net proceeds received during the year ended December 31, 2022 of $5.2 million from sales of our common stock under the ATM Agreements and Purchase Agreement.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Fresh Tracks Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Fresh Tracks Therapeutics, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, redeemable preferred stock and stockholders' equity and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

	Research and development costs
Description of the Matter	The Company incurred $14.0 million for research and development expenses for the year ended December 31, 2022, and accrued $0.4 million and prepaid $0.3 million of research and development expenses at December 31, 2022. The completeness and valuation of certain clinical study fees incurred in the Company's accrued research and development costs are subject to risk of estimation uncertainty related to services received and efforts expended. As discussed in Note 2 of the Company’s consolidated financial statements, costs for certain research and development activities, such as clinical trial expenses, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, and information provided to the Company by its vendors on their actual costs incurred or level of effort expended. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred. Auditing research and development costs was judgmental due to the estimation required by management in determining the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. The Company has contracts with contract research organizations (“CROs”) that conduct and manage clinical studies on its behalf. The payment terms of these agreements vary from contract to contract and may result in uneven payment flows.
How We Addressed the Matter in Our Audit	To test the estimated research and development costs, we performed audit procedures that included, among others, assessing methodologies and testing the assumptions discussed above, testing the underlying data used by management, and assessing the historical accuracy of management’s estimates. We performed inquiries of clinical research managers to understand the status of trials, discussed any delays or new developments with the studies to understand the impact of the activity on the accounting for the studies, and confirmed directly with CROs the status of significant cost drivers, such as patient enrollment, site activation and passthrough costs.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2017.

Denver, Colorado

March 30, 2023

FRESH TRACKS THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 8,680	$ 26,884
Prepaid expenses and other current assets	1,403	2,716
Total current assets	10,083	29,600
Property and equipment, net	75	58
Contract asset, net of current portion	64	—
Operating lease right-of-use asset	49	59
Total assets	$ 10,271	$ 29,717
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 571	$ 1,605
Accrued liabilities	2,457	3,136
Lease liability	49	69
Total current liabilities	3,077	4,810
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.01 par value, 300,000,000 shares authorized as of December 31, 2022 and 2021; 3,018,940 and 2,652,828 shares issued and outstanding as of December 31, 2022 and 2021, respectively	30	27
Additional paid-in capital	173,633	170,247
Accumulated deficit	(166,469)	(145,367)
Total stockholders' equity	7,194	24,907
Total liabilities and stockholders' equity	$ 10,271	$ 29,717

See accompanying notes to these consolidated financial statements.

FRESH TRACKS THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Year Ended December 31, 2022	Year Ended December 31, 2021
Revenue		
Contract revenue	$ 6,851	$ —
Royalty revenue	92	404
Total revenue	6,943	404
Operating expenses:		
Research and development	14,043	28,231
General and administrative	14,434	12,417
Total operating expenses	28,477	40,648
Loss from operations	(21,534)	(40,244)
Other income	441	839
Interest expense	(9)	(69)
Net loss attributable to common stockholders	$ (21,102)	$ (39,474)
Net loss per common share attributable to common stockholders, basic and diluted	$ (7.51)	$ (22.12)
Weighted-average shares used to compute net loss per common share attributable to common stockholders, basic and diluted	2,808,075	1,784,791

See accompanying notes to these consolidated financial statements.

FRESH TRACKS THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Series A Redeemable Preferred Stock		Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value	Shares	Par Value			
Balance, December 31, 2020	—	$ —	1,190,032	$ 12	$ 133,016	$ (105,893)	$ 27,135
Issuance of common stock under license agreement	—	—	62,597	1	1,970	—	1,971
Issuance of common stock upon exercise of warrants	—	—	276,553	3	8,966	—	8,969
Issuance of common stock upon restricted stock unit settlement, net of shares withheld for taxes	—	—	2,857	—	(55)	—	(55)
Issuance of common stock pursuant to public offerings and ATM agreements, net of issuance costs of $2,246	—	—	1,113,027	11	23,995	—	24,006
Issuance of common stock to settle accrued liabilities	—	—	4,444	—	63	—	63
Issuance of common stock for cash under employee stock purchase plan	—	—	3,318	—	29	—	29
Stock-based compensation	—	—	—	—	2,263	—	2,263
Net loss	—	—	—	—	—	(39,474)	(39,474)
Balance, December 31, 2021	—	—	2,652,828	27	170,247	(145,367)	24,907
Issuance of preferred stock	1	—	—	—	—	—	—
Redemption of preferred stock	(1)	—	—	—	—	—	—
Issuance of common stock pursuant to ATM agreement, net of issuance costs of $117	—	—	354,381	3	1,193	—	1,196
Issuance of common stock for cash under employee stock purchase plan	—	—	11,731	—	37	—	37
Stock-based compensation	—	—	—	—	2,156	—	2,156
Net loss	—	—	—	—	—	(21,102)	(21,102)
Balance, December 31, 2022	—	$ —	3,018,940	$ 30	$ 173,633	$ (166,469)	$ 7,194

See accompanying notes to these consolidated financial statements.

FRESH TRACKS THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31, 2022	Year Ended December 31, 2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (21,102)	$ (39,474)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,156	2,263
Non-cash operating lease expense	59	15
Depreciation	30	22
Issuance of common stock under license agreement	—	1,971
Gain on loan extinguishment	—	(437)
Issuance of common stock to settle accrued liabilities	—	63
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets, including noncurrent portion of contract asset	1,249	699
Accounts payable	(1,034)	1,023
Accrued liabilities	(624)	(2,288)
Operating lease liability	(69)	(5)
Net cash used in operating activities	(19,335)	(36,148)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital expenditures	(47)	(36)
Net cash used in investing activities	(47)	(36)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of common stock pursuant to public offerings and ATM agreements, net of issuance costs	1,196	24,006
Payments of taxes related to net share settlement of equity awards	(55)	(51)
Proceeds from the issuance of commons stock under employee stock purchase program	37	29
Proceeds from the exercise of warrants	—	8,969
Net cash provided by financing activities	1,178	32,953
NET DECREASE IN CASH AND CASH EQUIVALENTS	(18,204)	(3,231)
CASH AND CASH EQUIVALENTS—BEGINNING	26,884	30,115
CASH AND CASH EQUIVALENTS—ENDING	$ 8,680	$ 26,884
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Acquisition of right-of-use asset through lease liability	$ 49	$ —
Forgiveness of Paycheck Protection Program loan	$ —	$ 437

See accompanying notes to these consolidated financial statements.

FRESH TRACKS THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION AND NATURE OF OPERATIONS

Fresh Tracks Therapeutics, Inc. (the "Company" or "Fresh Tracks"), which changed its name from Brickell Biotech, Inc. effective September 7, 2022, 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 (formerly BBI-02), a DYRK1A inhibitor for the treatment of certain autoimmune and inflammatory diseases; FRTX-10 (formerly BBI-10), a preclinical-stage Stimulator of Interferon Genes ("STING") inhibitor candidate for the potential treatment of autoimmune, inflammatory, and rare genetic diseases; and a platform of next-generation kinase inhibitors with the potential to produce treatments for autoimmune, inflammatory, and other debilitating diseases.

Reverse Stock Split

On July 5, 2022, the Company effected a 1-for-45 reverse stock split of outstanding shares of its common stock. All common stock shares, per-share amounts, and other related balances and computations reported as of and for all periods presented in the consolidated financial statements and notes reflect the adjusted common stock share, per-share amounts, and other related balances and computations that were effective on and after July 5, 2022. Additional details of the reverse stock split are reported in Note 7. "*Capital Stock.*"

Liquidity and Capital Resources

The Company has incurred significant operating losses and has an accumulated deficit as a result of ongoing efforts to in-license and develop product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. For the year ended December 31, 2022, the Company had a net loss of $21.1 million and net cash used in operating activities of $19.3 million. As of December 31, 2022, the Company had cash and cash equivalents of $8.7 million and an accumulated deficit of $166.5 million.

The Company believes that its cash and cash equivalents as of December 31, 2022, combined with $6.6 million in net proceeds received in March 2023 from sales of the Company's common stock under the 2021 ATM Agreement (as defined in Note 7. "*Capital Stock*"), will be sufficient to fund its operations for at least the next 12 months.

The Company expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities. The Company's board of directors ("Board") and executive management team 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. 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 the Company's pipeline, it needs to raise additional funds. If such financing or a strategic partnership is not forthcoming in a timely manner, the Company will be unable to conduct certain additional research and development activities. To the extent that additional funds are raised through the sale of equity, the issuance of securities will result in dilution to the Company's stockholders.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Brickell Subsidiary, Inc., and are presented in United States ("U.S.") dollars and prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), which include all adjustments necessary for the fair presentation of the Company's financial position, results of operations, and cash flows for the periods presented. All significant intercompany balances have been eliminated in consolidation. The Company operates in one operating segment and, accordingly, no segment disclosures have been presented herein.

Reclassifications

Certain comparative figures in the prior year consolidated statement of cash flows within operating activities have been reclassified to conform to the current period presentation. These reclassifications did not impact total net cash used in operating activities.

Use of Estimates

The Company's consolidated financial statements are prepared in accordance with U.S. GAAP, which requires it to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Although these estimates are based on the Company's knowledge of current events and actions it may take in the future, actual results may ultimately differ from these estimates and assumptions.

Risks and Uncertainties

The Company's business is subject to significant risks common to early-stage companies in the pharmaceutical industry including, but not limited to, the ability to develop appropriate formulations, scale up and produce the compounds; dependence on collaborative parties; uncertainties associated with obtaining and enforcing patents and other intellectual property rights; clinical implementation and success; the lengthy and expensive regulatory approval process; compliance with regulatory and other legal requirements; competition from other products; uncertainty of broad adoption of its approved products, if any, by physicians and patients; significant competition; ability to manage third-party manufacturers, suppliers, contract research organizations, business partners and other alliances; and obtaining additional financing to fund the Company's efforts.

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to develop its product candidates. There can be no assurance that such financing will be available or will be at terms acceptable to the Company.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less from date of purchase to be cash equivalents. Cash equivalents consist primarily of amounts held in short-term money market accounts with highly rated financial institutions.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, accounts receivable, and contract asset. The Company maintains cash and cash equivalents balances in several accounts with one financial institution which, from time to time, are in excess of federally insured limits.

For the years ended December 31, 2022 and 2021, one third party individually accounted for the Company's total revenue, related accounts receivable and contract asset balances as of December 31, 2022 and 2021. Refer to Note 3. *"Strategic Agreements*" for a detailed discussion of agreements with Botanix SB Inc. and Botanix Pharmaceuticals Limited ("Botanix").

Property and Equipment

Property and equipment is stated at cost, less accumulated depreciation. Expenditures for major betterments and additions are charged to the asset accounts, while replacements, maintenance, and repairs, which do not improve or extend the lives of the respective assets, are charged to expense as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Depreciation expense amounted to $30 thousand and $22 thousand for the years ended December 31, 2022 and 2021, respectively.

Fair Value Measurements

Fair value is the price that the Company would receive to sell an asset or pay to transfer a liability in a timely transaction with an independent counterparty in the principal market, or in the absence of a principal market, the most advantageous market for the asset or liability. A three-tier hierarchy distinguishes between (1) inputs that reflect the assumptions market participants would use in pricing an asset or liability developed based on market data obtained from sources independent of the reporting entity (observable inputs) and (2) inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing an asset or liability developed based on the best information available in the circumstances (unobservable inputs). The hierarchy is summarized in the three broad levels listed below:

Level 1—quoted prices in active markets for identical assets and liabilities

Level 2—other significant observable inputs (including quoted prices for similar assets and liabilities, interest rates, credit risk, etc.)

Level 3—significant unobservable inputs (including the Company's own assumptions in determining the fair value of assets and liabilities)

The following table sets forth the fair value of the Company's financial assets measured at fair value on a recurring basis based on the three-tier fair value hierarchy (in thousands):

	Level 1	
	December 31,	
	2022	2021
Assets:		
Money market funds	$ 7,680	$ 25,875

Fair Value of Financial Instruments

The following methods and assumptions were used by the Company in estimating the fair values of each class of financial instrument disclosed herein:

Money Market Funds—The carrying amounts reported as cash and cash equivalents in the consolidated balance sheets approximate their fair values due to their short-term nature and market rates of interest.

The carrying values of cash equivalents, accounts receivable, accounts payable, and accrued liabilities approximate fair value due to the short-term maturity of those items.

Revenue Recognition

The Company has recognized revenue primarily from upfront fees, research and development milestones, research reimbursements, and consulting services fees related to the development of previously owned or sublicensed assets associated with the proprietary compound sofpironium bromide, as well as sublicense income and royalty fees on sales of sofpironium bromide gel, 5% (ECCLOCK®) in Japan.

The Company recognizes revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. In determining the appropriate amount of revenue to be recognized, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligations. At contract inception, the Company assesses the goods or services promised within each contract and assesses whether each promised good or service is distinct and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company utilizes judgment to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Contract Revenue

The Company evaluates its contracts, including asset sale arrangements that involve the Company's rights to intellectual property, to determine whether they are outputs of the Company's ordinary activities and whether the counterparty meets the definition of a customer. If the arrangement is determined to be a contract with a customer and the goods or services sold are determined to be distinct from other performance obligations identified in the arrangement, the Company recognizes revenue primarily from non-refundable upfront fees, milestone payments, sales-based payments, and fees for consulting services allocated to the goods or services when (or as) control is transferred to the customer, and the customer can use and benefit from the goods or services.

Licenses of Intellectual Property

If a license for the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue when the functional license is transferred to the customer, and the customer can use and benefit from the license.

Milestones

At the inception of each arrangement that includes milestone payments (variable consideration), excluding sales-based milestone payments discussed below, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. The most likely amount method is generally utilized when there are only two possible outcomes and represents the Company's best estimate of the single most likely outcome to be achieved. If it is probable that a significant revenue reversal would not occur, the variable consideration for the associated milestone is included in the transaction price. Milestone payments contingent on regulatory approvals that are not within the Company or the Company's collaboration partner's control, as applicable, are generally not considered probable of being achieved until those approvals are received. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of milestones and any related constraint, and if necessary, adjusts the Company's estimate of the variable consideration. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue in the period of adjustment.

Sales-Based Payments

For license arrangements that include sales-based payments such as royalties or milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the sales-based payments relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the sales-based payment has been allocated has been satisfied (or partially satisfied). Sales-based payments received under license arrangements are recorded as royalty revenue in the Company's consolidated statements of operations.

For non-license arrangements that include sales-based payments, including earnout payments and milestone payments based on the level of sales, the Company estimates the sales-based payments (variable consideration) to be achieved and recognizes revenue to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The Company may use either the most likely amount, as described above, or the expected value method, in making such estimates based on the nature of the payment to be received and whether there is a wide range of outcomes or only two possible outcomes. The expected value method represents the sum of probability-weighted amounts in a range of possible consideration amounts. The Company bases its estimates using the applicable method described above on factors such as, but not limited to, required regulatory approvals, historical sales levels, market events and projections, and other factors as appropriate. The Company updates its estimates at each reporting period based on actual results and future expectations as necessary.

Contract Asset

For non-license arrangements involving the sale and transfer of the Company's intellectual property rights, the Company recognizes estimated variable consideration as revenue as discussed above before the customer pays consideration or before payment is due. The estimated revenue recognized is presented as a contract asset on the Company's consolidated balance sheets. The current portion of the contract asset is presented in prepaid expenses and other current assets on the Company's consolidated balance sheets. Actual amounts paid or due by the customer are recorded as a reduction to the contract asset. Any revisions to the Company's estimated revenue based on actual results and future expectations are recognized as an adjustment to the contract asset.

Research and Development

Research and development costs are charged to expense when incurred and consist of costs incurred for independent and collaboration research and development activities. The major components of research and development costs include formulation development, nonclinical studies, clinical studies, clinical manufacturing costs, in-licensing fees for development-stage assets, salaries and employee benefits, and allocations of various overhead and occupancy costs. Research costs typically consist of applied research, preclinical, and toxicology work. Pharmaceutical manufacturing development costs consist of product formulation, chemical analysis, and the transfer and scale-up of manufacturing at contract manufacturers. Assets acquired (or in-licensed) that are utilized in research and development that have no alternative future use are expensed as incurred. Milestone payments related to the Company's acquired (or in-licensed) assets are recorded as research and development expenses when probable and reasonably estimable.

Costs for certain research and development activities, such as clinical trial expenses, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, and information provided to the Company by its vendor on their actual costs incurred or level of effort expended. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as prepaid expenses and other current assets or accrued expenses.

The Company has entered into and may continue to enter into licensing or subscription arrangements to access and utilize certain technology. In each case, the Company evaluates if the license agreement results in the acquisition of an asset or a business. To date, none of the Company's license agreements have been considered an acquisition of a business. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments made before product approval that do not meet the definition of a derivative, are immediately recognized as research and development expenses when they are paid or become payable, provided there is no alternative future use of the rights in other research and development projects.

Net Loss per Share

Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding. When the effects are not anti-dilutive, diluted earnings per share is computed by dividing the Company's net income by the weighted-average number of common shares outstanding and the impact of all potentially dilutive common shares. Diluted net loss per share is the same as basic net loss per share, as the effects of potentially dilutive securities are anti-dilutive for all periods presented.

The following table sets forth the potential common shares excluded from the calculation of diluted net loss per share because their inclusion would be anti-dilutive:

	Year Ended December 31,	
	2022	2021
Outstanding warrants	621,063	621,063
Outstanding options	215,316	222,919
Total	836,379	843,982

Leases

The Company determines if an arrangement is a lease at inception. Operating leases with a term greater than one year are recognized on the consolidated balance sheets as right-of-use assets and lease liabilities. The Company does not currently hold any finance leases. The Company has elected the practical expedient not to recognize on the consolidated balance sheets leases with terms of one year or less and not to separate lease components and non-lease components for real estate leases. Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company estimates the incremental borrowing rate in determining the present value of lease payments. Lease expense is recognized on a straight-line basis over the lease term.

Redeemable Preferred Stock

The Company issued one share of redeemable preferred stock in May 2022. The redeemable preferred stock contained provisions that required redemption under circumstances that were outside of the Company's control and was classified as a mezzanine instrument outside of the Company's capital accounts. The share of redeemable preferred stock was sold to one investor for $10 and was subsequently redeemed in July 2022, as described further in Note 7. "*Capital Stock.*"

Income Taxes

The Company accounts for income taxes by using an asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is recorded to the extent it is more likely than not that a deferred tax asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date.

The Company's significant deferred tax assets are for net operating loss ("NOL") carryforwards, tax credits, fixed assets, and intangible assets. The Company has provided a valuation allowance for its entire net deferred tax assets since inception as, due to its history of operating losses, the Company has concluded that it is more likely than not that its deferred tax assets will not be realized.

The Company recognizes interest and penalties arising from the underpayment of income taxes in theconsolidated statements of operations as a component of income tax expense. The Company had no accrual for interest or penalties on its consolidated balance sheets as of December 31, 2022 and 2021, and has not recognized interest or penalties in its consolidated statements of operations for the years ended December 31, 2022 and 2021.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that the Company adopts as of the specified effective date. The Company does not believe that the adoption of recently issued standards has had or will have a material impact on the Company's consolidated financial statements or disclosures.

NOTE 3. STRATEGIC AGREEMENTS

License and Development Agreement with Voronoi

On August 27, 2021, the Company entered into a License and Development Agreement (the "Voronoi License Agreement") with Voronoi Inc. ("Voronoi"), pursuant to which the Company acquired exclusive, worldwide rights to research, develop, and commercialize FRTX-02 and other next-generation kinase inhibitors. In accordance with the terms of the Voronoi License Agreement, in exchange for the licensed rights, the Company made a one-time payment of $2.5 million in cash and issued $2.0 million, or 62,597 shares, of its common stock to Voronoi, which was recorded as research and development expenses in the consolidated statements of operations during the year ended December 31, 2021.

With respect to FRTX-02, the Voronoi License Agreement provides that the Company will make payments to Voronoi of up to $ 211.0 million in the aggregate contingent upon achievement of specified development, regulatory, and commercial milestones. With respect to the compounds arising from the next-generation kinase inhibitor platform, the Company will make payments to Voronoi of up to $ 107.5 million in the aggregate contingent upon achievement of specified development, regulatory, and commercial milestones. Further, the Voronoi License Agreement provides that the Company will pay Voronoi tiered royalty payments ranging from low-single digits up to 10% of net sales of products arising from the DYRK1A inhibitor programs and next-generation kinase inhibitor platform. All of the contingent payments and royalties are payable in cash in U.S. Dollars, except for $1.0 million of the development and regulatory milestone payments, which amount is payable in equivalent shares of the Company's common stock. Under the terms of the Voronoi License Agreement, the Company is responsible for, and bears the future costs of, all development and commercialization activities, including patenting, related to all the licensed compounds. During the years ended December 31, 2022 and 2021 and through the date of this Annual Report, the Company did not make any payments or recorded any liabilities related to the specified development, regulatory, and commercial milestones or royalties on net sales pursuant to the Voronoi License Agreement.

Exclusive License and Development Agreement with Carna

On February 2, 2022, the Company entered into an Exclusive License Agreement (the "Carna License Agreement") with Carna Biosciences, Inc. ("Carna"), pursuant to which the Company acquired exclusive, worldwide rights to research, develop, and commercialize Carna's portfolio of novel STING inhibitors. In accordance with the terms of the Carna License Agreement, in exchange for the licensed rights, the Company made a one-time cash payment of $2.0 million, which was recorded as research and development expenses in the consolidated statements of operations during the year ended December 31, 2022.

The Carna License Agreement provides that the Company will make success-based payments to Carna of up to $258.0 million in the aggregate contingent upon achievement of specified development, regulatory, and commercial milestones. Further, the Carna License Agreement provides that the Company will pay Carna tiered royalty payments ranging from mid-single digits up to 10% of net sales. All of the contingent payments and royalties are payable in cash in U.S. Dollars. Under the terms of the Carna License Agreement, the Company is responsible for, and bears the future costs of, all development and commercialization activities, including patenting, related to all the licensed compounds. During the years ended December 31, 2022 and 2021 and through the date of this Annual Report, the Company did not make any payments or recorded any liabilities related to the specified development, regulatory, and commercial milestones or royalties on net sales pursuant to the Carna License Agreement.

Asset Purchase Agreement with Botanix

On May 3, 2022 (the "Effective Date"), the Company and Brickell Subsidiary entered into an asset purchase agreement with Botanix (the "Asset Purchase Agreement"), pursuant to which Botanix acquired and assumed control of all rights, title, and interests to assets primarily related to the proprietary compound sofpironium bromide that were owned and/or licensed by the Company or Brickell Subsidiary (the "Assets"). Prior to the sale of the Assets, the Company had previously entered into a License Agreement with Bodor Laboratories, Inc. ("Bodor"), dated December 15, 2012 (last amended in February 2020) that provided the Company with a worldwide exclusive license to develop, manufacture, market, sell, and sublicense products containing sofpironium bromide through which the Assets were developed (the "Amended and Restated License Agreement"). As a result of the Asset Purchase Agreement, Botanix is now responsible for all further research, development, and commercialization of sofpironium bromide globally and replaced the Company as the exclusive licensee under the Amended and Restated License Agreement.

In accordance with the sublicense rights provided to the Company under the Amended and Restated License Agreement, the Company also had previously entered into a License, Development, and Commercialization Agreement with Kaken Pharmaceutical Co., Ltd. ("Kaken"), dated as of March 31, 2015 (as amended in May 2018, the "Kaken Agreement"), under which the Company granted to Kaken an exclusive right to develop, manufacture, and commercialize the sofpironium bromide compound in Japan and certain other Asian countries (the "Territory"). In exchange for the sublicense, the Company was entitled to receive aggregate payments of up to $10.0 million upon the achievement of specified development milestones, which were earned and received in 2017 and 2018, and up to $19.0 million upon the achievement of sales-based milestones, as well as tiered royalties based on a percentage of net sales of licensed products in the Territory. In September 2020, Kaken received regulatory approval in Japan to manufacture and market ECCLOCK for the treatment of primary axillary hyperhidrosis, and as a result, the Company began recognizing royalty revenue earned on a percentage of net sales of ECCLOCK in Japan. Pursuant to the Asset Purchase Agreement, the Kaken Agreement was assigned to Botanix, which replaced the Company as the exclusive sub-licensor to Kaken. During the year ended December 31, 2022, prior to entering into the Asset Purchase Agreement, the Company recognized royalty revenue of $0.1 million under the Kaken Agreement. During the year ended December 31, 2021, the Company recognized royalty revenue of $0.4 million under the Kaken Agreement.

The Company determined that the development of and ultimate sale and assignment of rights to the Assets is an output of the Company's ordinary activities and Botanix is a customer as it relates to the sale of the Assets and related activities.

In accordance with the terms of the Asset Purchase Agreement, in exchange for the Assets, the Company (i) received an upfront payment at closing in the amount of $3.0 million, (ii) was reimbursed for certain recent development expenditures in advancement of the Assets, (iii) received a milestone payment of $2.0 million upon the acceptance by the FDA in December 2022 of the filing of a new drug application ("NDA") for sofpironium bromide gel, 15%, and (iv) will receive a contingent milestone payment of $4.0 million if marketing approval in the U.S. for sofpironium bromide gel, 15%, is received on or before September 30, 2023, or $2.5 million if such marketing approval is received after September 30, 2023 but on or before February 17, 2024. Botanix submitted an NDA for sofpironium bromide gel, 15%, to the FDA in September 2022, which was accepted by the FDA in December 2022. Under the Asset Purchase Agreement, the Company also is eligible to receive additional success-based regulatory and sales milestone payments of up to $168.0 million. Further, the Company will receive tiered earnout payments ranging from high-single digits to mid-teen digits on net sales of sofpironium bromide gel (the "Earnout Payments").

The Asset Purchase Agreement also provides that Botanix will pay to the Company a portion of the sales-based milestone payments and royalties that Botanix receives from Kaken under the assigned Kaken Agreement (together, the "Sublicense Income"). Sublicense Income represents the Company's estimate of payments that will be earned by the Company in the applicable period from sales-based milestone payments and royalties Botanix will receive from Kaken to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Royalties vary based on net sales that are impacted by a wide variety of market and other factors and, as such, the Company utilized the expected value approach, which the Company believes will best predict the amount of consideration to which it will be entitled. In relation to the sales-based milestone payments that Botanix may receive from Kaken in the future, the Company utilized the most likely amount method and determined it is not yet probable that the Company will receive any payments from Botanix in relation to such milestone payments. Therefore, the Company determined that such milestone payments are fully constrained as of December 31, 2022, and, as such, have not yet been recognized as contract revenue. With respect to the recognition of contract revenue for the Sublicense Income based on future royalties that will be due to Botanix from Kaken, certain amounts are not yet due from Botanix. Therefore, the Company has recorded a contract asset equal to the amount of revenue recognized related to the Sublicense Income, less the amount of payments received from or due by Botanix in relation to the Sublicense Income.

All other consideration due under the Asset Purchase Agreement is contingent upon certain regulatory approvals and future sales subsequent to such regulatory approvals, or is based upon future sales that the Company determined are not yet probable due to such revenues being highly susceptible to factors outside of the Company's influence and uncertainty about the amount of such consideration that will not be resolved for an extended period of time. Therefore, the Company determined that such variable consideration amounts are fully constrained as of December 31, 2022, and as such, did not recognize such amounts as contract revenue.

Transition Services Agreement with Botanix

In connection with the sale of the Assets, on the Effective Date, the Company and Botanix entered into a transition services agreement (the "TSA") whereby the Company is providing consulting services as an independent contractor to Botanix in support of and through filing and potential approval of the U.S. NDA for sofpironium bromide gel, 15%. In accordance with the terms of the TSA, in exchange for providing these services (i) prior to the acceptance of the filing by the FDA of such NDA in December 2022, the Company received from Botanix a fixed monthly amount of $71 thousand, and (ii) after the acceptance of the filing in December 2022, the Company will receive from Botanix a variable amount based upon actual hours worked, in each case plus related fees and expenses of the Company's advisors (plus a 5% administrative fee) and the Company's out-of-pocket expenses.

Contract Revenue and Contract Assets under the Botanix Agreements

The Company recognized the following as contract revenue during the year ended December 31, 2022 (in thousands):

	Year Ended December 31, 2022
Upfront consideration	$ 3,000
Milestone payment received upon acceptance by FDA of NDA filing	2,000
Consulting services provided under the TSA	794
Reimbursed development expenditures under the Asset Purchase Agreement	624
Sublicense Income	433
Total contract revenue	$ 6,851

The following table presents changes in the value of the Company's contract asset related to Sublicense Income for the year ended December 31, 2022 (in thousands):

Contract asset as of January 1, 2022	$ —
Sublicense Income recognized	433
Amounts received or receivable	(115)
Contract asset as of December 31, 2022	$ 318
Contract asset, included in prepaid expenses and other current assets	$ 254
Contract asset, net of current portion	$ 64

Agreements with Bodor

In connection with the sale of the Assets, on the Effective Date, the Company, Brickell Subsidiary, and Bodor entered into an agreement (the "Rights Agreement") to clarify that the Company and Brickell Subsidiary have the power and authority under the Amended and Restated License Agreement to enter into the Asset Purchase Agreement and the TSA, and that Botanix would assume the Amended and Restated License Agreement pursuant to the Asset Purchase Agreement. The Rights Agreement includes a general release of claims and no admission of liability between the parties. Pursuant to such Rights Agreement, as subsequently amended on November 10, 2022, the Company agreed to pay Bodor (i) 20% of the amount of each payment due to the Company from Botanix for upfront and milestone payments, subject to deductions, credits, or offsets applied under the Asset Purchase Agreement, as well as (ii) certain tiered payments, set as a percentage ranging from mid-single digits to mid-teen digits, of the amount of each of the applicable Earnout Payments due to the Company from Botanix after deductions, credits or offsets applied under the Asset Purchase Agreement.

Pursuant to the terms of the Asset Purchase Agreement, the Company retained its obligation under the Amended and Restated License Agreement to issue $1.0 million in shares of its common stock to Bodor upon the FDA's acceptance of an NDA filing for sofpironium bromide gel, 15%. On November 10, 2022, the Company entered into an Acknowledgment and Agreement Related to Asset Purchase Agreement and Amended and Restated License Agreement (the "Acknowledgment") with Brickell Subsidiary, Botanix, Botanix Pharmaceuticals

Limited, and Bodor. Pursuant to the Acknowledgment, the Company paid $1.0 million in cash to Bodor in full satisfaction of the Company's obligation to issue shares upon the FDA's acceptance of the NDA.

During the year ended December 31, 2022, $1.9 million was incurred and reported as general and administrative expenses in the consolidated statements of operations associated with achieved milestones related to sofpironium bromide gel, 15%. Prior to December 31, 2022, no expenses associated with milestones had been incurred. Prior to the execution of the Rights Agreement, the Company paid Bodor immaterial amounts with respect to the royalties the Company received from Kaken for sales of ECCLOCK in Japan during those periods.

NOTE 4. DETAILED ACCOUNT BALANCES

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2022	2021
Prepaid insurance	521	921
Contract asset	254	—
Prepaid research and development expenses	254	1,443
Accounts receivable	250	125
Other prepaid expenses	117	168
Other current assets	7	59
Total	$ 1,403	$ 2,716

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued compensation	$ 1,320	$ 1,861
Accrued professional fees	705	452
Accrued research and development expenses	432	823
Total	$ 2,457	$ 3,136

NOTE 5. NOTE PAYABLE

On April 15, 2020, the Company executed an unsecured promissory note to IberiaBank (the "PPP Loan") pursuant to the U.S. Small Business Administration's Paycheck Protection Program under Division A, Title I of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The Company used the PPP Loan proceeds in the principal amount of $0.4 million and bearing interest at a fixed rate of1.00% per annum to cover payroll costs and certain other permitted costs in accordance with the relevant terms and conditions of the CARES Act. In January 2021, the Company applied for forgiveness of the full amount of the PPP Loan, which was forgiven in full in June 2021. As a result, during the year ended December 31, 2021, the Company recognized a gain on extinguishment of debt of approximately $0.4 million in other income in the consolidated statements of operations.

NOTE 6. COMMITMENTS AND CONTINGENCIES

Operating Lease

In August 2016, the Company entered into a multi-year, noncancelable lease for its Colorado-based office space, which was amended on December 29, 2022 to, among other things, extend the lease term to December 31, 2025, eliminate options previously available to the Company to extend the lease, and provide that the Company may terminate the lease effective June 30, 2023 if notice is provided by April 30, 2023 (as amended, the "Boulder Lease"). Minimum base lease payments under the Boulder Lease are recognized on a straight-line basis over the term of the lease. In addition to base rental payments included in the contractual obligations table below, the Company is responsible for its pro rata share of the operating expenses for the building, which includes common area maintenance, utilities, property taxes, and insurance.

Upon modification of the Boulder Lease in December 2022, the Company reassessed classification of the lease and determined that the lease still met the criteria to be classified as an operating lease. Furthermore, the Company remeasured the lease liability as of the effective date by calculating the present value of the new lease payments, discounted at the Company's incremental borrowing rate of 11.0%, over the lease term of six months. The lease term includes periods covered by an option to terminate the lease that the Company is reasonably certain to exercise. The operating expenses are variable and are not included in the present value determination of the lease liability.

The following table presents lease cost, cash paid for amounts included in the measurement of lease liabilities, the weighted-average remaining lease term, and the weighted-average discount rate for the Company's operating leases (in thousands):

	Year Ended December 31, 2022	Year Ended December 31, 2021
Operating lease cost	$ 62	$ 62
Variable lease cost	$ 39	$ 37
Cash outflows from operating leases	$ 111	$ 88
Weighted-average remaining lease term	0.5 years	1.0 year
Weighted-average discount rate	11.0 %	11.0 %

The following is a summary of the contractual obligations related to operating lease commitments as of December 31, 2022 (in thousands):

Total maturities, through December 31, 2023	$ 50
Less imputed interest	(1)
Present value of lease liability	$ 49

Licensing and Other Agreements

Refer to Note 3. "*Strategic Agreements*" for more information about the Company's obligations under its licensing and other agreements.

NOTE 7. CAPITAL STOCK

Reverse Stock Split

On June 30, 2022, the stockholders of the Company approved an amendment to the Company's Restated Certificate of Incorporation to effect a reverse stock split of the Company's outstanding common stock. The Company effected the reverse stock split at a split ratio of 1-for-45 on July 5, 2022, at which date each forty-five (45) shares of common stock issued and outstanding immediately prior to the reverse stock split were automatically reclassified, combined, and converted into one (1) validly issued, fully paid and non-assessable share of the Company's common stock, subject to the treatment of fractional share interests as described below. Proportional adjustments were made to the number of shares of the Company's common stock subject to outstanding equity awards and warrants, as well as the applicable exercise price. Proportional adjustments were also made to the reserve of shares available for future issuance under the Company's equity incentive plans and the Fresh Tracks Therapeutics, Inc. Employee Stock Purchase Plan (the "ESPP").

No fractional shares were issued in connection with the reverse stock split. All fractional shares were aggregated and sold at the then-prevailing prices on The Nasdaq Capital Market on behalf of those stockholders who would otherwise be entitled to receive a fractional share as a result of the reverse stock split. After completion of such sale, stockholders who would have been entitled to a fractional share instead received a cash payment in an amount equal to their respective pro rata shares of the total proceeds of that sale net of any brokerage costs incurred to sell such stock.

All common stock shares, per-share amounts, and other related balances and computations reported as of and for all periods presented in the consolidated financial statements and notes thereto give effect to the 1-for-45 reverse stock split of the Company's outstanding shares of common stock that occurred on July 5, 2022. The number of shares of the Company's common stock authorized for issuance was not affected by the reverse stock split and was not proportionally decreased.

Common Stock

Under the Company's Restated Certificate of Incorporation, the Company's Board has the authority to issue up to 300,000,000 shares of common stock with a par value of $0.01 per share. Each share of the Company's common stock is entitled to one vote, and the holders of the Company's common stock are entitled to receive dividends when and as declared or paid by its Board. The Company had reserved authorized shares of common stock for future issuance as of December 31, 2022 as follows:

	December 31, 2022
Common stock warrants	621,063
Common stock options outstanding	215,316
Shares available for grant under the 2020 Omnibus Long-Term Incentive Plan	141,843
Shares available for grant under the ESPP	42,728
Total	1,020,950

The Company may be limited in its ability to sell a certain number of shares of its common stock under the Purchase Agreement or ATM Agreements described below, depending on the availability at any given time of authorized and available shares of common stock.

Public Offerings of Common Stock and Warrants

In October 2021, the Company completed a sale of 672,521 shares of its common stock at a public offering price of $17.10 per share in an underwritten public offering (the "October 2021 Offering"). The October 2021 Offering resulted in net proceeds of approximately $10.3 million, after deducting the underwriting discount and offering expenses payable by the Company.

In July 2021, the Company completed a sale of 288,530 shares of its common stock at a public offering price of $27.90 per share in an underwritten public offering (the "July 2021 Offering"). The July 2021 Offering resulted in net proceeds of approximately $7.3 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

In October 2020, the Company completed a sale of 422,300 shares of its common stock, and, to certain investors, pre-funded warrants to purchase 40,663 shares of its common stock, and accompanying common stock warrants to purchase up to an aggregate of 462,979 shares of its common stock (the "October 2020 Offering"). Each share of common stock and pre-funded warrant to purchase one share of the Company's common stock was sold together with a common warrant to purchase one share of the Company's common stock. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The common warrants are exercisable at a price of $32.40 per share of the Company's common stock and will expire five years from the date of issuance. The pre-funded warrants were exercised in October 2020. During the year ended December 31, 2021, 276,165 common warrants associated with the October 2020 Offering were exercised at a weighted-average exercise price of $32.40 per share, resulting in aggregate proceeds of approximately $8.9 million. No warrants associated with the October 2020 Offering were exercised during the year ended December 31, 2022.

In June 2020, the Company completed a sale of 328,669 shares of its common stock, and, to certain investors, pre-funded warrants to purchase 60,220 shares of its common stock, and accompanying common stock warrants to purchase up to an aggregate of 388,920 shares of its common stock (the "June 2020 Offering"). Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of common stock. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The pre-funded warrants were exercised in the third quarter of 2020. The common warrants were immediately exercisable at a price of $56.25 per share of common stock and will expire five years from the date of issuance. During the year ended December 31, 2021, 388 common warrants associated with the June 2020 Offering were exercised at a weighted-average exercise price of $56.25 per share, resulting in aggregate proceeds of approximately $22 thousand. No warrants associated with the June 2020 Offering were exercised during the year ended December 31, 2022.

At Market Issuance Sales Agreements

In March 2021, the Company entered into an At Market Issuance Sales Agreement (the "2021 ATM Agreement") with Oppenheimer & Co. Inc. ("Oppenheimer") and William Blair & Company, L.L.C. as the Company's sales agents (the "Agents"). Pursuant to the terms of the 2021 ATM Agreement, the Company may sell from time to time through the Agents shares of its common stock having an aggregate offering price of up to $50.0 million. Such shares are issued pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-254037). Sales of the shares are made by means of ordinary brokers' transactions on The Nasdaq Capital Market at market prices or as otherwise agreed by the Company and the Agents. Under the terms of the 2021 ATM Agreement, the Company may also sell the shares from time to time to an Agent as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the shares to an Agent as principal would be pursuant to the terms of a separate placement notice between the Company and such Agent. During the year ended December 31, 2022, the Company sold 354,381 shares of common stock under the 2021 ATM Agreement at a weighted-average price of $3.70 per share, for aggregate net proceeds of

$1.3 million, after giving effect to a 3% commission to the Agents. During the year ended December 31, 2021, the Company sold 98,882 shares of common stock under the 2021 ATM Agreement at a weighted-average price of $ 40.04 per share, for aggregate net proceeds of $3.8 million, after giving effect to a 3% commission to the Agents. As of December 31, 2022, approximately $44.7 million of shares of common stock were remaining, but had not yet been sold by the Company under the 2021 ATM Agreement.

In April 2020, the Company entered into an At Market Issuance Sales Agreement (the "2020 ATM Agreement" and, together with the 2021 ATM Agreement, the "ATM Agreements") with Oppenheimer as the Company's sales agent. Pursuant to the terms of the 2020 ATM Agreement, the Company may sell from time to time through Oppenheimer shares of its common stock having an aggregate offering price of up to $8.0 million. Such shares are issued pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-236353). Sales of the shares are made by means of ordinary brokers' transactions on The Nasdaq Capital Market at market prices or as otherwise agreed by the Company and Oppenheimer. Under the terms of the 2020 ATM Agreement, the Company may also sell the shares from time to time to Oppenheimer as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the shares to Oppenheimer as principal would be pursuant to the terms of a separate placement notice between the Company and Oppenheimer. During the year ended December 31, 2022, no sales of common stock under the 2020 ATM Agreement occurred. During the year ended December 31, 2021, the Company sold 24,201 shares of its common stock under the 2020 ATM Agreement at a weighted-average price of $69.62 per share, for aggregate net proceeds of approximately $1.6 million, after giving effect to a 3% commission to Oppenheimer as agent. As of December 31, 2022, approximately $2.6 million of shares of common stock were remaining, but had not yet been sold by the Company under the 2020 ATM Agreement.

The Company is subject to the SEC's "baby shelf rules," which prohibit companies with a public float of less than $75 million from issuing securities under a shelf registration statement in excess of one-third of such company's public float in a 12-month period. These rules may limit future issuances of shares by the Company under the ATM Agreements or other common stock offerings.

Private Placement Offerings

In February 2020, the Company and Lincoln Park Capital Fund, LLC ("Lincoln Park") entered into (i) a securities purchase agreement (the "Securities Purchase Agreement"); (ii) a purchase agreement (the "Purchase Agreement"); and (iii) a registration rights agreement (the "Registration Rights Agreement"). Pursuant to the Securities Purchase Agreement, Lincoln Park purchased, and the Company sold, (i) an aggregate of 21,111 shares of common stock (the "Common Shares"); (ii) a warrant to initially purchase an aggregate of up to 13,476 shares of common stock at an exercise price of $90.45 per share (the "Series A Warrant"); and (iii) a warrant to initially purchase an aggregate of up to 34,588 shares of common stock at an exercise price of $52.20 per share (the "Series B Warrant," and together with the Series A Warrant, the "Warrants"). No warrants associated with the Securities Purchase Agreement were exercised during the years ended December 31, 2022 or 2021.

Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $28.0 million in the aggregate of shares of common stock. In order to retain maximum flexibility to issue and sell up to the maximum of $28.0 million of the Company's common stock under the Purchase Agreement, the Company sought and, at its annual meeting on April 19, 2021, received, stockholder approval for the sale and issuance of common stock in connection with the Purchase Agreement under Nasdaq Listing Rule 5635(d). Sales of common stock by the Company will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on August 14, 2020 (the "Commencement Date").

Following the Commencement Date, under the Purchase Agreement, on any business day selected by the Company, the Company may direct Lincoln Park to purchase up to 2,222 shares of common stock on such business day (each, a "Regular Purchase"), provided, however, that (i) the Regular Purchase may be increased to up to 2,777 shares, provided that the closing sale price of the common stock is not below $3.00 on the purchase date; and (ii) the Regular Purchase may be increased to up to 3,333 shares, provided that the closing sale price of the common stock is not below $5.00 on the purchase date. In each case, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed $1,000,000. The purchase price per share for each such Regular Purchase will be based on prevailing market prices of common stock immediately preceding the time of sale. In addition to Regular Purchases, the Company may direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the Purchase Agreement. In all instances, the Company may not sell shares of its common stock to Lincoln Park under the Purchase Agreement if it would result in Lincoln Park beneficially owning more than 9.99% of the outstanding shares of common stock. During the year ended December 31, 2022, no sales of common stock under the Purchase Agreement occurred. During the year ended December 31, 2021, the Company sold to Lincoln Park 28,893 shares under the Purchase Agreement at a weighted-average price of $36.61 per share, for aggregate net proceeds of $1.0 million. As of December 31, 2022, approximately $26.9 million of shares of common stock were remaining, but had not yet been sold by the Company under the Purchase Agreement.

On September 9, 2022, a registration statement was declared effective covering the resale of up to 1,750,000 additional shares of the Company's common stock that the Company has reserved for issuance and sale to Lincoln Park under the Purchase Agreement (Registration Statement No. 333-267254).

The Company agreed with Lincoln Park that it will not enter into any "variable rate" transactions with any third party, subject to certain exceptions, for a period defined in the Purchase Agreement. The Company has the right to terminate the Purchase Agreement at any time, at no cost or penalty.

The Securities Purchase Agreement, the Purchase Agreement, and the Registration Rights Agreement contain customary representations, warranties, agreements, and conditions to completing future sale transactions, indemnification rights, and obligations of the parties.

Preferred Stock

Under the Company's Restated Certificate of Incorporation, the Company's Board has the authority to issue up to 5,000,000 shares of preferred stock with a par value of $0.01 per share, at its discretion, in one or more classes or series and to fix the powers, preferences and rights, and the qualifications, limitations, or restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, without further vote or action by the Company's stockholders. On May 25, 2022, the Company issued and sold one share of the Company's preferred stock, which was designated as Series A Preferred Stock (the "Series A Preferred Stock"), for a nominal amount. During the time the Series A Preferred Stock was outstanding, it had 80,000,000 votes exclusively with respect to any proposal to amend the Company's Restated Certificate of Incorporation to effect a reverse stock split of the Company's common stock. The terms of the Series A Preferred Stock provided that it would be voted, without action by the holder, on any such proposal in the same proportion as shares of the Company's common stock were voted. The Series A Preferred Stock otherwise had no voting rights except as otherwise required by the General Corporation Law of the State of Delaware. The Series A Preferred Stock was not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of the Company and had no rights with respect to any distribution of assets of the Company, including upon a liquidation, bankruptcy, reorganization, merger, acquisition, sale, dissolution or winding up of the Company, whether voluntarily or involuntarily. The holder of the Series A Preferred Stock was not entitled to receive dividends of any kind. The Series A Preferred Stock was redeemed in whole on July 5, 2022 upon the effectiveness of the amendment to the Restated Certificate of Incorporation implementing the reverse stock split. As of December 31, 2022, there were no shares of Series A Preferred Stock outstanding.

NOTE 8. STOCK-BASED COMPENSATION

Equity Incentive Plans

On April 20, 2020, the Company's stockholders approved the 2020 Omnibus Long-Term Incentive Plan (the "Omnibus Plan"), which replaced, with respect to new award grants, the Company's 2009 Equity Incentive Plan, as amended and restated (the "2009 Plan"), and the Vical Equity Incentive Plan (the "Vical Plan") (collectively, the "Prior Plans") that were previously in effect. Following the approval of the Omnibus Plan on April 20, 2020, no further awards were available to be issued under the Prior Plans, but awards outstanding under those plans as of that date remain outstanding in accordance with their terms. As of December 31, 2022, 25,069 and 1,836 shares were subject to outstanding awards under the 2009 Plan and Vical Plan, respectively.

On May 17, 2022, the Company's stockholders approved an increase in the number of shares of common stock authorized for issuance under the Omnibus Plan by119,377 shares. As of December 31, 2022, 323,364 shares were authorized, and188,411 shares were subject to outstanding awards under the Omnibus Plan. As of December 31, 2022, 141,843 shares remained available for grant under the Omnibus Plan.

Fair Value Assumptions

The Company accounts for share-based compensation expense for stock options granted to employees, members of its Board, and non-employees by estimating the fair value of each stock-based award on the date of grant using the Black-Scholes option pricing model. The Company recognizes share-based compensation expense on a straight-line basis over the vesting term. The Company applies an estimated forfeiture rate based on past history and makes revisions, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company considers the fair value of common stock to be equal to its current share price. If applicable, the current share price is adjusted to reflect material nonpublic information known to the Company but unavailable to market participants. The determination of the fair value of stock-based awards on the date of grant using an option-pricing model is affected by the value of the Company's stock price, as well as assumptions regarding subjective variables. These variables include expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate, and expected dividends.

Because the Company has a limited history of stock purchase and sale activity, the Company estimates expected volatility of the common stock by using the average share fluctuations of companies similar in size, operations, and life cycle. The expected term of stock options granted to employees, including members of the Board, is determined as the midpoint between the vesting date and the contractual end of the option grant. The expected term of all other stock options granted is based on the Company's historical share option exercise experience, which approximates the midpoint between the vesting date and the contractual end of the option grant. The risk-free interest rates used in the valuation model are based on U.S. Treasury yield issues in effect at the time of grant for a period commensurate with the expected term of the grant. The Company does not anticipate paying any dividends in the foreseeable future and therefore uses an expected dividend yield of zero.

Stock Options

Stock options granted by the Company have an exercise price per share equal to the closing sales price of the common stock on the day prior to the date of grant and expire ten years from the date of grant. The vesting term of granted stock options is stated in each individual grant agreement, which is generallyfour years. During the years ended December 31, 2022 and 2021, the Company granted stock options with a weighted-average grant date fair value of $7.95 per share and $29.34 per share, respectively. The assumptions used to calculate the fair value of stock options granted are as follows, presented on a weighted-average basis:

	Year Ended December 31,	
	2022	2021
Expected term	6.0 years	6.0 years
Expected volatility	97.8%	99.3%
Risk-free interest rate	3.0%	1.0%
Expected dividend yield	—%	—%

A summary of stock option activity under the Company's incentive plans is as follows:

	Shares	Weighted-Average Exercise Price	Total Intrinsic Value	Weighted-Average Remaining Contractual Life (In Years)
Outstanding as of December 31, 2021	156,765	$ 143.15	$ —	8.53
Granted	86,204	$ 10.95		
Forfeited	(19,361)	$ 28.74		
Expired	(8,292)	$ 569.23		
Outstanding as of December 31, 2022	215,316	$ 84.10	$ —	8.21
Options vested and exercisable as of December 31, 2022	78,751	$ 185.91	$ —	7.19
Options outstanding as of December 31, 2022 and expected to vest	197,097	$ 89.87	$ —	8.15

As of December 31, 2022, the Company had $2.0 million of total unrecognized share-based compensation expense related to stock options, which is expected to be recognized over a weighted-average period of approximately 2.7 years. The total estimated grant date fair value of stock options vested during the years ended December 31, 2022 and 2021 was $2.3 million and $0.7 million, respectively.

Employee Stock Purchase Plan

On April 19, 2021, the Company's stockholders approved the ESPP, which had a first eligible purchase period commencing on July 1, 2021. The ESPP allows qualified employees to purchase shares of the Company's common stock at a price per share equal to 85% of the lower of: (i) the closing price of the Company's common stock on the first trading day of the applicable purchase period or (ii) the closing price of the Company's common stock on the last trading day of the applicable purchase period. New six-month purchase periods begin each January 1 and July 1. As of December 31, 2022, the Company had 42,728 shares available for issuance and 15,049 cumulative shares had been issued under the ESPP.

Stock-Based Compensation Expense

Total stock-based compensation expense reported in the consolidated statements of operations was allocated as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Research and development	$ 425	$ 478
General and administrative	1,731	1,785
Total stock-based compensation expense	$ 2,156	$ 2,263

NOTE 9. INCOME TAXES

During the years ended December 31, 2022 and 2021, the Company recorded no income tax benefits for the NOL incurred in each year, due to its uncertainty of realizing a benefit from those items.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2022	2021
Federal statutory income tax rate	21.00 %	21.00 %
State taxes, net of federal benefit	2.88	4.93
Research and development tax credits	1.46	2.22
Permanent differences and other	(0.92)	1.29
Stock-based compensation	(0.46)	(0.36)
Change in deferred tax asset valuation allowance	(23.96)	(29.08)
Effective income tax rate	— %	— %

Approximate deferred tax assets (liabilities) resulting from timing differences between financial and tax bases were associated with the following items (in thousands):

	Year Ended December 31,	
	2022	2021
NOL carryforwards	$ 104,278	$ 100,831
Research and development and other tax credits	17,247	16,881
Depreciable assets	4,812	6,481
Capitalized research and development costs	2,347	—
Intangible assets	1,797	1,470
Stock-based compensation	1,505	1,238
Other	82	110
Net deferred tax asset	132,068	127,011
Less: valuation allowance	(132,068)	(127,011)
Net deferred tax assets	$ —	$ —

As of December 31, 2022, the Company had deferred tax assets of $132.1 million. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset the net deferred tax asset.

Pursuant to Sections 382 and 383 of the Internal Revenue Code ("IRC"), annual use of the Company's NOL and credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The most recent Section 382 analysis was completed through December 31, 2011 as a result of a previous ownership change on December 29, 2006, as determined per the provisions of Section 382 of the IRC as a result of various stock issuances used to finance the Company's operations. Such ownership change resulted in annual limitations on the utilization of tax attributes, including NOL carryforwards and tax credits. A Section 382 analysis has not been conducted for the period between January 1, 2012 through December 31, 2022. As such, the Company cannot provide any assurance that a change in ownership within the meaning of the IRC has not occurred between those dates. If a change in ownership were to have occurred, additional NOL and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

As of December 31, 2022 and 2021, the Company had available federal NOL carryforwards of approximately $454.5 million and $455.9 million, respectively. The NOLs generated after 2017, totaling $148.9 million, will carry forward indefinitely and be available to offset up to 80% of future taxable income each year. NOLs generated before 2018, totaling $299.1 million, will expire from 2023 through 2037.

In addition, the Company had federal research and development credits and orphan drug credit carryforwards of $24.8 million and $26.6 million as of December 31, 2022 and 2021, respectively, to reduce future federal income taxes, if any, which expire from 2023 through 2038. The Company also has available state NOL carryforwards of approximately $444.4 million and $429.0 million as of December 31, 2022 and 2021, respectively, which expire from 2028 to 2038.

All federal and state NOL and credit carryforwards listed above are reflected before the reduction for amounts effectively eliminated under Sections 382 and 383. Based upon statute, federal and state NOLs and credits are expected to expire as follows (in thousands):

Expiration Date:	Federal NOLs	State NOLs	Federal R&D Credit	Federal Orphan Drug Credit	State R&D Credit
2023	22,398	—	322	929	—
2024	25,032	—	213	663	—
2025	27,190	—	456	507	—
2026 and thereafter	224,441	383,032	8,374	13,306	—
Indefinite	148,920	61,330	—	—	9,645
Totals	$ 447,981	$ 444,362	$ 9,365	$ 15,405	$ 9,645

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2022 and 2021. Management reevaluates the positive and negative evidence at each reporting period. The Company's valuation allowance increased by approximately $5.1 million for the year ended December 31, 2022. For the year ended December 31, 2021, the valuation allowance increased by $11.5 million.

The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes that it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcome of examinations by tax authorities in determining the adequacy of its provision for income taxes.

The Company had previously acquired gross unrecognized tax benefits with a balance of $21.7 million as of December 31, 2022 and 2021, none of which would affect the effective tax rate, due to the Company's full valuation allowance on its deferred tax assets. The Company does not anticipate any significant decreases in its unrecognized tax benefits over the next 12 months.

As of December 31, 2022, the Company's U.S. federal and state tax returns remain subject to examination by tax authorities beginning with the tax year ended December 31, 2019. However, due to NOLs and credit carryforwards being generated and carried forward from prior tax years, substantially all tax years may also be subject to examination.

Effective for tax years beginning after December 31, 2021, Section 174 of the IRC requires that research and experimental expenses ("R&E") be capitalized and amortized. The amortization period is five years for domestic expenses and 15 years for foreign expenses. For the year ended December 31, 2022, the Company analyzed its expenses and determined that expenses of $10.1 million fell within the definition of Section 174. Accordingly, these expenditures were capitalized and amortized for tax purposes.

NOTE 10. SUBSEQUENT EVENTS

At Market Issuance Sales Agreements

Subsequent to December 31, 2022 and through March 30, 2023, the Company sold2,887,535 shares of its common stock under the 2021 ATM Agreement at a weighted-average price of $2.34 per share, for aggregate net proceeds of approximately $6.6 million.

Issuance of Restricted Stock Units

On January 24, 2023, the Company granted 141,250 restricted stock units to certain of its officers, employees, and consultants, which vest in full on the anniversary of the grant date.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Remediation of Material Weakness

As previously reported, we identified a material weakness in our internal control over financial reporting as of June 30, 2022, due to a design deficiency in the controls over the accounting treatment and disclosure requirements of subsequent events. The material weakness was continuing as of September 30, 2022.

In response to the material weakness, we designed and implemented remediation measures, which included enhancing our documentation standards around the accounting treatment and disclosure requirements of subsequent events each reporting period. Management implemented this set of formalized remediation procedures during the three months ended September 30, 2022, to address the control deficiency that led to the material weakness. Subsequently, management was able to operate the specifically identified controls for a sufficient period of time, and has concluded through testing that these controls are effective. As a result, management has concluded that, as of December 31, 2022, the material weakness has been remediated.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) and 15d-15(e) promulgated under the Exchange Act, as of the end of the period covered by this Annual Report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2022.

Management Report on Internal Controls over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP.

Management assessed our internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on this assessment, management has concluded that our internal control over financial reporting was effective as of the end of the fiscal year to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external reporting purposes in accordance with U.S. GAAP. We reviewed the results of management's assessment with the audit committee of our Board.

Inherent Limitations on Effectiveness of Controls

Our management, including the principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well-designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

Changes in Internal Control over Financial Reporting

Other than the remediation measures related to the accounting treatment and disclosure requirements of subsequent events described above, management has determined that there were no changes in our internal control over financial reporting that occurred during the three months ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our 2023 Proxy Statement.

Our Board has adopted a Code of Conduct applicable to all officers, directors, and employees, which is available on our website (https://www.ir.frtx.com) under "Governance." We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Conduct by posting such information on the website address and location specified above.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our 2023 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our 2023 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our 2023 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our 2023 Proxy Statement.

PART IV.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The financial statements required by this item are submitted in a separate section beginning on page67 of this Annual Report.

(a)(2) Financial Statement Schedules

Financial statement schedules have been omitted because they are either not required, not applicable, or the information is otherwise included.

(a)(3) Exhibits

See Exhibit Index, which is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit	Form	Date of Filing	Exhibit Number	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation, as amended through September 6, 2022	8-K	9/8/2022	3.2	
3.2	Amended and Restated Bylaws, as amended through September 6, 2022	10-Q	11/14/2022	3.2	
4.1	Specimen Common Stock Certificate	S-8	9/10/2019	4.1	
4.2	Form of Senior Indenture	S-3	3/9/2021	4.3	
4.3	Form of Subordinated Indenture	S-3	3/9/2021	4.4	
4.4	Form of Warrant to Purchase Common Stock issued in connection with the Company's October 2020 Offering	S-1	10/13/2020	4.2	
4.5	Form of Warrant Agency Agreement issued in connection with the Company's October 2020 Offering	S-1	10/13/2020	4.4	
4.6	Form of Warrant Agency Agreement between Brickell Biotech, Inc. and American Stock Transfer & Trust Company, LLC in connection with the Company's June 2020 Offering	S-1/A	6/17/2020	4.4	
4.7	Form of Warrant to Purchase Common Stock issued in connection with the Company's June 2020 Offering	S-1/A	6/17/2020	4.2	
4.8	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Exchange Act				×
10.1†	License and Development Agreement, dated as of August 27, 2021, by and between Voronoi Inc. and Brickell Biotech, Inc.	8-K	9/1/2021	10.1	
10.2†	Exclusive License Agreement, dated as of February 2, 2022, by and between Carna Biosciences, Inc. and Brickell Biotech, Inc.	8-K	2/2/2022	10.1	
10.3†	Asset Purchase Agreement, dated as of May 3, 2022, by and among Brickell Biotech, Inc., Brickell Subsidiary, Inc., Botanix SB Inc., and Botanix Pharmaceuticals Limited	8-K	5/3/2022	10.1	

10.4†	Acknowledgment and Agreement Related to Asset Purchase Agreement and Amended and Restated License Agreement, dated as of November 10, 2022, by and among Fresh Tracks Therapeutics, Inc., Brickell Subsidiary, Inc., Botanix SB Inc., Botanix Pharmaceuticals Limited and Bodor Laboratories, Inc.	10-Q	11/14/2022	10.6
10.5†	Transition Services Agreement, dated as of May 3, 2022, by and between Botanix SB Inc. and Brickell Biotech, Inc.	8-K	5/3/2022	10.2
10.6†	License, Development and Commercialization Agreement, dated March 31, 2015, including certain amendments, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd.	8-K	9/3/2019	10.2
10.7†	Amendment to License, Development and Commercialization Agreement, dated February 24, 2016, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd.	S-1/A	6/8/2020	10.2
10.8†	Amendment No. 2 to License, Development and Commercialization Agreement, dated October 6, 2017, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd., including Right of First Negotiation Agreement, as amended, dated October 6, 2017, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd.	8-K	9/3/2019	10.3
10.9†	Clinical Supply Agreement, dated as of July 30, 2019, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd., and First Amendment to Clinical Supply Agreement, dated as of October 18, 2019	S-1/A	6/8/2020	10.4
10.10†	Letter Agreement for Supply of API, dated as of April 26, 2020, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd.	S-1/A	6/8/2020	10.5
10.11†	Letter Agreement, dated as of September 3, 2020, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd.	S-1	10/13/2020	10.6
10.12†	Letter Agreement for Supply of API, dated as of December 8, 2020, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd.	10-K	3/9/2021	10.7
10.13†	Brickell-Kaken Amendment to Clinical Supply Agreement and License, Development and Commercialization Agreement, dated as of May 14, 2021, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd.	10-Q	8/12/2021	10.4
10.14†	Amended and Restated License Agreement, dated February 17, 2020, by and among Brickell Biotech, Inc., Brickell Subsidiary, Inc., Bodor Laboratories, Inc., and Dr. Nicholas S. Bodor	8-K	2/18/2020	10.1
10.15†	Settlement Agreement, dated February 17, 2020, by and among Brickell Biotech, Inc., Brickell Subsidiary, Inc., Bodor Laboratories, Inc., and Dr. Nicholas S. Bodor	8-K	2/18/2020	10.2
10.16†	Rights Agreement, dated as of May 3, 2022, by and among Brickell Biotech, Inc., Brickell Subsidiary, Inc., and Bodor Laboratories, Inc.	8-K	5/3/2022	10.3
10.17†	Amendment to Rights Agreement, dated as of November 10, 2022, by and among Fresh Tracks Therapeutics, Inc., Brickell Subsidiary, Inc. and Bodor Laboratories, Inc.	10-Q	11/14/2022	10.7

10.18	Boulder Lease Agreement, as amended, dated August 4, 2016, by and between Brickell Biotech, Inc. and BMC Properties, LLC	8-K	9/3/2019	10.10	
10.19	Fourth Amendment to Lease Agreement, dated as of June 17, 2021, by and between Brickell Biotech, Inc. and GPIF 5777 Flatiron LLC (f/k/a BMC Properties, LLC)	10-Q	8/12/2021	10.1	
10.20	Fifth Amendment to Lease Agreement, dated as of December 29, 2022, by and between Fresh Tracks Therapeutics, Inc. and BRE-BMR Flatiron VII LLC (f/k/a GPIF 5777 Flatiron LLC and BMC Properties, LLC)				×
10.21+	Form of Indemnification Agreement by and between the Company and its directors and executive officers				×
10.22+	Transition and Release Agreement, by and between Fresh Tracks Therapeutics, Inc. and Robert B. Brown, dated as of February 1, 2023	8-K	2/7/2023	10.1	
10.23	Consulting Agreement, by and between Fresh Tracks Therapeutics, Inc. and Dancing Bear Consulting, LLC, effective as of January 31, 2023	8-K	1/27/2023	10.1	
10.24+	Amended and Restated Employment Agreement by and between Fresh Tracks Therapeutics, Inc. and Brickell Subsidiary, Inc., on the one hand, and Andrew D. Sklawer, on the other hand, including the form of Non-Competition Agreement with Andrew D. Sklawer, dated as of February 21, 2023	8-K	2/24/2023	10.1	
10.25+	Consulting Agreement by and between Brickell Biotech, Inc. and Danforth Advisors LLC, effective as of December 1, 2020	8-K	11/24/2020	10.2	
10.26+	Amended and Restated Employment Agreement by and between Fresh Tracks Therapeutics, Inc. and Brickell Subsidiary, Inc., on the one hand, and Deepak Chadha, on the other hand, including the form of Non-Competition Agreement with Deepak Chadha. , dated as of February 21, 2023	8-K	2/24/2023	10.2	
10.27+	Amended and Restated Employment Agreement by and between Fresh Tracks Therapeutics, Inc. and Brickell Subsidiary, Inc., on the one hand, and David R. McAvoy, on the other hand, including the form of Non-Competition Agreement with David R. McAvoy, dated as of February 21, 2023				×
10.28+	Fresh Tracks Therapeutics, Inc. 2020 Omnibus Long-Term Incentive Plan, as amended on May 17, 2022	10-Q	11/14/2022	10.1	
10.29+	Form of Restricted Stock Unit Award Agreement under the Fresh Tracks Therapeutics, Inc. 2020 Omnibus Long-Term Incentive Plan	10-Q	11/14/2022	10.3	
10.30+	Form of Incentive Stock Option Award Agreement under the Fresh Tracks Therapeutics, Inc. 2020 Omnibus Long-Term Incentive Plan	10-Q	11/14/2022	10.4	
10.31+	Form of Non-Qualified Stock Option Award Agreement under the Fresh Tracks Therapeutics, Inc. 2020 Omnibus Long-Term Incentive Plan	10-Q	11/14/2022	10.5	
10.32+	Amended and Restated Stock Incentive Plan of Vical Incorporated	8-K	6/1/2017	99.1	
10.33+	Amended and Restated 2009 Equity Incentive Plan of Brickell Biotech, Inc.	S-8	9/10/2019	99.2	

10.34	Fresh Tracks Therapeutics, Inc. Employee Stock Purchase Plan				×
10.35	Securities Purchase Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC	8-K	2/18/2020	10.3	
10.36	Series A Warrant issued by Brickell Biotech, Inc. to Lincoln Park Capital Fund, LLC	S-3	2/28/2020	4.3	
10.37	Series B Warrant issued by Brickell Biotech, Inc. to Lincoln Park Capital Fund, LLC	S-3	2/28/2020	4.4	
10.38	Purchase Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC	8-K	2/18/2020	10.6	
10.39	Registration Rights Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC	8-K	2/18/2020	10.7	
10.40	At Market Issuance Sales Agreement, dated April 14, 2020, by and between Brickell Biotech, Inc. and Oppenheimer & Co. Inc.	8-K	4/14/2020	1.1	
10.41	At Market Issuance Sales Agreement, dated March 9, 2021, by and among the Company, Oppenheimer & Co. Inc. and William Blair & Company, L.L.C.	S-3	3/9/2021	1.2	
10.42+	Form of Employee Retention Bonus Agreement	8-K	2/24/2023	10.3	
21.1	List of Subsidiaries				×
23.1	Consent of Ernst & Young LLP				×
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended				×
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended				×
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				×
101.INS	Inline XBRL Instance Document				×
101.SCH	Inline XBRL Taxonomy Extension Schema Document				×
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				×
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				×
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				×
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				×
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				×

+ Indicates a management contract or compensatory plan.

† Certain confidential information contained in this agreement has been omitted because it is both not material and is the type that the registrant treats as private or confidential.

* This certification is being furnished pursuant to 18 U.S.C. Section 1350 and is not being filed for purposes of Section 18 of the Exchange Act and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof.

ITEM 16. FORM 10-K SUMMARY

None.

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, thereunto duly authorized.

Fresh Tracks Therapeutics, Inc.

Date: March 30, 2023

By: /s/ Andrew D. Sklawer
Andrew D. Sklawer
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Albert N. Marchio, II
Albert N. Marchio, II
Chief Financial Officer
(Principal Financial Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Andrew D. Sklawer Andrew D. Sklawer	President and Chief Executive Officer (Principal Executive Officer)	March 30, 2023
/s/ Albert N. Marchio, II Albert N. Marchio, II	Chief Financial Officer (Principal Financial Officer)	March 30, 2023
/s/ Aaron Fox-Collis Aaron Fox-Collis	VP of Finance and Chief Accounting Officer (Principal Accounting Officer)	March 30, 2023
/s/ Reginald L. Hardy Reginald L. Hardy	Co-Founder and Chairman of the Board of Directors	March 30, 2023
/s/ Robert B. Brown Robert B. Brown	Director	March 30, 2023
/s/ Vijay B. Samant Vijay B. Samant	Director	March 30, 2023
/s/ Gary A. Lyons Gary A. Lyons	Director	March 30, 2023

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of March 23, 2023, Fresh Tracks Therapeutics, Inc. (the "Company," "we," "our" and "us") maintained one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): its common stock, par value $0.01 per share (the "Common Stock").

Description of Common Stock

The following is a description of the material terms of our Common Stock. The description is qualified in its entirety by reference to our Amended and Restated Certificate of Incorporation (the "Certificate"), our Amended and Restated Bylaws (the "Bylaws") and the applicable provisions of the Delaware General Corporation Law, as amended (the "DGCL"). Our Certificate and Bylaws are incorporated by reference as exhibits to the Annual Report on Form 10-K for the year ended March 23, 2023.

General. Our authorized capital stock consists of 300,000,000 shares of Common Stock, par value $0.01 per share, and 5,000,000 shares of preferred stock, par value $0.01 per share. All outstanding shares of Common Stock are duly authorized, validly issued, fully paid and non-assessable.

Voting Rights. The holders of our Common Stock are entitled to one vote for each share held of record on all matters submitted to a vote of our stockholders. The holders of shares of our Common Stock are not entitled to cumulate their votes in the election of directors, which means that holders of a majority of the outstanding shares of our Common Stock can elect all of our directors.

Dividend Rights. The holders of our Common Stock are entitled to receive ratably the dividends, if any, that may be declared from time to time by our board of directors out of funds legally available for such dividends.

Liquidation Rights. In the event of a liquidation, dissolution or winding up of our Company, the holders of our Common Stock would be entitled to share ratably in all assets remaining after payment of liabilities and the satisfaction of any liquidation preferences granted to the holders of any outstanding shares of preferred stock.

Preemptive Rights. Holders of our Common Stock have no preemptive rights and no conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to our Common Stock. All the outstanding shares of Common Stock are, and all shares of Common Stock offered, when issued and paid for, will be, validly issued, fully paid and non-assessable. The rights, preferences and privileges of holders of our Common Stock are subject to, and may be adversely affected by, the rights of the holders of any shares of our preferred stock.

The Nasdaq Capital Market Listing

Our Common Stock is listed on The Nasdaq Capital Market under the symbol "FRTX."

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is American Stock Transfer & Trust Company, LLC. Its address is 6201 15th Avenue, Brooklyn, New York 11219 and its telephone number is (800) 937-5449.

Anti-Takeover Provisions

Our Certificate, Bylaws and certain provisions of the DGCL may have an anti-takeover effect. These provisions may delay, defer or prevent a tender offer or takeover attempt that a stockholder would consider in its best interest. This includes an attempt that might result in a premium over the market price for the shares of Common Stock held by stockholders. These provisions are expected to discourage certain types of coercive takeover practices and inadequate takeover bids. They are also expected to encourage persons seeking to acquire control of the Company to negotiate first with our board of directors. We believe that the benefits of these provisions outweigh the potential disadvantages of discouraging takeover proposals because, among other things, negotiation of takeover proposals might result in an improvement of their terms.

Delaware Anti-Takeover Law

We are a Delaware corporation and, as such, we are subject to Section 203 of the DGCL. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers of the corporation and (b) shares issued under employee stock plans under which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of its stock owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 of the DGCL defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person associated with, or controlling, controlled by, or under common control with, the entity or person.

Certificate and Bylaws

Some provisions of our Certificate and Bylaws could also have anti-takeover effects. These provisions:

- provide for a board comprised of three classes of directors with each class serving a staggered three-year term;
- authorize our board of directors to issue preferred stock from time to time, in one or more classes or series, without stockholder approval;
- require the approval of at least two-thirds of our outstanding voting stock to amend specified provisions of our Certificate;
- require the approval of at least two-thirds of our total number of authorized directors, or two-thirds of our outstanding voting stock, to amend our Bylaws;
- provide that special meetings of our stockholders may be called only by our Chief Executive Officer, or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- provide that vacancies on our board of directors and newly created directorships may be filled only by a majority of the directors then in office, though less than a quorum, or by a sole remaining director; and
- do not include a provision for cumulative voting for directors (under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors).

FIFTH AMENDMENT TO LEASE

THIS FIFTH AMENDMENT TO LEASE (this "Amendment") is entered into as of this 29th day of December, 2022, by and between BRE-BMR FLATIRON VII LLC, a Delaware limited liability company ("Landlord," as successor-in-interest to GPIF 5777 Flatiron LLC and BMC Properties, LLC), and FRESH TRACKS THERAPEUTICS, INC., a Delaware corporation ("Tenant," formerly known as Brickell Biotech, Inc.).

RECITALS

A. WHEREAS, Landlord and Tenant are parties to that certain Lease dated as of August 4, 2016 (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of August 26, 2016, that certain Second Amendment to Lease dated as of January 19, 2017, that certain Third Amendment to Lease dated as of January 1, 2018 and that certain Fourth Amendment to Lease dated as of June 17, 2021 (the "Fourth Amendment") (collectively, and as the same may have been further amended, amended and restated, supplemented or modified from time to time, the "Existing Lease"), whereby Tenant leases certain premises (the "Premises") from Landlord at 5777 Central Avenue in Boulder, Colorado (the "Building");

B. WHEREAS, Landlord and Tenant desire to extend the Term of the Existing Lease; and

C. WHEREAS, Landlord and Tenant desire to modify and amend the Existing Lease only in the respects and on the conditions hereinafter stated.

AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

1. Definitions. For purposes of this Amendment, capitalized terms shall have the meanings ascribed to them in the Existing Lease unless otherwise defined herein. The Existing Lease, as amended by this Amendment, is referred to collectively herein as the "Lease." From and after the date hereof, the term "Lease," as used in the Existing Lease, shall mean the Existing Lease, as amended by this Amendment.

2. Fifth Amendment Extension Term. The Term of the Lease is hereby extended until, and the Expiration Date is hereby amended to mean, December 31, 2025. The period commencing at 12:00 noon on December 31, 2022, and ending on such amended Expiration Date shall be referred to herein as the "Fifth Amendment Extension Term."

3. Base Rent. During the Fifth Amendment Extension Term, Base Rent shall be as set forth in the table below:

Dates	Square Feet of Rentable Area	Base Rent per Square Foot of Rentable Area	Monthly Base Rent	Annual Base Rent
12/31/22 – 12/31/23	3,038	$28.00 annually	$7,088.67	$85,064.00
1/1/24 – 12/31/24	3,038	$28.84 annually	$7,301.33	$87,615.92
1/1/25 – 12/31/25	3,038	$29.71 annually	$7,521.58	$90,258.98

4. Condition of Premises. Tenant acknowledges that (a) it is in possession of and is fully familiar with the condition of the Premises and, notwithstanding anything contained in the Lease to the contrary, agrees to take the same in its condition "as is" as of the first day of the Fifth Amendment Extension Term, and (b) Landlord shall have no obligation to alter, repair or otherwise prepare the Premises for Tenant's continued occupancy for the Fifth Amendment Extension Term or to pay for any improvements to the Premises, except as may be expressly provided in the Lease. Nothing in this Section shall take away from Landlord's ongoing repair and maintenance obligations as expressly set forth in the Existing Lease.

5. Additional Insureds. With respect to the comprehensive general liability insurance policy required to be maintained by Tenant under Section 15(a) of the Original Lease, Tenant shall ensure that such policy names Landlord, BioMed Realty, L.P., and their respective officers, employees, directors, representatives, agents, general partners, members, subsidiaries, affiliates and lenders as additional insureds.

6. Option to Extend. Notwithstanding anything to the contrary, any options to renew or extend the Term that may have been granted to Tenant under the Existing Lease (including, without limitation, any such rights set forth in Article 31 of the Original Lease and/or Article 4 of the Fourth Amendment) are hereby deleted from the Lease in their entirety and shall no longer be of any further force or effect.

7. Expansion Rights. Any and all rights of first refusal, rights of first offer, expansion rights or other rights to lease any other rentable premises within the Building that may have been granted to Tenant under the Existing Lease (including, without limitation, the rights of first refusal set forth in Article 6 of the Fourth Amendment) are hereby deleted from the Lease in their entirety and shall no longer be of any further force or effect.

8. Cosmetic Alterations. Tenant may make strictly cosmetic changes to the Premises that do not require any demolition, permits or more than three (3) total contractors and subcontractors ("Cosmetic Alterations") without Landlord's consent; provided that (y) the cost of any Cosmetic Alterations does not exceed Five Thousand Dollars ($5,000) in any one instance, and (z) such Cosmetic Alterations are not reasonably expected to have any material adverse effect on the Premises and do not (i) require any structural or other substantial modifications to the Premises, (ii) require any changes to or adversely affect the Building systems, (iii) affect any portion of the Building that is exterior to the Premises or (iv) trigger any

requirement under any federal, state, municipal and local laws, codes, ordinances, rules and regulations, that would require Landlord to make any alteration or improvement to the Premises or Building.

9. Electricity Submeter. In the event that Landlord, in Landlord's sole and absolute discretion, desires to have electricity to the Premises submetered, Landlord shall install such submeter at Landlord's sole cost and expense.

10. Tenant Access. During the Term of the Lease, Tenant shall, subject to force majeure and all of the terms, conditions and provisions of the Existing Lease, have access to the Premises and the parking facilities serving the Premises twenty-four (24) hours per day, seven (7) days per week.

11. After-Hours HVAC. Landlord shall not charge Tenant any separate cost or fee for the provision of HVAC to the Premises outside of normal business hours; provided, however, that nothing in this Section shall relieve Tenant from Tenant's obligations under the Lease with respect to utilities and Operating Expenses.

12. Telephone Closet. In the event that Tenant desires to access the telephone close located on the second (2nd) floor of the Building (the "Telephone Closet"), Landlord shall use commercially reasonable efforts to provide such access; provided, however, that Landlord shall be permitted to have a representative of Landlord present during any such access; provided, further, that Tenant shall not be permitted to (a) modify or alter any existing systems or equipment located in the Telephone Closet, or (b) install any new systems or equipment in the Telephone Closet, in each case without first procuring Landlord's prior written consent (which Landlord may withhold in Landlord's sole and absolute discretion).

13. Termination Option. Tenant shall have the one-time option to terminate the Lease (the "Termination Option") effective as of June 30, 2023 (such date, the "Termination Date"), subject to the terms, conditions and provisions of this Article.

13.1 The Termination Option is conditional upon Tenant delivering the following items to Landlord on or before April 30, 2023 (such date, the "Exercise Date"): (a) written notice of Tenant's election to exercise the Termination Option (the "Termination Notice") and (b) the Termination Fee (as defined below). Tenant shall not be deemed to have exercised the Termination Option unless and until Tenant has delivered to Landlord both the Termination Notice and the Termination Fee. Time shall be of the essence as to Tenant's exercise of the Termination Option. Tenant acknowledges that it would be inequitable to require Landlord to accept any exercise of the Termination Option after the Exercise Date. Any attempted exercise of the Termination Option after the Exercise Date shall be void and of no force or effect.

13.2 For purposes of this Article, the "Termination Fee" means an amount equal to the unamortized amount (as of the Termination Date) of all leasing commissions paid by Landlord in connection with this Amendment, with such amortization calculated on a straight line basis commencing on December 31, 2022 and ending on December 31, 2025.

1.1 If Tenant exercises the Termination Option in accordance with this Article on or before the Exercise Date, then the Lease shall terminate on the Termination Date and the Lease shall thereafter be of no further force or effect, except for those provisions that, by their express terms, survive the expiration or earlier termination of the Lease. In such event, Tenant shall surrender the Premises to Landlord on or before the Termination Date in accordance with all of the terms, conditions and provisions of the Lease.

14. Broker. Tenant represents and warrants that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment, other than Dean Callan & Company, Inc. and CBRE, Inc. (collectively, "Landlord's Broker") and WWR Real Estate Services, LLC ("Tenant's Broker"), and agrees to reimburse, indemnify, save, defend (at Landlord's option and with counsel reasonably acceptable to Landlord, at Tenant's sole cost and expense) and hold harmless Landlord and its affiliates, employees, agents and contractors; and any lender, mortgagee, ground lessor or beneficiary (each, a "Lender" and, collectively with Landlord and its affiliates, employees, agents and contractors, the "Landlord Indemnitees"), for, from and against any and all cost or liability for compensation claimed by any such broker or agent, other than Landlord's Broker or Tenant's Broker, employed or engaged by it or claiming to have been employed or engaged by it. Tenant's Broker is entitled to a leasing commission in connection with the making of this Amendment, and Landlord shall pay such commission to Tenant's Broker pursuant to a separate agreement between Landlord and Tenant's Broker.

Landlord represents and warrants that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment, other than Landlord's Broker and Tenant's Broker, and agrees to reimburse, indemnify, save, defend (at Tenant's option and with counsel reasonably acceptable to Tenant, at Landlord's sole cost and expense) and hold harmless Tenant and its affiliates, employees, agents and contractors; and any lender, mortgagee, ground lessor or beneficiary, for, from and against any and all cost or liability for compensation claimed by any such broker or agent, other than Landlord's Broker or Tenant's Broker, employed or engaged by it or claiming to have been employed or engaged by it.

15. No Default. Tenant represents, warrants and covenants that, to the best of Tenant's knowledge, Landlord and Tenant are not in default of any of their respective obligations under the Existing Lease and no event has occurred that, with the passage of time or the giving of notice (or both) would constitute a default by either Landlord or Tenant thereunder. Landlord represents, warrants and covenants that, to the best of Landlord's knowledge, Landlord and Tenant are not in default of any of their respective obligations under the Existing Lease and no event has occurred that, with the passage of time or the giving of notice (or both) would constitute a default by either Landlord or Tenant thereunder.

16. Notices. Notwithstanding anything in the Lease to the contrary, any notice, consent, demand, invoice, statement or other communication required or permitted to be given under the Lease shall be in writing and shall be given by (a) personal delivery, (b) overnight delivery with a reputable international overnight delivery service, such as FedEx, or (c) email transmission, so long as such transmission is followed within one (1) business day by delivery utilizing one of the methods described in (a) or (b). Any such notice, consent, demand, invoice, statement or other communication shall be deemed delivered (x) upon receipt, if given in

accordance with subsection (a); (y) one business (1) day after deposit with a reputable international overnight delivery service, if given if given in accordance with subsection (b); or (z) upon transmission, if given in accordance with subsection (c). Tenant confirms that, notwithstanding anything in the Lease to the contrary, notices delivered to Tenant pursuant to the Lease should be sent to:

Fresh Tracks Therapeutics, Inc.
Attn: Mr. Andy Sklawer
5777 Central Avenue, Suite 102
Boulder, Colorado 80301
asklawer@brickellbio.com

17. Effect of Amendment. Except as modified by this Amendment, the Existing Lease and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. In the event of any conflict between the terms contained in this Amendment and the Existing Lease, the terms herein contained shall supersede and control the obligations and liabilities of the parties.

18. Successors and Assigns. Each of the covenants, conditions and agreements contained in this Amendment shall inure to the benefit of and shall apply to and be binding upon the parties hereto and their respective heirs, legatees, devisees, executors, administrators and permitted successors and assigns and sublessees. Nothing in this section shall in any way alter the provisions of the Lease restricting assignment or subletting.

19. Miscellaneous. This Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Amendment are inserted and included solely for convenience and shall not be considered or given any effect in construing the provisions hereof. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or option for a lease, and shall not be effective as a lease, lease amendment or otherwise until execution by and delivery to both Landlord and Tenant.

20. Authority. Tenant guarantees, warrants and represents that the individual or individuals signing this Amendment on its behalf have the power, authority and legal capacity to sign this Amendment on behalf of and to bind all entities, corporations, partnerships, limited liability companies, joint venturers or other organizations and entities on whose behalf such individual or individuals have signed. Landlord guarantees, warrants and represents that the individual or individuals signing this Amendment on its behalf have the power, authority and legal capacity to sign this Amendment on behalf of and to bind all entities, corporations, partnerships, limited liability companies, joint venturers or other organizations and entities on whose behalf such individual or individuals have signed.

21. Attorneys' Fees. Except as otherwise expressly set forth in the Lease, each party shall pay its own costs and expenses incurred in connection with the Lease and such party's performance under the Lease; provided that, if either party commences an action, proceeding, demand, claim, action, cause of action or suit against the other party arising from or in

connection with the Lease, then the substantially prevailing party shall be reimbursed by the other party for all reasonable costs and expenses, including reasonable attorneys' fees and expenses, incurred by the substantially prevailing party in such action, proceeding, demand, claim, action, cause of action or suit, and in any appeal in connection therewith (regardless of whether the applicable action, proceeding, demand, claim, action, cause of action, suit or appeal is voluntarily withdrawn or dismissed).

22. Counterparts; Facsimile and PDF Signatures. This Amendment may be executed in one or more counterparts, each of which, when taken together, shall constitute one and the same document. A facsimile or portable document format (PDF) signature on this Amendment shall be equivalent to, and have the same force and effect as, an original signature.

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IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment as of the date and year first above written.

LANDLORD:

BRE-BMR FLATIRON VII LLC,
a Delaware limited liability company

By: /s/ Kevin Simonsen
Name: Kevin Simonsen
Title: EVP, General Counsel & Secretary

TENANT:

FRESH TRACKS THERAPEUTICS, INC.,
a Delaware corporation

By: /s/ Andy Sklawer
Name: Andy Sklawer
Title: President

Exhibit 10.21

INDEMNITY AGREEMENT

This Indemnification Agreement ("Agreement") is made effective retroactive as of ***[insert date person became a director/officer/employee/agent of the Company for which indemnification will be provided]***, by and between Fresh Tracks Therapeutics, Inc., a Delaware corporation (the "Company"), and _____________, a _________ resident, with a domicile address of ___________________ ("Indemnitee").

RECITALS

WHEREAS, highly competent persons have become more reluctant to serve corporations as officers and directors or in other capacities unless they are provided by such corporations with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them for personal liability arising out of their service to and activities on behalf of the corporation they benefit;

WHEREAS, the Board of Directors of the Company (the "Board") has determined that, in order to attract and retain qualified individuals, the Company will maintain on an ongoing basis, at its sole cost, sufficient liability insurance to protect its officers and directors serving the Company and its subsidiaries from certain liabilities. Although the furnishing of such insurance has been a customary and widespread practice among United States-based corporations and other business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors and officers to corporations or business enterprises increasingly are being subjected to expensive and time-consuming litigation against them individually relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The Certificate of Incorporation of the Company (the "Certificate of Incorporation") and the Bylaws of the Company (the "Bylaws") require indemnification of the officers and directors of the Company. Indemnitee also may be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware (the "DGCL"). The Certificate of Incorporation, the Bylaws and the DGCL do not require that the indemnification provisions set forth therein be exclusive, thereby allowing for contracts to be entered into between the Company and its directors, officers and other persons with respect to indemnification;

WHEREAS, the uncertainties relating to such insurance and to indemnification have increased the difficulty of attracting and retaining such qualified persons;

WHEREAS, the Board of the Company has determined that the increased difficulty in attracting and retaining such qualified persons is detrimental to the best interests of the Company and its stockholders and that the Company should act to assure such persons that there will be increased certainty of the protections described above now and in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance Expenses (defined below, Section 2) to be incurred on behalf of, such qualified persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the Bylaws and the Certificate of Incorporation and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder;

[WHEREAS, Indemnitee had served as [a director][an officer] of Brickell Subsidiary, Inc., a Delaware corporation ("Subsidiary" and, collectively with the Company, the "Covered Entities" and, also with the Company, each individually a "Covered Entity") prior to acquisition of Subsidiary by the Company and][WHEREAS, Indemnitee] has been serving as [a director][an officer] of the Company, or has been serving at the request of the Company as a director, officer, employee and/or other agent of another corporation, partnership, joint venture, trust or other Enterprise (defined below, Section 2) and in such capacity has been performing a valuable service for the Company; and

WHEREAS, Indemnitee did not regard the protection(s) available under the Bylaws, the Certificate of Incorporation, insurance and the DGCL as necessarily adequate and may not be willing to continue serving as [a director][an officer] of the Company without additional adequate protection, and the Company desires Indemnitee to serve in such capacity; and Indemnitee is willing to serve on the condition that he/she be indemnified as herein provided;

WHEREAS, it is intended that Indemnitee shall be paid promptly by the Company all amounts necessary to effectuate in full the indemnity and benefits provided herein;

NOW, THEREFORE, in consideration of the premises and the covenants contained in this Agreement, and intending to be legally bound thereby, the Company and Indemnitee do hereby covenant and agree as follows:

Section 1. **Services to the Company.**

(a) Indemnitee agrees to serve as [a director][an officer] of the Company until such time as he or she resigns [or fails to stand for election] or is removed from his or her position. Indemnitee may at any time and for any reason resign or be removed from such position (subject to any other restriction on removal imposed by law), and the Company agrees that any such resignation or removal after the date of execution of this Agreement shall not affect the adequacy of the consideration received by the Company for its agreement to provide the protections set forth in this Agreement. This Agreement shall not be deemed an employment contract between the Company (or any of its subsidiaries or any Enterprise) and Indemnitee. The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve as [a director][an officer] of the Company, as provided in Section 16 hereof.

(b) The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in consideration for the Indemnitee's past service as [a director][an officer] and in order to induce Indemnitee to continue serving as [a director][an officer] of the Company. The Company acknowledges that Indemnitee is relying upon this Agreement in agreeing to continue serving as [a director][an officer] of the Company.

Section 2. **Definitions.** As used in this Agreement:

(a) References to "agent" shall mean any person who is or was a director, officer, or employee of [a Covered Entity][the Company] or a subsidiary of [a Covered Entity][the Company] or other person authorized by [a Covered Entity][the Company] to act for [such Covered Entity][the Company], to include such person serving in such capacity as a director, officer, employee, fiduciary or other official of another corporation, partnership, limited liability company, joint venture, trust or other enterprise at the request of, for the convenience of, or to represent the interests of [a Covered Entity][the Company] or a subsidiary of [a Covered Entity][the Company].

(b) A "Change in Control" shall be deemed to occur upon the earliest to occur after the date of execution of this Agreement of any of the following events:

i. Acquisition of Stock by Third Party. Any Person (as defined below) who is or becomes the Beneficial Owner (also as defined below), directly or indirectly, of securities of the Company representing twenty percent (20%) or more of the combined voting power of the Company's then outstanding securities unless the change in relative Beneficial Ownership of the Company's securities by any Person results solely from a reduction in the aggregate number of outstanding shares of securities entitled to vote generally in the election of directors;

ii. Change in Board of Directors. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in Sections 2(b)(i), 2(b)(iii) or 2(b)(iv)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Board;

iii. Corporate Transactions. The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than 51% of the combined voting power of the voting securities of the surviving entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such surviving entity;

iv. Liquidation. The approval by the stockholders of the Company of a complete liquidation, bankruptcy, dissolution or wind-down of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets; and/or

v. Other Events. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Company is then subject to such reporting requirement.

For purposes of this Section 2(b) of the Agreement, the following terms shall have the following meanings:

(A) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time.

(B) "Person" shall have the meaning as set forth in Sections 13(d) and 14(d) of the Exchange Act; provided, however, that Person shall exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and/or (iii) any corporation owned, directly or indirectly, by the stockholders of the

Company in substantially the same proportions as their ownership of stock of the Company.

(C) “Beneficial Owner” shall have the meaning given to such term in Rule 13d-3 under the Exchange Act; provided, however, that Beneficial Owner shall exclude any Person otherwise becoming a Beneficial Owner by reason of the stockholders of the Company approving a merger or consolidation of the Company with another entity.

(c) “Corporate Status” describes the status of a person who is or was a director, trustee, partner, managing member, officer, employee, agent and/or fiduciary of [a Covered Entity][the Company] or of any other corporation, limited liability company, partnership or joint venture, trust or other enterprise which such person is or was serving at the request of [a Covered Entity][the Company].

(d) “Disinterested Director” shall mean a director of the Company who is not and was not a party to the Proceeding (as defined below) in respect of which indemnification is sought by Indemnitee.

(e) “Enterprise” shall mean the [Covered Entities][Company] and any other corporation, limited liability company, partnership, joint venture, trust or other enterprise of which Indemnitee is or was serving at the request of [a Covered Entity][the Company] as a director, officer, trustee, partner, managing member, employee, agent and/or fiduciary.

(f) “Expenses” shall include all direct and indirect costs (including but not limited to reasonable attorneys’ fees, retainers, court costs, transcripts, fees of experts and other professionals, witness fees, travel costs, duplicating costs, printing and binding costs, wiring fees, telephone charges, postage, delivery service fees, fax transmission charges, secretarial and administrative services, any federal, state, local or foreign or other governmental taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, ERISA excise taxes and penalties, and all other disbursements, obligations or out-of-pocket expenses and reasonable compensation for time spent by Indemnitee for which he or she is otherwise not compensated by the Company) actually and reasonably incurred in connection with, or as a result of, a Proceeding or establishing or enforcing a right to indemnification under this Agreement, the DGCL, or otherwise. Expenses also shall include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including but not limited to the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent, (ii) Expenses incurred in connection with recovery under any directors’ and officers’ liability insurance policies maintained by the Company, regardless of whether the Indemnitee ultimately is determined to be entitled to such indemnification, advancement or Expenses or insurance recovery, as the case may be, and (iii) for purposes of Section 14(d) only, Expenses incurred by or on behalf of Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee’s rights under this Agreement, by litigation or otherwise. The parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee’s counsel as being reasonable shall be presumed conclusively to be reasonable. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(g) “Independent Counsel” shall mean a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five (5) years has been, retained to represent: (i) the [Covered Entities][Company, Brickell Subsidiary, Inc.] or Indemnitee in any matter material to [either such party][any of them] (other than with respect to matters concerning the Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either [the Company or] Indemnitee [or a Covered Entity] in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees and cost of the Independent Counsel referred to above and to indemnify fully such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(h) The term "Proceeding" shall include any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, investigation, audit, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of [a Covered Entity][the Company] or otherwise and whether of a civil, criminal, administrative, regulatory, legislative, or audit or investigative (formal or informal) nature, including any appeal therefrom, in which Indemnitee was, is or will be involved as a party, potential party, non-party witness or otherwise by reason of the fact that Indemnitee is or was a director, officer, employee and/or agent of [a Covered Entity][the Company], by reason of any action taken by him/her (or a failure to take action by him/her) or of any action (or failure to act) on his/her part while acting pursuant to his/her Corporate Status, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification, reimbursement, or advancement of Expenses can be provided under this Agreement. If the Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph and the Agreement.

(i) References to "other enterprise" shall include but not be limited to employee benefit plans; references to "fines" shall include but not be limited to any excise tax assessed with respect to any employee benefit plan; references to "serving at the request of [a Covered Entity][the Company]" shall include but not be limited to any service as a director, officer, employee and/or agent of [any Covered Entity][the Company] which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner he/she reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the [Covered Entity][Company]" as referred to in this Agreement.

Section 3. **Indemnity in Third-Party Proceedings.**

The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of [a Covered Entity][the Company] to procure a judgment in its favor which shall be governed pursuant to Section 4 below. Pursuant to this Section 3, Indemnitee shall be indemnified by Company to the fullest extent permitted by applicable law against all Expenses, judgments, liabilities, fines, penalties and amounts paid in settlement (including but not limited to all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, liabilities, fines, penalties and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on his/her behalf in connection with such Proceeding or any claim, issue or matter therein, if

Indemnitee acted in good faith and in a manner he/she reasonably believed to be in or not opposed to the best interests of the [Covered Entity][Company] and, in the case of a criminal Proceeding had no reasonable cause to believe that his/her conduct was unlawful. The parties hereto intend that this Agreement shall provide to the fullest extent permitted by law for indemnification or the like in excess of that expressly permitted by statute, including but not limited to any indemnification provided by the Company's Certificate of Incorporation, the Bylaws, vote of its stockholders or Disinterested Directors, or applicable law, including the DGCL.

Section 4. **Indemnity in Proceedings by or in the Right of [a Covered Entity.][the Company.]**

The Company shall indemnify Indemnitee in accordance with the provisions of this Section 4 of the Agreement if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of [a Covered Entity][the Company] to procure a judgment in its favor. Pursuant to this Section 4, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses actually and reasonably incurred by him/her or on his/her behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he/she reasonably believed to be in or not opposed to the best interests of the [Covered Entity.][Company.] If applicable law so provides, no indemnification for Expenses shall be made under this Section 4 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the [Covered Entity][Company], unless and only to the extent the Court of Chancery of the State of Delaware or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification.

Section 5. **Indemnification for Expenses of Party Who is Wholly or Partly Successful.**

Notwithstanding any other provision of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is a party to (or a participant in) and is successful, on the merits or otherwise, in any Proceeding or in defense of any claim, issue or matter therein, in whole or in part, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him/her or on his/her behalf in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him/her or on his/her behalf in connection with or related to each successfully resolved claim, issue or matter to the fullest extent permitted by law. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

Section 6. **Indemnification for Expenses as Witness or Some Other Capacity in a Proceeding.**

Notwithstanding any other provision of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of his/her Corporate Status, a witness or otherwise asked to participate in any aspect of a Proceeding to which Indemnitee is not a party, he/she shall be indemnified by Company against all Expenses actually and reasonably incurred by him/her or on his/her behalf in connection therewith.

Section 7. **Partial Indemnification.**

If Indemnitee is entitled under any provision of this Agreement to indemnification or the like by the Company for some or a portion of Expenses, but not, however, for the total amount thereof, the Company nevertheless shall indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

Section 8. **Additional Indemnification.**

(a) Notwithstanding any limitation in Sections 3, 4, or 5 of the Agreement, the Company shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is a party to or threatened to be made a party to or a participant in any Proceeding (including a Proceeding by or in the right of [a Covered Entity][the Company] to procure a judgment in its favor) against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by or on behalf of Indemnitee in connection with the Proceeding.

(b) For purposes of Section 8(a) of this Agreement, the meaning of the phrase "to the fullest extent permitted by applicable law" shall include but not be limited to:

i. to the fullest extent permitted by the provision of the DGCL or other applicable law that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to or replacement of the DGCL or such other law, and

ii. to the fullest extent authorized or permitted by any amendments to or replacements of the DGCL or other law adopted after the date of execution of this Agreement that increase the extent to which a corporation may indemnify its directors, officers, employees and/or agents.

Section 9. **Exclusions.**

Notwithstanding any other provision in this Agreement, the Company shall not be obligated under the Agreement to make any indemnification payment or advancement of Expenses in connection with any claim or demand made against Indemnitee:

(a) for which payment actually has been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision; provided, however, that notwithstanding the availability of such other indemnification and reimbursement, Indemnitee may claim indemnification and advancement of Expenses pursuant to this Agreement by assigning to the Company, at its request, Indemnitee's claims under such insurance or other indemnity provision to the extent Indemnitee has been paid by the Company; or

(b) for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Exchange Act (as defined in Section 2(b) hereof) or similar provisions of state statutory law or common law, or (ii) any reimbursement of the Company by the Indemnitee of any bonus or other incentive-based or equity-based compensation, or of any profits realized by the Indemnitee from the sale of securities of the Company, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the

"Sarbanes-Oxley Act"), or (iii) the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act);

(c) except as provided in Section 14(d) of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against [a Covered Entity][the Company] or its directors, officers, employees, agents and/or other indemnitees, unless (i) such indemnification is expressly required to be made by the DGCL, (ii) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation, (iii) such payment arises in connection with any mandatory counterclaim or cross-claim or affirmative defense brought or raised by Indemnitee in any Proceeding (or any part of any Proceeding), or (iv) the Company provides the indemnification or the like, in its sole discretion, pursuant to the powers vested in the Company under applicable law;

(d) on account of Indemnitee's conduct that is established by a final judgment as constituting a breach of Indemnitee's duty of loyalty to [a Covered Entity][the Company] or resulting in any personal profit or advantage to which Indemnitee was not legally entitled; or

(e) if it is ultimately determined by a court of competent jurisdiction in a final judgment, not subject to appeal, that indemnification is not lawful (and, in this respect, both the Company and Indemnitee have been advised that the Securities and Exchange Commission believes that indemnification for liabilities arising under the federal securities laws is against public policy and is, therefore, unenforceable and that claims for indemnification should be submitted to appropriate courts for adjudication).

Section 10. **Advances of Expenses.**

Notwithstanding any provision of this Agreement to the contrary, the Company shall advance, to the extent not prohibited by law, the Expenses incurred by or on behalf of Indemnitee in connection with any Proceeding (or any part of any Proceeding) not initiated by Indemnitee, and such advancement shall be made within thirty (30) calendar days after receipt by the Company of a statement or statements requesting such advances from time to time (which shall include invoices received by the Indemnitee in connection with such Expenses but, in the case of invoices in connection with legal services, any references to legal work performed or to expenditures made that would cause Indemnitee to waive any privilege accorded by applicable law shall not be so included), whether prior to or after final disposition of any Proceeding. Advances shall be unsecured and interest free. Advances shall be made without regard to Indemnitee's ability to repay the Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. In accordance with Section 14(d), advances shall include any and all reasonable Expenses incurred pursuing an action to enforce this right of advancement, including but not limited to Expenses incurred preparing and forwarding statements to the Company to support the advances claimed. The Indemnitee shall qualify for advances upon the execution and delivery to the Company of this Agreement, which shall constitute an undertaking providing that the Indemnitee undertakes to repay the amounts advanced (without interest) to the extent that it is ultimately determined by a court of competent jurisdiction in a final judgment, not subject to appeal, that Indemnitee is not entitled to be indemnified by the Company. No other form of undertaking shall be required other than the execution by both parties of this Agreement. This Section 10 of the Agreement shall not apply to any claim made by Indemnitee for which an indemnity is excluded pursuant to Section 9 thereof.

Section 11. **Procedure for Notification and Defense of Claim**.

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of written notice thereof or Indemnitee's becoming aware thereof. The written notification to the Company shall include a description of the nature of the Proceeding and the facts underlying the Proceeding, in each case to the extent actually known to Indemnitee. The Secretary of the Company, promptly upon receipt of such a request for indemnification, shall advise the Board in writing, copying the CEO and General Counsel of the Company, that Indemnitee has requested indemnification or the like.

(b) To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification under this Agreement following the final disposition of such Proceeding. The failure by Indemnitee to notify the Company hereunder will not relieve the Company from any liability which it may have to Indemnitee under this Agreement or otherwise, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights under this Agreement.

(c) The Company will be entitled to participate in the Proceeding at its own expense. Indemnitee agrees to provide any consent or other authorization promptly to allow such participation by the Company.

(d) The Company shall not be liable to indemnify Indemnitee under this Agreement for any amounts paid in settlement of any Proceeding effected without the Company's prior written consent; provided, however, that the Company will not unreasonably withhold its consent to any proposed settlement.

(e) Indemnitee shall submit any claim for indemnification and/or advancement of Expenses within a reasonable time not to exceed seven (7) years after any judgment, order, settlement, dismissal, arbitral award, conviction, acceptance of a plea of nolo contendere or its equivalent, final termination or other disposition or partial disposition of any Proceeding, whichever is the later date for which Indemnitee requests indemnification and/or advancement of Expenses.

Section 12. **Procedure Upon Application for Indemnification**.

(a) Upon written request by Indemnitee for indemnification pursuant to Section 11(a) of the Agreement, a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case: (i) if a Change in Control shall have occurred, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee; or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee, or (D) if so directed by the Board, by the stockholders of the Company; and, if it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten (10) business days after such determination. Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to make such determination. Any costs or Expenses (including attorneys' fees and disbursements) incurred by or on behalf of Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Company will advise Indemnitee promptly in writing with respect to any determination that Indemnitee is or is not entitled to indemnification, including a description of any reason or basis for which indemnification has been denied.

(b) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) hereof, the Independent Counsel shall be selected as provided in this Section 12(b). If a Change in Control shall not have occurred, the Independent Counsel shall be selected by the Board, and the Company shall give written notice to Indemnitee advising him/her of the identity of the Independent Counsel so selected. If a Change in Control shall have occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within ten (10) calendar days after such written notice of selection shall have been given, deliver to the Company or to Indemnitee, as the case may be, a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 2 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or the Court of Chancery of the State of Delaware, United States of America, has determined that such objection is without merit. If, within twenty (20) calendar days after the later of submission by Indemnitee of a written request for indemnification pursuant to Section 11(a) hereof and the final disposition of the Proceeding, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Court of Chancery of the State of Delaware, United States of America, for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by such court or by such other person as such court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 12(a) hereof. The Company shall pay any and all reasonable fees and expenses of Independent Counsel incurred by such Independent Counsel in connection with acting pursuant to this Section 12(b), and the Company shall pay all reasonable fees and expenses incident to the procedures of this Section 12(b), regardless of the manner in which such Independent Counsel was selected or appointed. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 14(a) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

(c) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement of Indemnitee to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

Section 13. **<u>Presumptions and Effect of Certain Proceedings</u>.**

(a) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall, to the fullest extent not prohibited by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 11(a) of this Agreement. The Company, to the fullest extent not prohibited by law, shall have the burden of proof and the burden of persuasion by clear and convincing evidence to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 14(e), if the person, persons or entity empowered or selected under Section 12 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) calendar days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification, to the fullest extent not prohibited by law, shall be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification; provided, however, that such 60-calendar day period may be extended for a reasonable time, not to exceed an additional thirty (30) calendar days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 13(b) shall not apply if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 12(a) of this Agreement and if (A) within fifteen (15) calendar days after receipt by the Company of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy-five (75) calendar days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) calendar days after such receipt for the purpose of making such determination, such meeting is held for such purpose within sixty (60) calendar days after having been so called and such determination is made thereat.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of <u>nolo</u> <u>contendere</u> or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he/she reasonably believed to be in or not opposed to the best interests of the [Covered Entity][Company] or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his/her conduct was unlawful.

(d) The Company acknowledges that a settlement or other disposition short of final judgment may be successful if it permits a party to avoid expense, delay, distraction, disruption and uncertainty. In the event that any Proceeding to which Indemnitee is a party or in which Indemnitee is otherwise involved or a participant is resolved in any manner other than by adverse judgment against Indemnitee (including, without limitation, settlement of such Proceeding with or without payment of money or other consideration) it shall be presumed that Indemnitee has been successful on the merits or otherwise in such Proceeding. Anyone seeking to overcome this presumption shall have the burden of proof and the burden of persuasion by clear and convincing evidence.

(e) For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise, including financial statements, or on information supplied to Indemnitee by the directors, officers, employees and/or agents of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser or other expert selected with the reasonable care by the Enterprise. The provisions of this Section 13(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which the Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement. Whether or not the foregoing provisions of this Section 13(d) are satisfied, it shall in any event be presumed that Indemnitee has at all times acted in good faith and in a manner he/she reasonably believed to be in or not opposed to the best interests of the [Covered Entity][Company].

(f) The knowledge and/or actions, or failure to act, of any director, officer, trustee, partner, managing member, fiduciary, agent or employee of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

Section 14. **Remedies of Indemnitee.**

(a) Subject to Section 14(e), in the event that (i) a determination is made pursuant to Section 12 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 10 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 12(a) of this Agreement within ninety (90) calendar days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Section 5, 6 or 7 or the last sentence of Section 12(a) of this Agreement within ten (10) business days after receipt by the Company of a written request therefor, (v) payment of indemnification pursuant to Section 3, 4 or 8 of this Agreement is not made within ten (10) business days after a determination has been made that Indemnitee is entitled to indemnification, (vi) the Company or any other person or entity takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or proceeding designed to deny, limit, or to recover from, Indemnitee the benefits provided or intended to be provided to the Indemnitee hereunder, or (vii) Indemnitee otherwise seeks enforcement of this Agreement, Indemnitee shall be entitled to a final adjudication by a court of his/her entitlement to such indemnification or advancement of Expenses. Alternatively, Indemnitee, at his/her option, may seek a final award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee shall commence such proceeding seeking an adjudication or an award in arbitration within one hundred and eighty (180) calendar days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 14(a); provided, however, that the foregoing clause shall not apply in respect of a proceeding brought by Indemnitee to enforce his/her rights under Section 5 of this Agreement. The Company shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) In the event that a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is not entitled to indemnification, in whole or in part, any judicial proceeding or arbitration commenced pursuant to this Section 14 shall be conducted in all respects as a *de novo* trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 14 the Company shall have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) If a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this Section 14, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a specific finding (which has become final, conclusive and binding) by the Chancery Court of the State of Delaware, USA that all or any part of such indemnification is expressly prohibited by applicable law.

(d) The Company, to the fullest extent not prohibited by law, shall be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 14 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the Company (i) is bound by all the provisions of this Agreement and (ii) is precluded from making any assertion to the contrary. It is the intent of the Company that, to the fullest extent permitted by law, the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder. The Company shall, to the fullest extent permitted by law, indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) business days after receipt by the Company of a written request therefor) advance, to the extent not prohibited by law, such Expenses to Indemnitee, which are incurred by or on behalf of Indemnitee in connection with any request or action brought by Indemnitee for indemnification or advancement of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company if, in the case of indemnification, Indemnitee is wholly successful on the underlying claims; if Indemnitee is not wholly successful on the underlying claims, then such indemnification shall be only to the extent Indemnitee is successful on such underlying claims or otherwise as permitted by law, whichever is greater.

(e) If the Company disputes a portion of the amounts for which indemnification is requested, the undisputed portion shall be paid and only the disputed portion withheld from Indemnitee pending resolution of any such dispute as governed by this Agreement.

Section 15. **<u>Non-Exclusivity; Survival of Rights: Insurance; Subrogation</u>**.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement (i) shall not be deemed exclusive of any other rights to which Indemnitee may now or in the future be entitled under applicable law, the Company's Certificate of Incorporation, the Bylaws, any agreement, a vote of stockholders or a resolution of the Board, or otherwise and (ii) shall be interpreted independently of, and without reference to, any other such rights to which Indemnitee may at any time be entitled. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such

Indemnitee in his/her Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in the DGCL or other applicable law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Bylaws or the Certificate of Incorporation of the Company and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change(s). No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance or other forms of indemnification or the like for directors, officers, employees or agents of the Enterprise, Indemnitee shall be covered by such policy or policies or other forms in accordance with its or their terms to the maximum extent of the coverage or allowance available for any such director, officer, employee and/or agent under such policy or policies or other forms. If, at the time of receipt of a notice of a claim pursuant to the terms hereof, the Company has director and officer liability insurance in effect, the Company shall give prompt written notice of such claim or of the commencement of a Proceeding, as the case may be, to the insurers or their other equivalent counterparts in accordance with the procedures set forth in the respective policies or other forms. The Company shall thereafter take all necessary or desirable action(s) to cause such insurers or other counterparts to pay, on behalf of the Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies or other forms.

(c) In the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights and Indemnitee shall take such actions promptly upon request by the Company.

(d) The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable (or for which advancement of Expenses is provided hereunder) if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

Section 16. **Duration of Agreement**.

(a) This Agreement shall continue until and terminate upon the later of (i) twenty (20) years after the date that Indemnitee shall have ceased to serve as a director, officer, employee and/or agent of [a Covered Entity][the Company] or (ii) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding (including any appeal) commenced by Indemnitee pursuant to Section 14 of this Agreement relating thereto.

(b) The rights of indemnification and advancement of Expenses provided by or granted pursuant to this Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, acquisition, combination, consolidation or otherwise to all or substantially all of the business or assets of the Company), shall continue as to an Indemnitee who has ceased to be a director, officer, employee and/or agent of [a Covered Entity][the

Company] or of any other Enterprise for any reason, and shall inure to the benefit of Indemnitee and his or her spouse, assigns, heirs, devisees, executors and administrators and other personal and legal representatives.

(c) The Company shall require and cause any successor (whether direct or indirect by purchase, merger, acquisition, combination, consolidation or otherwise) to all or substantially all of the business or assets of the Company to expressly, by written agreement with Indemnitee, assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no such succession or assignment had taken place.

(d) No legal action will be brought and no cause of action will be asserted by or in the right of the Company against an Indemnitee or an Indemnitee's estate, spouse, heirs, executors or personal or legal representatives after the expiration of five (5) years from the date of accrual of such cause of action, and any claim or cause of action of the Company will be extinguished and deemed released unless asserted by the timely filing of a legal action within such five (5)-year period; provided, however, that if any shorter period of limitations is otherwise applicable to such cause of action, such shorter period will govern.

Section 17. **Severability.**

If any provision or provisions of this Agreement (or any portion thereof) shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including but not limited to each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including but not limited to each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

Section 18. **Entire Agreement.**

This Agreement constitutes the entire agreement between the parties with respect to the specific subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the same subject matter hereof; provided, however, that this Agreement is a supplement to and in furtherance of the Company’s Certificate of Incorporation, the Bylaws, any directors’ and officers’ insurance coverage maintained by the Company, and applicable law, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder.

Section 19. **Modification, Waiver, Termination and Cancellation.**

No supplement, modification, amendment, termination, or cancellation of this Agreement shall be binding unless executed in writing by both of the parties hereto, or as otherwise expressly provided herein. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement (whether or not similar), nor shall any waiver constitute a continuing waiver.

Section 20. **Notices.**

All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail with postage prepaid, on the fifth (5^{th}) business day after the date on which it is so mailed, (c) one (1) business day after timely deposit with a nationally recognized overnight courier for next business day delivery, or (d) sent by email, with receipt of oral confirmation that such email has been received, in all cases with all postage, delivery or similar charges prepaid and addressed to the party or parties to be notified at the addresses set forth below:

(a) If to Indemnitee, at the address indicated on the first page of this Agreement for Indemnitee.

(b) If to the Company, at:

Fresh Tracks Therapeutics, Inc.
5777 Central Avenue, Suite 102
Boulder, CO 80301
Attention: David R. McAvoy, General Counsel, Chief Compliance Officer and Secretary
Phone: 720-505-4755
Email: dmcavoy@frtx.com

Either party may change the address, email address or person to which any such notice shall be sent by like notice in writing to the other party, provided that no such change shall be effective as against a party unless and until actually received by such party.

Section 21. **Contribution.**

(a) To the fullest extent permissible under applicable law and not inconsistent with the remaining provisions of this Section 21, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by or on behalf of Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement, and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by [a Covered Entity][the Company] and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the [Covered Entity][Company] (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

(b) Whether or not the indemnification provided in this Agreement is available, in respect of any Proceeding in which [a Covered Entity][the Company] is jointly liable with Indemnitee (or would be if joined in such Proceeding), the Company shall pay, in the first instance, the entire amount of any judgment or settlement of such Proceeding without requiring Indemnitee to contribute to such payment and the Company hereby waives and relinquishes any right of contribution it may have against Indemnitee. The Company shall not enter into any settlement of any Proceeding in which [a Covered Entity][the Company] is jointly liable with Indemnitee (or would be if joined in such Proceeding) unless such settlement provides for a full and final release of all claims asserted against Indemnitee.

(c) Without diminishing or impairing the obligations of the Company set forth in the preceding subparagraph, if, for any reason, Indemnitee shall elect or be required to pay all or any portion of any judgment or settlement in any Proceeding in which [a Covered Entity][the Company] is jointly liable with Indemnitee (or would be if joined in such Proceeding), the Company shall contribute to the amount of Expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred and paid or payable by Indemnitee in proportion to the relative benefits received by the [Covered Entity][Company] and all officers, directors, employees or agents of the [Covered Entity][Company], other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, from the transaction or events from which such Proceeding arose; provided, however, that the proportion determined on the basis of relative benefit may, to the extent necessary to conform to law, be further adjusted by reference to the relative fault of the [Covered Entity][Company] and all officers, directors, employees or agents of the [Covered Entity][Company] other than Indemnitee who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, in connection with the transaction or events that resulted in such Expenses, judgments, fines or settlement amounts, as well as any other equitable considerations which applicable law may require to be considered. The relative fault of the [Covered Entity][Company] and all officers, directors, employees and/or agents of the [Covered Entity][Company], other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, shall be determined by reference to, among other things, the degree to which their actions were motivated by intent to gain personal profit or advantage, the degree to which their liability is primary or secondary, and the degree to which their conduct is active or passive.

Section 22. **Applicable Law and Consent to Jurisdiction.**

This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, USA, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 14(a) of this Agreement, the Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Chancery Court of the State of Delaware, USA (the "Delaware Court") and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (iv) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum. If the laws of the State of Delaware, USA, are hereafter amended to permit the Company to provide broader indemnification rights than said laws permitted the Company to provide prior to such amendment, the rights of indemnification and advancement of Expenses conferred by this Agreement automatically shall be broadened to the fullest extent permitted by the laws of the State of Delaware, as so amended and of the effective date of such amendment.

Section 23. **Identical Counterparts.**

This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

Section 24. **Miscellaneous.**

Use of the masculine pronoun shall be deemed to include usage of the feminine pronoun where appropriate. The headings of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

[THIS SPACE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed between them as of the date of last signature immediately below.

FRESH TRACKS THERAPEUTICS, INC. ______________________

By: ______________________	By: ______________________
Name: ______________________	Name: ______________________
Title: ______________________	Title: ______________________
Date: ______________________	Date: ______________________

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT ("Agreement") is made as of February 21, 2023 (the "Effective Date") by and between **FRESH TRACKS THERAPEUTICS, INC.,** f/k/a Brickell Biotech, Inc., the parent of Brickell Sub ("Brickell Parent") and **BRICKELL SUBSIDIARY, INC.,** d/b/a Brickell Biotech, Inc. ("Brickell Sub"), both being Delaware companies with a principal business address located at 5777 Central Avenue, Suite 102, Boulder, CO 80301 (Brickell Sub and, together with Brickell Parent and any predecessors of Brickell Sub or Brickell Parent, collectively referred to herein as the "Company"), and David R. McAvoy**,** an Indiana resident, with an address of [***] (the "Executive").

R E C I T A L S:

WHEREAS, the Company and the Executive previously entered into an Employment Agreement, dated as of July 1, 2019, and amended as of August 27, 2019 (the "Prior Employment Agreement");

WHEREAS, the Company and the Executive desire to amend and restate and supersede the Prior Employment Agreement in its entirety with this Agreement;

WHEREAS, the Company seeks to continue to employ and retain Executive as General Counsel and Chief Compliance Officer of the Company, and to have Executive serve as the Company's Corporate Secretary, on the terms and conditions hereafter set forth;

WHEREAS, the Executive is willing to continue to make the Executive's services available to the Company on the terms and conditions hereafter set forth;

WHEREAS, during the Executive's employment with the Company, the Executive has become acquainted with and will become acquainted with technical and nontechnical information which the Company has developed, acquired, and uses, and/or which the Company will develop, acquire, or use, and which is or will be commercially valuable and sensitive confidential and proprietary information to the Company and which the Company desires to protect, and the Executive may contribute to such information through inventions, discoveries, improvements, or otherwise;

WHEREAS, the Company and the Executive previously entered into an Employee Confidentiality and Inventions Assignment Agreement, executed by the Executive and the Company on July 7, 2021 (the "CIAA");

WHEREAS, the Company and the Executive previously entered in an Indemnification Agreement signed by the Company on May 24, 2020 and signed by the Executive on May 25, 2020, and made retroactive to January 6, 2019 (the "Indemnification Agreement"); and

WHEREAS, contemporaneous with the Company and the Executive executing this Agreement, the Company and the Executive are executing a Non-Competition Agreement effective as of the same date as the Effective Date (the "Non-Competition Agreement").

NOW, THEREFORE, in consideration of the recitals, premises, and mutual covenants set forth herein, the parties agree as follows:

1 . Employment/Duties of Executive. During the Term of Employment under this Agreement, the Executive shall serve as General Counsel and Chief Compliance Officer of the

/s/ DRM /s/ AS /s/ RLH

Company, and also shall serve as the Company's Corporate Secretary, agreeing to satisfactorily complete the responsibilities commensurate with those duties and responsibilities of such positions, and consistent with these positions, namely to be lead legal counsel and ethics and compliance officer for the Company and to provide secretarial service to the Company's Board of Directors (the "Board") all in support of good corporate governance. Executive shall report to the Company's Chief Executive Officer ("CEO"). Additionally, the Executive diligently shall perform all other necessary and appropriate services to further the Company's objectives and exercise such power and authority as may from time to time be delegated to the Executive by the CEO or the Board. The foregoing shall not limit the Executive's right to be involved in not-for-profit, civic, or charitable activities -- nor limit the Executive's right to serve as a compensated advisor and/or board member -- for other non-competing corporate or not-for-profit entities, provided such outside activities do not conflict or impede the Executive's performance of the Executive's duties and responsibilities to the Company or would conflict or impede with the Company's business. The Company reserves the right to request that the Executive resign from such outside roles in the event that the CEO or the Board perceives that the Executive is devoting less than the Executive's full-time attention to the Executive's responsibilities at the Company or that a potential conflict of interest arises as to the Company. The Executive agrees to inform the Company in advance of accepting any such outside roles to ensure alignment with the Company's needs. Further, the Executive will adhere and comply with all Company policies as provided to the Executive by the Company's Human Resources Department, including, but not limited to, the Company's conflict of interest policy. The Executive hereby represents and confirms that the Executive is under no contractual or legal commitments that would prevent the Executive from fulfilling the Executive's duties and responsibilities as set forth in this Agreement.

2. Term. The Executive began employment with the Company on July 1, 2019. The Executive's employment with the Company has been and shall continue to be at-will, meaning that the Executive or the Company may terminate the employment relationship at any time, with or without Cause (as defined below) or Good Reason (as defined below), and with or without notice, subject to severance provisions set forth below. The period during which the Executive shall be employed by the Company pursuant to the terms of this Agreement following the Effective Date is sometimes referred to in this Agreement as the "Term of Employment", and the date on which the Executive's employment with the Company terminates pursuant to **Article 5** and the Term of Employment ends is sometimes referred to in this Agreement as the "Termination Date").

3. Compensation.

3.1 Base Salary. Retroactive to January 1, 2023, the Company shall pay Executive an initial base salary at the annual rate of Three Hundred Fifty Thousand United States Dollars ($350,000.00) (the "Base Salary"). The Board shall review the Executive's Base Salary from time to time and the Company may, but shall not be required to, increase the Base Salary during the Term of Employment. However, the Executive's Base Salary may not be decreased during the Term of Employment other than as part of an across-the-board salary reduction that applies in the same manner to all Section 16 officers of the Company as determined within the meaning of Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended, and Rule 3b-7 under the Securities Exchange Act of 1934, as amended ("Section 16 Officers") and, to extent they are not designated to be Section 16 Officers by the Board, and the positions exist within the Company, the CEO, the Chief Financial Officer, the Chief Business (or Operating) Officer and the Chief Medical Officer of the Company (hereafter, collectively with Section 16 Officers known as "Company Executives"). All Base Salary is payable subject to applicable tax withholding requirements and appropriate standard deductions in accordance with the Company's customary payroll practices.

3.2 Equity and Performance Bonuses.

a. Annual Performance Bonus. For each fiscal year of the Term of Employment ("Bonus Period"), Executive will be eligible to earn and receive an annual target performance bonus of forty percent (40%) of Base Salary (the "Performance Bonus"), with the actual Performance Bonus based upon the achievement of mutually agreed performance milestones established by the CEO and the Board; provided, however, nothing herein shall be a guarantee of any amount of Performance Bonus, or any Performance Bonus at all. In order to be eligible to earn and receive a Performance Bonus, in addition to the other requirements of this Agreement, the Executive must be employed by the Company for the full fiscal year to which the Performance Bonus applies. The Company shall have no obligation to provide the Executive a Performance Bonus for any year, unless and until such a determination has been made by the Company consistent with the criteria described above at the conclusion of the applicable Bonus Period. Such Performance Bonus, if any, is subject to applicable tax withholding requirements and appropriate standard deductions in accordance with the Company's customary payroll practices and earned by the Executive only if the Executive is employed by the Company on the last day of the applicable Bonus Period. Any Performance Bonus earned by the Executive and payable to the Executive pursuant to this **Section 3.2.a** shall be paid by the Company to the Executive no later than March 15 of the calendar year immediately after the end of the calendar year to which the Performance Bonus relates. The Company will review the Performance Bonus from time to time and the Company may, but shall not be required to, increase the annual target percentage for the Performance Bonus during the Term of Employment. However, the Executive's annual target percentage for the Performance Bonus may not be decreased during the Term of Employment other than as part of a similar across-the-board Performance Bonus target reduction that applies in the same manner to all Company Executives.

b. Equity Awards. The Company and the Executive agree that as of the Effective Date the Executive has received the equity awards identified in **Exhibit A** to this Agreement (together with any equity awards that may be issued by the Company to the Executive in the future as non-cash compensation paid in terms of ownership interests in the Company, including, but not limited to, stock options of any type, restricted shares, warrants, and employee stock purchase plans, the "Equity Awards"). The Equity Awards shall be governed by and remain in effect in accordance with the terms and conditions of (i) the Company's 2020 Omnibus Long-Term Incentive Plan, as amended May 17, 2022, and as may further be amended, (ii) other Company plans covering Equity Awards that may become relevant during the Term of Employment, and (iii) applicable equity award agreements with respect to the Equity Awards entered into between Executive and the Company; provided, however, in the event of a termination of the Executive for any reason other than by the Company for Cause or due to Executive's disability pursuant to **Section 5.2**, there shall be full acceleration of vesting on any unvested Equity Awards as of the Termination Date and an exercise period of three (3) years from that accelerated vesting date will apply, notwithstanding anything else to the contrary.

4. Expense Reimbursement and Other Benefits.

4.1 Reimbursement of Expenses. Upon the submission of proper substantiation by the Executive, and subject to such rules, guidelines and policies as the Company may from time to time adopt, and except as otherwise provided in **Section 4.3.d**, the Company will timely reimburse the Executive for all reasonable expenses actually paid or incurred by the Executive during the Term of Employment in the course of and pursuant to the business of the Company. The Executive shall account to the Company in writing for all expenses for which reimbursement is sought and supply to the Company copies of all relevant invoices, receipts, or other evidence reasonably requested by the Company.

4.2 Employee Benefit Plans and Programs. During the Term of Employment, the Executive shall be entitled to participate in all medical, dental, and vision insurance plans (the "Healthcare Plans"), retirement plans, and any and all other employee benefit plans as are presently and hereafter offered by the Company to its executives and their spouses, domestic partners, immediate families and any other qualifying dependents. The Executive acknowledges and agrees that the Executive will be subject to all eligibility requirements and all other provisions of these benefit plans and that the Company is under no obligation to the Executive to establish and maintain any employee benefit plan, or specific benefit administered thereunder, in which the Executive may participate as long as the Company's actions are made similarly for all Company Executives. As of the Effective Date, the Company permits its full-time employees and eligible covered dependents to enroll in the Company's Healthcare Plans with the Company paying the total costs of all of the related premiums; however, this policy is subject to change by the Company at its sole discretion and the Company may end this practice and not pay for all or any of the Healthcare Plans premiums for its full-time employees and covered dependents and/or may terminate its Healthcare Plans at any time. Subject to the foregoing, from the Effective Date, and during the Executive's full-time employment, the Company will pay directly the costs of the Executive's Healthcare Plans premiums chosen by the Company so long as the Executive and any eligible dependents timely enroll and retain eligibility in the Company's Healthcare Plans, as instructed.

4.3 Other Benefits.

a. Flexible Time Off. The Executive shall be entitled to personal time off in accordance with the Company's current flexible time-off ("FTO"), Company holiday, and sick leave policies. Personal days shall not interfere with the duties required to be rendered by the Executive hereunder.

b. Paid Time-Off Balance. Upon termination of the Executive's employment for any reason, whether at the initiative of the Executive or the Company, the Company shall pay to the Executive on the same date on which the Company pays the Executive's final wage payment an amount equal to (i) the Executive's Base Salary as of the Termination Date divided by 2080, multiplied by (ii) eight (8), multiplied by (ii) the number of days identified in the Paid-Time Off ("PTO") Balance Acknowledgment Form attached as **Exhibit B** to this Agreement, less applicable taxes and subject to the Company's appropriate standard deductions and withholdings.

c. Association Dues. During the Term of this Agreement, the Company will pay (i) reasonable initiation fees and dues payable in connection with the Executive's membership(s) in those clubs and activities that in the opinion of the Company as determined by the CEO are in furtherance and directly related to the active conduct of the Company's business and are consistent with sound financial and tax planning; and (ii) the continuing legal education costs to fulfill the state bar requirements applicable to the Executive, and the annual fees charged by the Indiana and/or other state judicial system(s) for maintaining attorney licensing in good standing.

d. Location and Travel Expenses. As part of Executive's employment, Executive understands and agrees to spend an average of five (5) business days per month in the Company's principal place of business (as of the Effective Date, the Company's Boulder, Colorado office), and as additionally and reasonably requested by the Company as business needs dictate, and/or at another mutually agreed upon off-site premise, at the reasonable expense of the Company and subject to the Company's expense and travel policy. The Company agrees to pay the Executive Three Thousand United States Dollars ($3,000.00) per month, less applicable taxes and subject to the Company's appropriate standard deductions and withholding, to defray the costs of leasing a corporate apartment at the Company's principal place of business in exchange that the Executive will be responsible at the Executive's own cost to pay for travel, lodging, meals and other costs in super-commuting between the Executive's residence in Indiana and the Company's principal place of business; provided, however, the Company will reimburse the Executive for all his business expenses incurred to participate in group employee meetings not associated with the Executive's super-commuting to meet his minimum required presence at the Company's principal place of business, per this **Section 4.3.d**.

e . Miscellaneous Benefits. The Executive shall receive additional employee benefits, if any, as the Board and/or the Company shall from time to time determine.

5. Termination.

5.1 Termination for Cause. The Company shall at all times have the right, upon written notice to the Executive, to terminate the Term of Employment for Cause. For purposes of this Agreement, the term "Cause" shall mean any of the following: (i) an action or omission of the Executive which constitutes a willful and material breach of, gross negligence in connection with, or failure or refusal (other than by reason of the Executive's disability or death) to perform the Executive's duties and responsibilities under this Agreement or any other agreements between the Executive and the Company, including without limitation the CIAA, which breach, failure, or refusal is not cured by the Executive within fifteen (15) calendar days after the Executive's receipt of written notice of such act or omission from the Company; (ii) the Executive's material violation of any Company policy; (iii) the Executive committing fraud, embezzlement, dishonesty, misappropriation of funds, harassment, violation of securities laws, physical violence, a breach of trust or fiduciary duties, or gross misconduct in connection with the Executive's employment by the Company; (iv) the Executive being charged with any felony, or being convicted for or pleading guilty or no contest to any criminal offense involving dishonesty or a breach of trust; (v) libel, slander, or defamation by Executive of the Company or its employees, officers, and directors; and/or (vi) the Executive entering into direct competition with the Company. Any termination of the Executive's employment by the Company for Cause shall be made in writing by the Company to the Executive, which notice shall set forth in specific detail all acts or omissions by Executive that qualify for Cause as defined above and upon which the Company is relying for such termination. The Executive shall have the right to address the Board regarding the acts of Cause set forth in the notice of termination prior to the termination taking effect. Upon any termination of the Executive's employment with the Company for Cause pursuant to this **Section 5.1**, the Company shall, less applicable taxes and subject to the Company's appropriate standard deductions and withholdings, (i) pay to the Executive any unpaid Base Salary through the Termination Date; (ii) pay to the Executive the PTO balance amount as set forth in **Section 4.3.b**; (iii) pay to the Executive any earned but unpaid Performance Bonus pursuant to **Section 3.2**, if any, for the Bonus Period ending prior to the Termination Date; (iv) reimburse the Executive for actual and reasonable business expenses incurred by the Executive for the Company prior to the Termination Date pursuant to **Sections 4.1** and **4.3.d**; and (v) provide the Executive with any vested benefits under any Company-sponsored employee benefit plan, as determined under the applicable Company-sponsored benefit plan, with payment for all of the foregoing payable not later than the next regularly scheduled payroll date following the Termination Date unless required otherwise by applicable law or this Agreement (collectively, the "Accrued Obligations"), and the Company shall have no further liability hereunder.

5.2 Disability. The Company shall at all times have the right, upon written notice to the Executive, to terminate the Term of Employment if the Executive shall become entitled to long-term benefits under the Company's disability plan as then in effect, or, if the Executive shall as the result of mental or physical incapacity, illness, or disability as demonstrated by independent competent medical determination, become unable to perform the Executive's obligations hereunder for a period of one hundred eighty (180) calendar days in any rolling twelve (12)-month period. Upon any termination of the Executive's employment with the Company pursuant to this **Section 5.2**, the Company shall pay to the Executive the Accrued Obligations, and the Company shall have no further liability hereunder.

5.3 Death. Upon the death of the Executive during the Term of Employment, the Company shall pay to the estate or the applicable beneficiary of the deceased Executive the Accrued Obligations, and the Company shall have no further liability hereunder.

5.4 Termination Without Cause. At any time, the Company shall have the right to terminate the Term of Employment by written notice for any reason to the Executive. Upon any termination of the Executive's employment with the Company pursuant to this **Section 5.4**, the Company shall pay to the Executive the Accrued Obligations. Subject to **Section 5.7** and **Article 19**, the Company shall further (i) pay to the Executive the equivalent of nine (9) months of Executive's Base Salary as of the Termination Date, less applicable taxes and subject to the Company's appropriate standard deductions and withholdings, payable in substantially equal installments in accordance with the Company's regular payroll schedule over the course of the nine (9) month period immediately after the Termination Date; provided, however, the first installment of such payments will be delayed until the Company's first regularly scheduled payroll date following the effective date of the Release described in **Section 5.7** below and include payment for any other installments that otherwise would have been paid after the Termination Date and before such payroll date but for such delay; and provided further that if such first regular payroll date following the effective date of the Release described in **Section 5.7** below could occur in two separate calendar years, then the first installment of the severance payments will be made in the second of such calendar years; and (ii) pay to the Executive an additional total amount equivalent to the amount necessary to cover the third-party health insurance premiums for Executive and Executive's dependents as of the Termination Date, including for medical, dental, and vision insurance coverages, for a period of nine (9) months after the Termination Date, payable on the same payroll date as the first separation payment installment described above and deposited into a taxable or tax-exempt health reimbursement account ("HRA") that may be available to Executive to receive such a payment that Executive designates in writing to the Company prior to the payment being paid (with Company reasonably assisting Executive with setting up an HRA for this purpose under applicable law within the aforementioned timing), or the Company, at its sole discretion, may elect to pay such premiums directly to the third-party provider(s) it utilizes to provide Company employee health insurance, or some other provider (collectively, the "Severance Benefits"), and the Company shall have no further liability hereunder (other than for payment of the Accrued Obligations). To the extent allowed by Section 409A, the Company alternatively reserves its right, in its sole discretion, to pay the Severance Benefits to Executive as a lump sum, less applicable taxes and subject to the Company's appropriate standard deductions and withholdings, payable on the next regularly scheduled payroll date following the effective date of the Release described in **Section 5.7** below (but no later than sixty (60) calendar days after the Termination Date).

5.5 Termination by Executive Without Good Reason or for Good Reason.

a. The Executive at all times shall have the right, upon fifteen (15) calendar 6days written notice to the Company, to terminate the Term of Employment for any reason, except that termination for Good Reason (defined below in **Section 5.5(c)**) shall be handled pursuant to **Section 5.5(b)**. Upon termination of the Term of Employment pursuant to this **Section 5.5(a)** by the Executive, the Company shall pay to the Executive the Accrued Obligations, and the Company shall have no further liability hereunder.

b. Upon termination of the Term of Employment pursuant to this **Section 5.5(b)** by the Executive for Good Reason, the Company shall pay to the Executive the Accrued Obligations. Subject to **Section 5.7** and **Article 19**, the Company shall further pay to the

Executive the Severance Benefits, and the Company shall have no further liability hereunder (other than for payment of the Accrued Obligations). To the extent allowed by Section 409A, the Company alternatively reserves its right, in its sole discretion, to pay the Severance Benefits to Executive as a lump sum, less applicable taxes and subject to the Company's appropriate standard deductions and withholdings, payable on the next regularly scheduled payroll date following the effective date of the Release described in **Section 5.7** below (but no later than sixty (60) calendar days after the Termination Date).

c. For purposes of this Agreement, "Good Reason" shall mean any one of the following that occurs without the Executive's prior written consent: (i) the assignment to the Executive of any duties and responsibilities inconsistent with the Executive's Section 16 Officer position as the Company's General Counsel and Chief Compliance Officer and role as public company Board Secretary (including titles and reporting requirements, authority, duties, and/or responsibilities as provided by **Article 1** of this Agreement, including, but not limited to, a requirement to report to any person or entity other than the CEO), or any other action by the Company which results in an actual material diminution in such position, authority, duties, and/or responsibilities, excluding for this purpose an isolated, insubstantial, and inadvertent action not taken by the Company in bad faith and which the Company remedies promptly after receipt of written notice thereof given by the Executive; (ii) any failure by the Company to comply with any of the provisions of **Article 3** of this Agreement, other than an isolated, insubstantial, and inadvertent failure by the Company not occurring in bad faith and which is remedied by the Company promptly after receipt of written notice thereof given by the Executive; (iii) relocation of the Executive's primary work location more than thirty (30) miles from that primary work location on the Effective Date (being in this case, Indianapolis, Indiana); (iv) an act requiring the Executive to take certain action(s) that the Executive reasonably believes are under a false pretext or would violate applicable Company policies, or applicable laws; (v) a change of the required reporting of the Executive to someone materially less qualified than the Executive; (vi) any material reduction in the package of benefits and/or incentives provided by Company to the Executive, or any action by the Company which would materially and adversely affect the Executive's participation or reduce the Executive's benefits under any such plans, including, but not limited to, any of the benefits provided to the Executive under the Company's retirement, health, medical, dental, and vision plans, except when, in the absence of a Change in Control, such benefits and/or incentives of all other Company Executives are similarly reduced, or, alternatively, if there is a Change in Control, a material adverse reduction or change is made to the benefits and/or incentives enjoyed by the Executive that were in effect at any time within ninety (90) calendar days preceding the effective date of the Change in Control or at any time thereafter; or (vii) the Company's material breach of this Agreement; provided, however, that, in each case, in order to effect resignation for Good Reason all of the following additionally must occur: (x) Executive must provide the Company with written notice within the sixty (60)-calendar day period following the event(s) giving rise to the Executive's intent voluntarily to resign the Executive's employment from the Company for Good Reason; (y) such event is not remedied by the Company within thirty (30) calendar days following the Company's receipt of such written notice; and (z) the Executive's resignation is effective not later than thirty (30) calendar days after the expiration of such thirty (30)-calendar day cure period.

5.6 Change in Control of the Company.

a . Payments. In the event that a termination of employment without Cause or for Good Reason occurs within twelve (12) months following a Change in Control (as defined in **Section 5.6.b**) in the Company, the Company shall pay to the Executive the Accrued Obligations. Subject to **Section 5.7** and **Article 19**, the Company shall further (i) pay to the Executive the equivalent of the sum of (A) twelve (12) months of the Executive's Base Salary as of the Termination Date plus (B) an amount equal to one hundred percent (100%) of the target Performance Bonus for the year in which the Termination Date occurs, in the form of a lump-sum payment, less applicable taxes and subject to the Company's appropriate standard deductions and withholdings, on the next regularly scheduled payroll date following the effective date of the Release described in **Section 5.7** below (but no later than sixty (60) calendar days after the Termination Date); and (ii) pay to the Executive a total amount equivalent to the amount necessary to cover the third-party health insurance premiums for Executive and Executive's dependents as of the Termination Date, including for medical, dental, and vision insurance coverages, for a period of twelve (12) months after the Termination Date, payable on the same payroll date as the amount payable under (i) above and deposited into a taxable or tax-exempt HRA that may be available to Executive to receive such a payment that Executive designates in writing to the Company prior to the payment being paid (with Company reasonably assisting Executive with setting up an HRA for this purpose under applicable law within the aforementioned timing) (collectively, the "Change in Control Severance Benefits"), and the Company shall have no further liability hereunder (other than for payment of the Accrued Obligations).

b. For purposes of this Agreement, the term "Change in Control" shall mean approval by the shareholders and/or the Board of the Company, as required, of (i) an acquisition, reorganization, merger, reverse merger, consolidation, or other form of corporate transaction or series of transactions, in each case, with respect to which persons who were the shareholders of the Company immediately prior to such acquisition, reorganization, merger, reverse merger, consolidation, or other transaction, do not, immediately thereafter, own more than fifty percent (50%) of the combined voting power entitled to vote generally in the election of directors of the acquired, reorganized, merged, reverse merged, or consolidated Company's then outstanding voting securities, in substantially the same proportions as their ownership immediately prior to such acquisition, reorganization, merger, reverse merger, consolidation, or other transaction; or (ii) any liquidation, dissolution, winding-up, insolvency, entering receivership, or bankruptcy of the Company; or (iii) the sale, transfer, and/or assignment of all or substantially all of the assets of the Company (unless such acquisition, reorganization, merger, reverse merger, consolidation, or other corporate transaction, liquidation, dissolution, wind-up, insolvency, receivership, bankruptcy, or sale, transfer, or assignment is subsequently abandoned).

5.7 Release and Resignation Requirement. The Executive's receipt of either the Severance Benefits or the Change in Control Severance Benefits (as applicable) are conditioned on (i) the Executive delivering to the Company and making effective and irrevocable in favor of the Company and the Company's employees, officers, and directors a general release of all claims related to the Executive's employment with the Company, in a form reasonably acceptable to the Company (the "Release"), which Release shall be effective not later than forty-five (45) calendar days following the Termination Date; (ii) Executive complying with the Release, including any cooperation, non-disparagement, and/or confidentiality provisions contained therein, and continuing to comply with the Executive's obligations under the surviving terms of this Agreement, including the non-solicit provisions thereof, and the surviving terms of the CIAA, and the Non-Competition Agreement; and (iii) the Executive's resignation from all positions with the Company, to be effective no later than the date of the Executive's termination or resignation date (or such other date as reasonably requested by the Company).

5.8 Survival. The provisions of this **Article 5** shall survive the termination or expiration of this Agreement, as applicable.

6. Restrictive Covenants.

6.1 Non-Competition. The Executive acknowledges and agrees that the Non-Competition Agreement, attached as **Exhibit C** to this Agreement, will be effective and applicable to the Executive by its stated terms during the Term of this Agreement and as it survives thereafter.

6 . 2 Nondisclosure and Confidentiality Protections. The Executive acknowledges and agrees that the CIAA, attached as **Exhibit D** to this Agreement, is and will remain in effect and applicable to the Executive by its stated terms during the Term of this Agreement and as it survives thereafter.

6.3 Non-solicitation of Executives and Clients/Customers. At all times while the Executive is employed by the Company and for a one (1) year period after the termination of the Executive's employment with the Company for any reason, the Executive shall not, directly or indirectly, for himself or for any other person, firm, company, partnership, association, or other entity (a) employ or attempt to employ or enter into any contractual arrangement with any executive or other employee or former executive or other former employee of the Company, unless such person (i) has not been employed by the Company for a period in excess of six (6) months, or (ii) has contacted the Executive in an unsolicited manner seeking employment or a contractual relationship, or (iii) was recruited from a general ad or recruiting outreach that was not person-specific, and/or (b) knowingly call on or solicit any of the actual or targeted prospective clients or customers of the Company on behalf of any person or entity in connection with any business competitive with the business of the Company, nor shall the Executive knowingly make known the names and addresses of such clients or customers or any information relating to the Company's trade or business relationships with such clients or customers, other than in connection with the performance of the Executive's duties and responsibilities under this Agreement. For avoidance of doubt, and notwithstanding the CIAA, independent contractors, consultants, vendors, agents and/or representatives of the Company, former and existing as of the Effective Date ("Excluded Persons"), are not subject to the restrictions in this **Section 6.3** or section 4 of the CIAA; provided, however, during the period that **Section 6.3** otherwise covers, the Executive will not induce or attempt to induce any of the foregoing Excluded Persons to terminate or adversely alter their relationship with the Company.

6.4 Books and Records. All books, records, and accounts relating in any manner to the business of the Company, customers, clients, or prospects of the Company, reports, documents, analyses, or any information, whether prepared by or for the Executive or otherwise coming into the Executive's possession or control, shall be the sole and exclusive property of the Company and shall be returned immediately to the Company by Executive on termination of the Executive's employment hereunder or on the Company's written request at any time.

6 . 5 Definition of Company. The term "Company" also shall include for purposes of this Agreement any existing or future affiliates or subsidiaries of the Company that are operating during the time periods described herein and any other entities that directly or indirectly, through one or more intermediaries, control, are controlled by, or are under common control with, the Company during the periods described herein.

6 . 6 Acknowledgment by Executive. The Executive acknowledges and confirms, and in exchange for other consideration provided to the Executive herein, that (a) the restrictive covenants contained in this **Article 6** are reasonably necessary to protect the legitimate business interests of the Company, and (b) the restrictions contained in this **Article 6** (including without limitation the length of the term of the provisions of this **Article 6**) are not overbroad, overlong, or unfair and are not the result of overreaching, duress, or coercion of any kind. The Executive further acknowledges and confirms that the Executive's full, uninhibited, and faithful observance of each of the covenants contained in this **Article 6** will not cause the Executive any undue hardship, financial or otherwise, and that enforcement of each of the covenants contained herein will not impair the Executive's ability to obtain employment commensurate with the

Executive's abilities and on terms fully acceptable to the Executive or otherwise to obtain income required for the comfortable support of the Executive and the Executive's family and the satisfaction of the needs of the Executive's creditors. The Executive acknowledges and confirms that the Executive's special knowledge of the business of the Company is such as would cause the Company serious injury or loss if the Executive were to use such ability and knowledge to the benefit of a competitor or were to compete with the Company in violation of the terms of this Agreement. The Executive further acknowledges and confirms that the restrictions contained in this **Article 6** are intended to be, and shall be, for the benefit of, and shall be enforceable by, the Company's successors and assigns.

6.7 Reformation by Court. Notwithstanding anything in **Article 13** (or otherwise in the Agreement) to the contrary, in the event that a court of competent jurisdiction shall determine that any provision of this **Article 6** is invalid or more restrictive than permitted under the governing law of such jurisdiction, then only as to enforcement of this **Article 6** within the jurisdiction of such court, such provision shall be interpreted and enforced as if it provided for the maximum restriction permitted under such governing law.

6.8 Extension of Time. If the Executive shall be in violation of any provision of this **Article 6**, then each time limitation set forth in this **Article 6** shall be extended for a period of time equal to the period of time during which such violation or violations occur. If the Company seeks injunctive relief from such violation in any court, then the covenants set forth in this **Article 6** shall be extended for a period of time equal to the pendency of such proceeding including all appeals by the Executive.

6.9 Survival. The provisions of this **Article 6** shall survive the termination or expiration of this Agreement, as applicable.

7. Arbitration. Any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration in Boulder County, Colorado in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association then in effect (except to the extent that the procedures outlined below differ from such rules or the parties agree otherwise in writing). Within thirty (30) calendar days after written notice by either party has been given to the other party that a dispute exists and that arbitration is required, each party must select an arbitrator, notify the other party of that selection, and, then, those two arbitrators shall promptly, but in no event later than thirty (30) calendar days after their selection, select a third arbitrator. The parties agree to act as expeditiously as possible to select arbitrators and conclude the dispute. The selected arbitrators must render their decision in writing. The arbitral decisions shall be final, complete, and binding without appeal. The cost and expenses of the arbitration, reasonable attorneys' fees for the Executive and the Company, and of enforcement of any award in any court by either party shall be borne solely and exclusively by the Company. Judgment may be entered on the arbitrators' award in any court having jurisdiction. Although arbitration is contemplated to resolve disputes hereunder, either party may proceed to court to seek to obtain an injunction to enforce and protect its rights hereunder, the parties agreeing that either could suffer irreparable harm by reason of any breach of this Agreement. Pursuit of an injunction shall not impair arbitration on all remaining issues.

8. Assignment. This Agreement is personal in nature and accordingly may not be assigned by the Executive, in whole or in part, without the prior written consent of the Company, which may be withheld in the Company's sole discretion. The Company, in its sole discretion, may assign this Agreement and all of its rights, benefits, and obligations hereunder, whether by agreement or by operation of law.

9. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Colorado without regard to conflict of laws issues.

10. Entire Agreement. This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and, upon its effectiveness, shall fully rescind, supersede, and replace all prior agreements, understandings, and arrangements, both oral and written, between the Executive and the Company with respect to such subject matter, including, but not limited, to the Prior Employment Agreement and any earlier offers to the Executive by the Company; provided, however, this Agreement is not intended to rescind, supersede, or replace, or otherwise affect the (i) Indemnification Agreement, (ii) the Equity Awards, (iii) the Non-Competition Agreement, or (iv) the CIAA, between the parties that are still in effect, and attached as exhibits hereto, incorporated fully herein by reference, each of which shall remain in effect in accordance with their terms; provided further, however, to the extent any provision of this Agreement would conflict with any provision in the Indemnification Agreement or the Non-Competition Agreement, then those other agreements will control, and as to the Equity Awards or the CIAA, including, but not limited to, section 4 of the CIAA, this Agreement will control. This Agreement may not be modified in any way unless by a prior written instrument signed by both the Company and the Executive.

11. Notices. All notices required or permitted to be given hereunder shall be in writing and shall be personally delivered by courier, sent by registered or certified mail, return receipt requested, or sent by confirmed e-mail, or facsimile transmission, addressed as set forth herein. Notices personally delivered, sent by e-mail or facsimile, or sent by overnight courier shall be deemed given on the date of delivery and notices mailed in accordance with the foregoing shall be deemed given upon the earlier of receipt by the addressee, as evidenced by the return receipt thereof, or three (3) business days after deposit in the U.S. mail. Notice shall be sent (i) if to the Company, addressed to Fresh Tracks Therapeutics, Inc., 5777 Central Avenue, Suite 102, Boulder, CO 80301, Attention: CEO, and (ii) if to the Executive, to the Executive's address as reflected on the payroll records of the Company, or to such other address as either party hereto may from time to time give written notice of to the other.

12. Benefits; Binding Effect. This Agreement shall be for the benefit of and binding upon the parties hereto and their respective heirs, personal representatives, legal representatives, successors, and, where applicable, assigns, including without limitation any successor to the Company, whether by acquisition, reorganization, merger, reverse merger, consolidation, or other transaction, sale of stock, sale of assets, or otherwise.

13. Severability. Subject to the application of **Section 6.7**, the invalidity of any one or more of the words, phrases, sentences, clauses, or sections contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part thereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses, or sections contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, or section or sections had not been inserted. If such invalidity is caused by length of time or size of area, or both, the otherwise invalid provision will be considered to be reduced to a period or area, which would cure such invalidity.

14. Waivers. The waiver by either party hereto of a breach or violation of any term or provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or violation.

15. Damages. Nothing contained herein shall be construed to prevent the Company or the Executive from seeking and recovering from the other damages sustained by either or both of them as a result of its or the Executive's material breach of any term or provision of this

Agreement, subject to the dispute resolution provisions of the Agreement. In the event that either party hereto brings suit for the collection of any damages resulting from, or the injunction of any action constituting, a breach of any of the terms or provisions of this Agreement, then the non-prevailing party shall pay all reasonable court costs and reasonable attorneys' fees of the other.

16. Section Headings. The section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

17. No Third-Party Beneficiary. Nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person or entity other than the Company, the parties hereto, and their respective heirs, personal representatives, legal representatives, successors, and assigns, any rights or remedies under or by reason of this Agreement.

18. Indemnification. The Company will indemnify the Executive pursuant to the terms and conditions of the Indemnification Agreement attached as **Exhibit E** to this Agreement and the indemnification provisions set forth in the Company's certificate of incorporation.

19. Section 409A - Nonqualified Deferred Compensation, Other.

19.1 General Compliance. This Agreement is intended to comply with section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A") covering, among other things, nonqualified deferred compensation, or an exemption thereunder, and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this Agreement, payments provided under this Agreement may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service, or as a short-term deferral, or any other eligible payments, including, but not limited to, payments from qualified plans like pension and 401(k) plans, death benefit plan, and welfare benefits including vacation leave, paid time-off (and PTO herein), sick leave, and/or disability pay, shall be excluded from Section 409A to the maximum extent possible. For purposes of Section 409A, each installment payment provided under this Agreement shall be treated as a separate payment. Any payments to be made under **Sections 5.4-5.6** of this Agreement upon a termination of employment shall only be made upon a "separation from service" under Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A, and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest, or other expenses that may be incurred by the Executive on account of non-compliance with Section 409A.

19.2 Specified Employees. Notwithstanding any other provision of this Agreement, if any payment or benefit provided to the Executive in connection with the Executive's termination of employment is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and the Executive is determined to be a "specified employee" as defined in Section 409A(a)(2)(b)(i), then such payment or benefit shall not be paid until the first payroll date to occur following the six (6)-month anniversary of the Termination Date or, if earlier, on the Executive's death (the "Specified Employee Payment Date"). The aggregate of any payments that would otherwise have been paid before the Specified Employee Payment Date and interest on such amounts calculated based on the applicable federal rate published by the Internal Revenue Service for the month in which the Executive's separation from service occurs shall be paid to the Executive in a lump sum on the Specified Employee Payment Date and, thereafter, any remaining payments shall be paid without delay in accordance with their original schedule.

19.3 Reimbursements. To the extent required by Section 409A, each reimbursement or in-kind benefit provided under this Agreement shall be provided in accordance with the following:

(a) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during each calendar year cannot affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year;

(b) any reimbursement of an eligible expense shall be paid to the Executive on or before the last day of the calendar year following the calendar year in which the expense was incurred; and

(c) any right to reimbursements or in-kind benefits under this Agreement shall not be subject to liquidation or exchange for another benefit.

20. 280G Limitations. In the event that the severance and other benefits provided for in this Agreement or otherwise payable to the Executive hereunder (a) constitute "parachute payments" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended, and (b) would be subject to the excise tax imposed by Code Section 4999, then such benefits shall either be: (i) delivered in full, or (ii) delivered as to such lesser extent which would result in no portion of such severance benefits being subject to excise tax under Code Section 4999, whichever of the foregoing amounts, taking into account the applicable federal, state, and local income and employment taxes and the excise tax imposed by Code Section 4999, results in the receipt by the Executive, on an after-tax basis, of the greatest amount of benefits, notwithstanding that all or some portion of such benefits may be subject to excise tax under Code Section 4999. Any determination required under this **Article 20** will be made in writing by an accounting firm selected by the Company or such other person or entity to which the parties mutually agree (the "Accountants"), whose determination will be conclusive and binding upon the Executive and the Company for all purposes. For purposes of making the calculations required by this **Article 20**, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Code Sections 280G and 4999. The Company and the Executive shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this **Article 20**. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this **Article 20**. Any reduction in payments and/or benefits required by this **Article 20** shall occur in the following order: (A) cash payments shall be reduced first and in reverse chronological order such that the cash payment owed on the latest date following the occurrence of the event triggering such excise tax will be the first cash payment to be reduced; (B) accelerated vesting of stock awards, if any, shall be cancelled/reduced next and in the reverse order of the date of grant for such stock awards (i.e., the vesting of the most recently granted stock awards will be reduced first), with full-value awards reversed before any stock option or stock appreciation rights are reduced; and (C) deferred compensation amounts subject to Section 409A shall be reduced last.

21. Counterparts. This Agreement may be executed in one or more counterparts (including, but not limited to, by means of telecopied, facsimile, .PDF format, DocuSign, or other electronic signature pages), each of which shall be deemed an original but all of which together shall constitute one and the same agreement. Signatures delivered by telecopied, facsimile, .PDF format, DocuSign, or other electronic signature shall constitute original signatures.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the Effective Date first above written.

Company:

FRESH TRACKS THERAPEUTICS, INC.
A Delaware Company

By: /s/ Reginald Hardy
Reginald Hardy, Board Chair

BRICKELL SUBSIDIARY, INC.
A Delaware Company

By: /s/ Andrew Sklawer
Andrew Sklawer, President

Executive:

By: /s/ David R. McAvoy
David R. McAvoy, Individually

Exhibit A

Equity Awards

Exhibit B

Paid Time Off (PTO) Balance Acknowledgment Form

Exhibit C

Non-Competition Agreement

NON-COMPETITION AGREEMENT

This **NON-COMPETITION AGREEMENT** ("Agreement") is made as of February 21, 2023 (the "Effective Date") by and between **FRESH TRACKS THERAPEUTICS, INC.,** f/k/a Brickell Biotech, Inc., the parent of Brickell Sub ("Brickell Parent") and **BRICKELL SUBSIDIARY, INC.,** d/b/a Brickell Biotech, Inc. ("Brickell Sub"), both being Delaware companies with a principal business address located at 5777 Central Avenue, Suite 102, Boulder, CO 80301 (Brickell Sub and, together with Brickell Parent and any predecessors of Brickell Sub or Brickell Parent, collectively referred to herein as the "Company"), and David R. McAvoy**,** an Indiana resident, with an address of [***] (the "Executive").

RECITALS:

WHEREAS, the Executive is employed by the Company;

WHEREAS, during the Executive's employment with the Company, the Executive has become acquainted with and will become acquainted with technical and nontechnical information which the Company has developed, acquired, and uses, and/or which the Company will develop, acquire, or use, and which is or will be commercially valuable and sensitive confidential and proprietary information to the Company and which the Company desires to protect, and the Executive may contribute to such information through inventions, discoveries, improvements or otherwise;

WHEREAS, contemporaneous with the Company and the Executive executing this Agreement, the Company and the Executive are executing an AMENDED AND RESTATED EMPLOYMENT AGREEMENT effective as of the same date as the Effective Date (the "Employment Agreement"); and

WHEREAS, the Executive executing this Agreement and agreeing to the terms of this Agreement is a condition to the Company agreeing to enter into the Employment Agreement and provide the Executive the consideration the Executive will receive pursuant to the Employment Agreement, and the Company would not enter into the Employment Agreement if the Executive did not agree to the terms of this Agreement.

NOW, THEREFORE, in consideration of the recitals, premises, and mutual covenants set forth herein, the parties agree as follows:

1. Non-Competition.

Except as stated otherwise herein, at all times while the Executive is employed by the Company and for a one (1) year period after the Termination Date, the Executive shall not engage in any Prohibited Capacity with or for a Competing Business within the Restricted Territory or have any material (greater than fifty percent (50%)) ownership or other property interest in any sole proprietorship, partnership, company, or business, or in any other person or entity (whether as a sole or partial owner, partner, security holder, creditor, or like capacity), that directly or indirectly through any affiliated entity engages in any Competing Business within the Restricted Territory; provided that such provision shall not apply to the Executive's ownership of Common Stock of the Company or the acquisition by the Executive, solely as an investment, of securities of any issuer that is registered under Section 12(b) or 12(g) of the Securities Exchange Act of 1934, as amended, and that are listed or admitted for trading on any United States national securities exchange, or that are quoted on the National Association of Securities Dealers Automated Quotations System, or any similar system or automated dissemination of quotations of securities prices in common use, so long as the Executive does not control, acquire a controlling interest in, or become a member of a group which exercises direct or indirect control or, more than five percent (5%) of any class of capital stock, of such Competing Business. Notwithstanding the foregoing, the post-employment restrictions included in this Agreement will not apply following any termination of the Executive's employment for reasons related to or caused by any liquidation, dissolution, winding-up, insolvency, entering receivership, and/or bankruptcy of the Company.

2. Definitions. For purposes of this Agreement, the following terms have the following meanings:

"Competing Business" means any person or entity that (i) engages in the commercialization of drugs utilizing the specific pharmaceutical compounds developed, licensed, and/or owned by the Company, (ii) develops, manufactures, produces, sells, distributes, or provides any Competing Product, or (iii) is competitive directly and then presently with the commercial products of the Company.

"Competing Product" means: (i) any product that is (or once developed would) directly compete with any of the products manufactured, supplied, offered, sold, or provided by the Company during the Executive's employment with the Company and as of the Termination Date; and/or (ii) any product that is (or once developed would) directly compete with any of the products that the Company had under research and development during the Executive's employment with the Company and as of the Termination Date; and, in the case of (i) and (ii), the product targets the same mechanism(s) of action and disease state indication(s) as these Company products.

"Prohibited Capacity" means: (i) the same capacity or function to that in which the Executive worked for the Company at any time during the then prior 12-month period (or, in the case of the post-employment restricted period, during the 12-month period immediately preceding the Termination Date); (ii) any executive or officer capacity or function; (iii) any business development capacity or function; (iv) any product development capacity or function; (v) any consulting or contractor capacity or function; and/or (vi) any capacity or function in which the customer goodwill the Executive helped to develop on behalf of the Company would facilitate or support the Executive's work for a Competing Business.

"Restricted Territory" means: (i) the United States, and (ii) any other country in which the Company manufactured, supplied, offered, sold, or provided products during the Executive's employment with the Company and as of the Termination Date.

"Termination Date" means the Executive's last day of employment (or engagement) with the Company for any reason and whether the termination of the Executive's employment (or engagement) with the Company is at the initiative of the Executive or the Company.

"Territories" means (i) American Samoa, (ii) the Commonwealth of the Northern Mariana Islands, (iii) the Commonwealth of Puerto Rico, (iv) Guam, (v) the United States Virgin Islands, and (vi) any other territory or possession of the United States.

"United States" means the United States of America, its Territories and possessions, any state of the United States, and the District of Columbia.

3. Acknowledgment by Executive.

(a) The Executive acknowledges and confirms, and in exchange for other consideration provided to the Executive herein and in the Employment Agreement, that (i) the restrictive covenants contained in **Section 1** are reasonably necessary to protect the legitimate business interests of the Company, including the Company's trade secrets, Confidential Information and goodwill, and (ii) the restrictions contained in **Section 1** (including without limitation the length of the term of the provisions of **Section 1**) are not overbroad, overlong, or unfair and are not the result of overreaching, duress, or coercion of any kind.

(b) The Executive further acknowledges and confirms that the Executive's full, uninhibited, and faithful observance of each of the covenants contained in **Section 1** will not cause the Executive any undue hardship, financial or otherwise, and that enforcement of each of the covenants contained herein will not impair the Executive's ability to obtain employment commensurate with the Executive's abilities and on terms fully acceptable to the Executive or otherwise to obtain income required for the comfortable support of the Executive and the Executive's family and the satisfaction of the needs of the Executive's creditors. The Executive acknowledges and confirms that the Executive's special knowledge of the business of the Company is such as would cause the Company serious injury or loss if the Executive were to use such ability and knowledge to the benefit of a competitor or were to compete with the Company in noncompliance with the terms of this Agreement. The Executive further acknowledges and confirms that the restrictions contained in this **Section 1** are intended to be, and shall be, for the benefit of, and shall be enforceable by, the Company's successors and assigns.

4. Reformation by Court.

Notwithstanding anything in **Section 11** (or otherwise in the Agreement) to the contrary, in the event that a court of competent jurisdiction shall determine that any provision of **Section 1** is invalid or more restrictive than permitted under the governing law of such jurisdiction, then only as to enforcement of this **Section 1** within the jurisdiction of such court, such provision shall be interpreted and enforced as if it provided for the maximum restriction permitted under such governing law.

5. Extension of Time.

If the Executive shall be in violation of any provision of **Section 1**, then each time limitation set forth in **Section 1** shall be extended for a period of time equal to the period of time during which such violation or violations occur. If the Company seeks injunctive relief from such violation in any court, then the covenants set forth in **Section 1** shall be extended for a period of time equal to the pendency of such proceeding including all appeals by the Executive.

6. Survival.

The provisions of **Section 1** shall survive the termination or expiration of this Agreement, as applicable.

7. Assignment.

This Agreement is personal in nature and accordingly may not be assigned by the Executive, in whole or in part, without the prior written consent of the Company, which may be withheld in the Company's sole discretion. The Company, in its sole discretion, may assign this Agreement and all of its rights, benefits, and obligations hereunder, whether by agreement or by operation of law, with written notice to Executive in accordance with the same notice requirements as specified in the Employment Agreement.

8. Governing Law.

This Agreement and any action related thereto shall be governed, controlled, interpreted, and defined by and construed in accordance with the laws of the State of Indiana, United States, without giving effect to any conflicts of laws principles that require the application of the law of a different state or jurisdiction.

9. Dispute Resolution and Venue.

Any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration in Boulder County, Colorado in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association then in effect (except to the extent that the procedures outlined below differ from such rules or the parties agree otherwise in writing). Within thirty (30) calendar days after written notice by either party has been given to the other party that a dispute exists and that arbitration is required, each party must select an arbitrator, notify the other party of that selection, and, then, those two arbitrators shall promptly, but in no event later than thirty (30) calendar days after their selection, select a third arbitrator. The parties agree to act as expeditiously as possible to select arbitrators and conclude the dispute. The selected arbitrators must render their decision in writing. The arbitral decisions shall be final, complete, and binding without appeal. The cost and expenses of the arbitration, reasonable attorneys' fees for the Executive and the Company, and of enforcement of any award in any court by either party shall be borne solely and exclusively by the Company. Judgment may be entered on the arbitrators' award in any court having jurisdiction. Although arbitration is contemplated to resolve disputes hereunder, either party may proceed to court to seek to obtain an injunction to enforce and protect its rights hereunder, the parties agreeing that either could suffer irreparable harm by reason of any breach of this Agreement. Pursuit of an injunction shall not impair arbitration on all remaining issues.

10. Entire Agreement.

This Agreement constitutes the entire agreement between the parties hereto with respect to the specific subject matter hereof and, upon its effectiveness, shall fully rescind, supersede, and replace all prior agreements, understandings, and arrangements, both oral and written, between the Executive and the Company with respect to such subject matter, including section 6.1 of the Prior Employment Agreement as defined by the Employment Agreement; provided, however, this Agreement is not intended to rescind, supersede, or replace, or otherwise affect the Employment Agreement, the Indemnification Agreement, the Equity Awards, or the CIAA (each as defined in the Employment Agreement), each of which shall remain in effect in accordance with its own terms. This Agreement may not be amended or altered in any way unless by a prior written instrument signed by both the Company and the Executive.

11. Severability.

Subject to the application of **Section 4**, the invalidity of any one or more of the words, phrases, sentences, clauses, or sections contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part thereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses, or sections contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, or section or sections had not been inserted. If such invalidity is caused by length of time or size of area, or both, the otherwise invalid provision will be considered to be reduced to a period or area which would cure such invalidity.

12. Waivers.

The waiver by either party hereto of a breach or violation of any term or provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or violation.

13. Damages.

Nothing contained herein shall be construed to prevent the Company or the Executive from seeking and recovering from the other damages sustained by either or both of them as a result of its or the Executive's material breach of any term or provision of this Agreement, subject to the dispute resolution provisions of the Agreement. In the event that either party hereto brings suit for the collection of any damages resulting from, or the injunction of any action constituting, a breach of any of the terms or provisions of this Agreement, then the non-prevailing party shall pay all reasonable court costs and reasonable attorneys' fees of the other.

14. Section Headings.

The section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the Effective Date first above written.

Company:	Executive:
FRESH TRACKS THERAPEUTICS, INC. A Delaware Company	
By: ______________________ Reginald Hardy, Board Chair	By: ______________________ David R. McAvoy, Individually
BRICKELL SUBSIDIARY, INC. A Delaware Company	
By: ______________________ Andrew Sklawer, President	

Exhibit D

Employee Confidentiality and Inventions Assignment Agreement

Exhibit E

Indemnification Agreement

FRESH TRACKS THERAPEUTICS, INC.

EMPLOYEE STOCK PURCHASE PLAN

1. ***Purpose of the Plan***. The purpose of this Fresh Tracks Therapeutics, Inc. Employee Stock Purchase Plan (the "Plan") is to provide the employees of Fresh Tracks Therapeutics, Inc. (the "Company") and its participating subsidiaries with a convenient means of purchasing shares of Company common stock from time to time at a discount to market prices through the use of payroll deductions. The Company intends that the Plan shall qualify as an "employee stock purchase plan" under Code § 423. Accordingly, the Plan will be construed so as to extend and limit Plan participation in any Offering subject to Code § 423 in a uniform and nondiscriminatory basis consistent with the requirements of Code § 423.

2. ***Definitions***. The terms defined in this section are used (and capitalized) elsewhere in this Plan.

2.1. "*Affiliate*" means each domestic or foreign entity that is a "parent corporation" or "subsidiary corporation" of the Company, as defined in Code §§ 424(e) and 424(f) or any successor provisions.

2.2. "*Board*" means the Board of Directors of the Company.

2.3. "*Code*" means the Internal Revenue Code of 1986, as amended and in effect from time to time. For purposes of the Plan, references to sections of the Code shall be deemed to include any applicable regulations thereunder and any successor or similar statutory provisions.

2.4. "*Committee*" means the Compensation Committee of the Board (or such successor committee responsible for executive compensation matters).

2.5. "*Common Stock*" means the common stock, par value $0.01 per share, of the Company.

2.6. "*Company*" means Fresh Tracks Therapeutics, Inc., a Delaware corporation, or any successor corporation.

2.7. "*Corporate Transaction*" means (i) a merger, consolidation or other reorganization of the Company with or into another corporation, or (ii) the sale of all or substantially all of the assets of the Company.

2.8. "*Designated Affiliate*" means any Affiliate which has been expressly designated by the Committee as a corporation whose Eligible Employees may participate in the Plan.

2.9. "*Eligible Compensation*" shall be defined from time to time by the Committee in its sole discretion with respect to any Offering and Purchase Period. Except as otherwise defined by the Committee from time to time in its sole discretion, (i) Eligible Compensation means the base salary amount paid by the Company or any Designated Affiliate to a Participant in accordance with the Participant's terms of employment, (ii) Eligible Compensation includes contributions made by the Participant by payroll deduction to any qualified cash or deferred arrangement that forms part of a plan maintained by the Company or an Affiliate (while it is an Affiliate), or to a cafeteria plan maintained by the Company or an Affiliate (while it is an Affiliate), or under any qualified transportation fringe benefit plan, and (iii) Eligible Compensation shall not include any commissions, overtime earnings, bonuses, employer contributions to a 401(k) or other retirement plan, amounts deferred to a non-qualified deferred compensation plan, any expense reimbursements or allowances, vacation pay in lieu of time off, coverage provided or amounts paid under any welfare benefit plan (unless provided above), amounts paid by an insurance company, amounts paid in a form other than cash and other fringe benefits, or any income (whether paid in Shares or cash) realized by the Participant as a result of participation in any equity-based compensation plan of the Company or an Affiliate.

2.10. "*Eligible Employee*" means any employee of the Company or a Designated Affiliate, except for any employee who, immediately after a right to purchase is granted under the Plan, would be deemed, for purposes of Code § 423(b)(3), to own stock possessing 5% or more of the total combined voting power or value of all classes of stock of the Company or any Affiliate. Notwithstanding the foregoing, with respect to any Offering, the Committee may provide for the exclusion of certain employees within the limitations described in Treasury Regulations §1.423-2(e)(1), (2) and (3).

2.11. "*Enrollment Period*" means the period of time prior to a Purchase Period during which Eligible Employees may elect to participate in the Plan as determined by the Committee for an Offering.

2.12. "*Fair Market Value*" of a Share of Common Stock as of any date means the closing sale price for a Share on the principal securities market on which the Shares trade on said date.

2.13. "*Offering*" means the right provided to Participants to purchase Shares under the Plan with respect to a Purchase Period.

2.14. "*Offering Date*" means the first Trading Day of a Purchase Period.

2.15. "*Participant*" means an Eligible Employee who has elected to participate in the Plan in the manner set forth in Section 4 and whose participation has not ended pursuant to Section 8.1 or Section 9.

2.16. "*Plan*" means this Fresh Tracks Therapeutics, Inc. Employee Stock Purchase Plan, as it may be amended from time to time.

2.17. "*Purchase Date*" means the last Trading Day of a Purchase Period.

2.18. "*Purchase Period*" means a period of time during which offers to purchase Common Stock are outstanding under the Plan. The Committee shall determine the length of each Purchase Period, which need not be uniform; provided that no Purchase Period shall exceed twenty-seven (27) months in length. A Purchase Period shall commence on such date as may be established by the Committee. Unless the Committee determines otherwise, the Purchase Period will be a period of six months beginning either (i) on January 1 of each calendar year and ending on the next June 30, or (ii) on July 1 in each calendar year and ending on the next December 31.

2.19. "*Recordkeeping Account*" means the account maintained in the books and records of the Company (or its agent) recording the amount contributed to the Plan by each Participant through payroll deductions.

2.20. "*Shares*" means shares of Common Stock.

2.21. "*Trading Day*" means a day on which the national stock exchanges in the United States are open for trading.

3. ***Shares Available***. Subject to adjustment as provided in Section 14.1, the maximum number of Shares that may be sold by the Company to Eligible Employees under the Plan shall be 57,777 Shares. If the purchases by all Participants in an Offering would otherwise cause the aggregate number of Shares to be sold under the Plan to exceed the number specified in this Section 3, the Company shall make to each Participant in that Offering a pro rata allocation in a uniform and nondiscriminatory manner of the remaining number of Shares which may be sold under the Plan.

4. ***Eligibility and Participation***. To be eligible to participate in the Plan for a given Purchase Period, an employee must be an Eligible Employee on the first day of such Purchase Period. An Eligible Employee may elect to participate in the Plan by filing an election form with the Company (or its agent) before the Offering Date for a Purchase Period that authorizes regular payroll deductions from Eligible Compensation beginning with the first payday in such Purchase Period and continuing until the Plan is terminated or the Eligible Employee withdraws from the Plan, modifies his or her authorization, or ceases to be an Eligible Employee, as hereinafter provided.

5. ***Amount of Common Stock Each Eligible Employee May Purchase***.

5.1. *Purchase Amounts and Limitations*. Subject to the provisions of this Plan, each Participant shall be offered the right to purchase on the Purchase Date the maximum number of whole Shares that can be purchased with the balance in the Participant's Recordkeeping Account at the per Share price specified in Section 5.2. Notwithstanding the foregoing, no Participant shall be entitled to:

(a) the right to purchase Shares under this Plan and all other employee stock purchase plans (within the meaning of Code § 423(b)), if any, of the Company and its Affiliates that accrues at a rate which in the aggregate exceeds $25,000 of Fair Market Value (determined on the Offering Date of a Purchase Period when the right is granted) for each calendar year in which such right is outstanding at any time; or

(b) purchase Shares in excess of 80,000 Shares per Offering (or such other maximum Share limit as established by the Committee in its sole discretion), with such limit subject to adjustment from time to time as provided in Section 14.1.

5.2. *Purchase Price*. Unless a different purchase price is established by the Committee for an Offering prior to the commencement of the applicable Purchase Period, the purchase price of each Share sold pursuant to this Plan will be the lesser of (i) 85% of the Fair Market Value of such Share on the Offering Date of the applicable Purchase Period, or (ii) 85% of the Fair Market Value of such Share on the Purchase Date (such lesser price, the “Purchase Price”). In no event shall the Purchase Price be less than the lesser of (i) 85% of the Fair Market Value of such Share on the Offering Date of the applicable Purchase Period, or (ii) 85% of the Fair Market Value of such Share on the Purchase Date.

6. ***Method of Participation***.

6.1. *Notice and Date of Grant*. The Company shall give notice to each Eligible Employee of the opportunity to purchase Shares pursuant to this Plan and the terms and conditions of such Offering. The Company contemplates that for tax purposes, the Offering Date for a Purchase Period will be considered the date of the grant of the right to purchase such Shares.

6.2. *Contribution Elections*. Each Eligible Employee who desires to participate in the Plan for a Purchase Period shall signify his or her election to do so by completing an election with the Company (or its agent) in a manner approved by the Committee. An Eligible Employee may elect to have any whole percent of Eligible Compensation (that is, 1%, 2%, 3%, etc.) withheld as a payroll deduction, but not exceeding 10% per pay period (or such other maximum percentage as the Committee may establish from time to time prior to the commencement of an Offering). An election to participate in the Plan and to authorize payroll deductions as described herein must be made prior to the Offering Date of a Purchase Period in accordance with the rules set by the Committee for the Purchase Period, and shall be effective beginning with the first payday in the Purchase Period immediately following the filing of such election. Any election submitted shall remain in effect until the Plan is terminated or such Participant withdraws from the Plan, modifies his or her authorization, or ceases to be an Eligible Employee, as hereinafter provided.

6.3 *Additional Contributions*. If specifically provided by the Committee in connection with an Offering (including for purposes of complying with applicable local law), in addition to or instead of making contributions by payroll deductions, a Participant may make additional contributions to his or her Recordkeeping Account through the payment by cash or check prior to a Purchase Date. A Participant may make such additional contributions into his or her Recordkeeping Account only if the Participant has not already had the maximum permitted amount withheld during the Offering through payroll deductions, subject to the limitations set forth in Section 5.1.

6.4. *Offering Terms and Conditions*. Each Offering shall consist of a single Purchase Period and shall be in such form and shall contain such terms and conditions as the Committee shall deem appropriate, consistent with the terms of the Plan. The Committee may provide for separate Offerings for different Designated Affiliates, and the terms and conditions of the separate Offerings, including the applicable Purchase Period, need not be consistent. Any Offering shall comply with the requirement of Code § 423 that all Participants shall have the same rights and privileges for such Offering. The terms and conditions of any Offering shall be incorporated by reference into the Plan and treated as part of the Plan.

7. ***Recordkeeping Accounts***.

7.1. *Crediting Payroll Deduction Contributions*. The Company (or its agent) shall maintain a Recordkeeping Account for each Participant. Payroll deductions pursuant to Section 6 will be credited to such Recordkeeping Accounts on or within a reasonable amount of time following each payday.

7.2. *No Interest Payable*. No interest will be credited to a Participant's Recordkeeping Account (unless required under local law).

7.3. *No Segregation of Accounts*. The Recordkeeping Account is established solely for accounting purposes, and all amounts credited to the Recordkeeping Account will remain part of the general assets of the Company and need not be segregated from other corporate funds (unless required under local law).

7.4. *Additional Contributions*. A Participant may not make any separate cash payment into a Recordkeeping Account, except as may be permitted in accordance with Section 6.3, and any such additional contributions will be credited to the Recordkeeping Accounts within a reasonable amount of time following receipt by the Company.

8. ***Right to Adjust Participation; Withdrawals from Recordkeeping Account***.

8.1. *Withdrawal from Plan*. A Participant may at any time withdraw from the Plan by complying with the rules set by the Committee. If a Participant withdraws from the Plan, the Company will pay to the Participant in cash the entire balance in such Participant's Recordkeeping Account and no further deductions will be made from the Participant's Eligible Compensation during such Purchase Period. A Participant who withdraws from the Plan will not be eligible to reenter the Plan until the next succeeding Purchase Period, and any such reentry shall be through the enrollment process described in Section 6.2.

8.2. *Adjusting Level of Participation*. A Participant may adjust his or her rate of payroll deduction contributions to the Plan as follows:

(a) A Participant may, by written notice during an Enrollment Period, direct the Company to increase or decrease his or her rate of payroll deduction contributions, with such change to be effective as of the first day of the next Purchase Period.

(b) A Participant may, by written notice that complies with the rules set by the Committee, direct the Company to decrease his or her rate of payroll deduction contributions during a Purchase Period to 0%, which shall be considered a suspension of contributions and shall become effective as soon as reasonably practicable. Any Participant who has decreased his or her rate of payroll deductions to 0% and does not increase such rate of payroll deductions from 0% to at least 1% in accordance with Section 8.2(a) during the next Enrollment Period will be withdrawn from the Plan effective as of the first day of that next Purchase Period.

8.3. *Submission of Notices*. Notification of a Participant's election to withdraw from the Plan as provided in Section 8.1 or to change his or her rate of payroll deductions as provided in Section 8.2 shall be made by completing an updated election or notice with the Company (or its agent) in a manner approved by the Committee. The Committee may promulgate rules regarding the time and manner for submitting any such updated election or notice, which may include a requirement that the election or notice be on file for a reasonable period before it will be effective.

8.4. *Adjustments by the Company*. To the extent necessary to comply with Code § 423(b)(8) or Section 5.1, a Participant's payroll deduction contributions to the Plan may be decreased by the Company to 0% at any time during a Purchase Period.

9. ***Termination of Employment***.

9.1. *Refund of Recordkeeping Account.* If the employment of a Participant is terminated for any reason, including death, disability, or retirement, the entire balance in the Participant's Recordkeeping Account will be refunded in cash to the Participant within 30 days after the date of termination of employment. For purposes of the Plan, a Participant will not be deemed to have terminated employment while the Participant is on sick leave, military leave or other leave of absence approved by the Company. Where the period of leave exceeds 90 days and the Participant's right to reemployment is not guaranteed either by statute or by contract, the employment relationship shall be deemed to have terminated on the ninety-first day of such leave. Unless determined otherwise by the Committee in a manner that is permitted by, and in compliance with Code § 423, a Participant whose employment transfers between entities through a termination with an immediate rehire (with no break in service) by the Company or a Designated Affiliate shall not be treated as a termination under the Plan.

9.2. *Designation of Beneficiary.* If permitted by the Committee, a Participant may file a beneficiary designation for who is to receive the Participant's Recordkeeping Account or Share subaccount, if any, following the death of a Participant. If no beneficiary is named, the beneficiary shall be the Participant's spouse, or if none, the Participant's estate. All beneficiary designations will be in such form and manner as the Committee may designate from time to time.

10. ***Purchase of Shares***.

10.1. *Number of Shares Purchased*. As of each Purchase Date, the balance in each Participant's Recordkeeping Account will be used to purchase the maximum number of whole Shares (subject to the limitations of Section 5.1) at the Purchase Price determined in accordance with Section 5.2, unless the Participant has filed an appropriate form with the Company in advance of that date to withdraw from the Plan in accordance with Section 8.1. Any amount remaining in a Participant's Recordkeeping Account that represents the Purchase Price for any fractional share will be carried over in the Participant's Recordkeeping Account to the next Purchase Period. Any amount remaining in a Participant's Recordkeeping Account that represents the Purchase Price for any whole Shares that could not be purchased by reason of the limitations of Section 5.1 or under the circumstances described in Section 3 will be refunded to the Participant.

10.2. *Conversion of Foreign Currency*. In circumstances where payroll deductions have been taken from a Participant's Eligible Compensation in a currency other than United States dollars, Shares shall be purchased by converting the balance in the Participant's Recordkeeping Account to United States dollars at the exchange rate in effect for payroll purposes for the month in which the Purchase Date occurs as determined by the Company's finance department or at such other exchange rate determined by the Committee or its delegate for this purpose, and such dollar amount shall be used to purchase Shares as of the Purchase Date.

10.3. *Crediting of Shares*. Promptly after the end of each Purchase Period, the number of Shares purchased by all Participants as of the applicable Purchase Date shall be issued and delivered to an agent selected by the Company. Delivery of the shares to the agent shall be effected by an appropriate book-entry in the stock register maintained by the Company's transfer agent or delivery of a certificate. The agent will hold the Shares for the benefit of all Participants who have purchased Shares and will maintain a Share subaccount for each Participant reflecting the number of Shares credited to each Participant. Each Participant will be entitled to direct the voting by the agent of all Shares credited to such Participant's Share subaccount, and the agent may reinvest any dividends paid on Shares credited to a Participant's Share subaccount in additional Shares in accordance with such rules as the Committee may prescribe. Each Participant may also direct the agent to sell any or all of the Shares credited to the Participant's Share subaccount and distribute the net proceeds of such sale to the Participant.

10.4 *Withdrawal of Shares from Share Subaccount*. Except for sales through the agent as provided in Section 10.3, a Participant may not withdraw Shares or otherwise transfer Shares from the Participant's Share subaccount.

11. ***Rights as a Shareholder***. A Participant shall not be entitled to any of the rights or privileges of a shareholder of the Company with respect to Shares offered for purchase under the Plan, including the right to vote or direct the voting or to receive any dividends that may be declared by the Company, until (i) the Participant actually has paid the Purchase Price for such Shares and (ii) such Shares have been issued and delivered, as provided in Section 10.3.

12. ***Rights Not Transferable***. A Participant's rights under this Plan are exercisable only by the Participant during his or her lifetime, and may not be sold, pledged, assigned, transferred or disposed of in any manner other than by will or the laws of descent and distribution. Any attempt to sell, pledge, assign, transfer or dispose of the same shall be void and without effect. The amounts credited to a Recordkeeping Account may not be sold, pledged, assigned, transferred or disposed of in any way, and any attempted sale, pledge, assignment, transfer or other disposition of such amounts will be void and without effect.

13. ***Administration of the Plan***.

13.1. *Authority of the Committee*. This Plan shall be administered by the Committee. Subject to the express provisions of the Plan and applicable law, and in addition to other express powers and authorizations conferred on the Committee by the Plan, the Committee shall have full power and authority to:

(a) Determine when each Purchase Period under this Plan shall occur, and the terms and conditions of each related Offering (which need not be identical);

(b) Designate from time to time which Affiliates of the Company shall be eligible to participate in the Plan;

(c) Construe and interpret the Plan and establish, amend and revoke rules, regulations and procedures for the administration of the Plan. The Committee may, in the exercise of this power, correct any defect, omission or inconsistency in the Plan, in such manner and to the extent it may deem necessary, desirable or appropriate to make the Plan fully effective;

(d) Exercise such powers and perform such acts as the Committee may deem necessary, desirable or appropriate to promote the best interests of the Company and its Designated Affiliates and to carry out the intent that the Offerings made under the Plan are treated as qualifying under Code § 423(b);

(e) As more fully described in Section 18, to adopt such rules, procedures and sub-plans as may be necessary, desirable or appropriate to permit participation in the Plan by employees who are foreign nationals or employed outside the United States by a non-U.S. Designated Affiliate, and to achieve tax, securities law and other compliance objectives in particular locations outside the United States; and

(f) Adopt and amend, as the Committee deems appropriate, a Plan rule specifying that Shares purchased by a Participant during a Purchase Period may not be sold by the Participant for a specified period of time after the Purchase Date on which the Shares were purchased by the Participant, and establish such procedures as the Committee may deem necessary to implement such rule.

13.2. *Interpretations and Decisions by the Committee*. Unless otherwise expressly provided in the Plan, all designations, determinations, interpretations, and other decisions under or with respect to the Plan shall be within the sole discretion of the Committee, may be made at any time and shall be final, conclusive, and binding upon all persons, including the Company, any Affiliate, any Participant and any Eligible Employee.

13.3. *Delegation by the Committee*. Subject to the terms of the Plan and applicable law, the Committee may delegate ministerial duties associated with the administration of the Plan to such of the Company's officers, employees or agents as the Committee may determine.

13.4. *Indemnification*. No member of the Board or Committee shall be liable for any action taken or determination made in good faith with respect to the Plan. In addition to such other rights of indemnification as they may have as members of the Board or officers or employees of the Company or a Designated Affiliate, members of the Board and Committee and any officers or employees of the Company or Designated Affiliate to whom authority to act for the Committee is delegated shall be indemnified by the Company from and against any and all liabilities, costs and expenses incurred by such persons as a result of any act or omission to act in connection with the performance of such person's duties, responsibilities and obligations under the Plan if such person has acted in good faith and in a manner that he or she reasonably believes to be in, or not opposed to, the best interests of the Company.

14. ***Changes in Capitalization and Corporate Transactions***.

14.1. *Adjustments*. In the event of any change in the Common Stock of the Company by reason of a stock dividend, stock split, reverse stock split, corporate separation, recapitalization, merger, consolidation, combination, exchange of shares and the like, the Committee shall make such equitable adjustments as it deems appropriate in the aggregate number and class of Shares or other securities available under this Plan, the Share limitation referred to in Section 5.1(b) of the Plan, and the number, class and Purchase Price of Shares or other securities subject to purchase under any pending Offering.

14.2. *Corporate Transactions*. In the event of a Corporate Transaction, each right to acquire Shares on any Purchase Date that is scheduled to occur after the date of the consummation of the Corporate Transaction may be continued or assumed or an equivalent right may be substituted by the surviving or successor corporation or a parent or subsidiary of such corporation. If such surviving or successor corporation or parent or subsidiary thereof refuses to continue, assume or substitute for such outstanding rights, then the Board may, in its discretion, either terminate the Plan or shorten the Purchase Period then in progress by setting a new Purchase Date for a specified date before the date of the consummation of the Corporate Transaction. Each Participant shall be notified in writing, prior to any new Purchase Date, that the Purchase Date for the existing Offering has been changed to the new Purchase Date and that the Participant's right to acquire Shares will be exercised automatically on the new Purchase Date unless prior to such date the Participant's employment has been terminated or the Participant has withdrawn from the Plan. In the event of a dissolution or liquidation of the Company, any Offering and Purchase Period then in progress will terminate immediately prior to the consummation of such action, unless otherwise provided by the Board.

15. ***Amendment or Suspension of Plan***. The Committee, in its sole discretion, may at any time suspend this Plan or amend it in any respect, but no such amendment may, without shareholder approval, increase the number of shares reserved under this Plan, or effect any other change in the Plan that would require shareholder approval under applicable law or regulations or the rules of any securities exchange on which the Shares may then be listed, or to maintain compliance with Code § 423. No such amendment or suspension shall adversely affect the rights of Participants pursuant to Shares previously acquired under the Plan. During any suspension of the Plan, no new Offering or Purchase Period shall begin and no Eligible Employee shall be offered any new right to purchase Shares under the Plan or any opportunity to elect to participate in the Plan, and any existing payroll deduction authorizations shall be suspended, but any such right to purchase Shares previously granted for a Purchase Period that began prior to the Plan suspension shall remain subject to the other provisions of this Plan and the discretion of the Board and the Committee with respect thereto.

16. ***Effective Date and Term of Plan****.* The Plan will become effective on the date it is approved by the shareholders of the Company, which approval must be within 12 months of the date the Plan is adopted by the Board. The Plan and all rights of Participants hereunder shall terminate (i) at any time, at the discretion of the Committee, or (ii) upon the completion of any Offering under which the limitation on the total number of Shares to be issued during the entire term of the Plan, as determined in accordance with Section 3, has been reached. Except as otherwise determined by the Board, upon termination of this Plan, the Company shall pay to each Participant cash in an amount equal to the entire remaining balance in such Participant's Recordkeeping Account.

17. ***Governmental Regulations and Listing****.* All rights granted or to be granted to Eligible Employees under this Plan are expressly subject to all applicable laws and regulations and to the approval of all governmental authorities required in connection with the authorization, issuance, sale or transfer of the Shares reserved for this Plan, including, without limitation, there being a current registration statement of the Company under the Securities Act of 1933, as amended, covering the Shares purchasable on the Purchase Date applicable to such Shares. If applicable, all such rights hereunder are also similarly subject to effectiveness of an appropriate listing application to a national securities exchange covering the Shares issuable under the Plan upon official notice of issuance.

18. ***Rules for Foreign Jurisdictions***. The Committee may adopt rules, procedures or subplans relating to the operation and administration of the Plan to accommodate the specific requirements of local laws and procedures. Without limiting the generality of the foregoing, the Committee is specifically authorized to adopt rules and procedures regarding handling of payroll deductions, payment of interest, conversion of local currency, payroll tax, the definition of Eligible Compensation, withholding procedures and handling of stock certificates that vary with local requirements.

19. ***Miscellaneous***.

19.1. *Effect on Employment Status*. This Plan shall not be deemed to constitute a contract of employment between the Company or any Designated Affiliate and any Participant, nor shall it interfere with the right of the Company (or any Affiliate) to terminate the employment of any Participant and treat him or her without regard to the effect that such treatment might have upon him or her under this Plan.

19.2. *Governing Law*. This Plan, and all agreements hereunder, shall be construed in accordance with and governed by the laws of the State of Delaware.

19.3. *Electronic Documentation and Signatures*. Any reference in the Plan to election or enrollment forms, notices, authorizations or any other document to be provided in writing shall include the provision of any such form, notice, authorization or document by electronic means, including through the Company's intranet or with the Company's agent, and any reference in the Plan to the signing of any document shall include the authentication of any such document provided in electronic form, in each case in accordance with procedures established by the Committee.

19.4. *Book-Entry and Electronic Transfer of Shares.* Any reference in this Plan to the issuance or transfer of a stock certificate evidencing Shares shall be deemed to include, in the Committee's discretion, the issuance or transfer of such Shares in book-entry or electronic form. Uncertificated Shares shall be deemed delivered for all purposes of this Plan when the Company or its agent shall have provided to the recipient of the Shares a notice of issuance or transfer by electronic mail (with proof of receipt) or by United States mail, and have recorded the issuance or transfer in its records.

19.5. *Registration of Share Accounts and Certificates.* Any Share account contemplated by Section 10.3 and certificate to be issued to a Participant shall be registered in the name of the Participant, or jointly in the name of the Participant and another person, as the Participant may direct on an appropriate form filed with the Company or the agent.

19.6. *Code § 409A*. The Plan is exempt from the application of Code § 409A and any ambiguities herein will be interpreted to so be exempt from Code § 409A. In furtherance of the foregoing and notwithstanding any provision in the Plan to the contrary, if the Committee determines that an option granted under the Plan may be subject to Code § 409A or that any provision in the Plan would cause an option under the Plan to be subject to Code § 409A, the Committee may amend the terms of the Plan and/or of an outstanding Offering under the Plan, or take such other action as the Committee determines is necessary or appropriate, in each case, without the Participant's consent, to exempt any outstanding option or future option that may be granted under the Plan from or to allow any such options to comply with Code § 409A, but only to the extent any such amendments or actions by the Committee would not violate Code § 409A. Notwithstanding the foregoing, the Company and the Committee shall have no liability to a Participant or any other party if the option to purchase Shares under the Plan that is intended to be exempt from or compliant with Code § 409A is not exempt or compliant or for any action taken by the Committee with respect thereto. The Company makes no representations that the option to purchase Shares under the Plan is compliant with Code § 409A.

19.7. *Severability*. If any provision of the Plan is or becomes or is deemed to be invalid, illegal, or unenforceable for any reason in any jurisdiction or as to any Participant, such invalidity, illegality or unenforceability shall not affect the remaining parts of the Plan and the Plan shall be construed and enforced as to such jurisdiction or Participant as if the invalid, illegal or unenforceable provision had not been included.

Exhibit 21.1

Subsidiaries of the Registrant
(as of March 30, 2023)

Name of Subsidiary	Jurisdiction of Incorporation
Brickell Subsidiary, Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-60293) pertaining to the Stock Incentive Plan of Vical Incorporated,
(2) Registration Statement (Form S-8 No. 333-80681) pertaining to the Stock Incentive Plan of Vical Incorporated,
(3) Registration Statement (Form S-8 No. 333-66254) pertaining to the Stock Incentive Plan of Vical Incorporated,
(4) Registration Statement (Form S-8 No. 333-97019) pertaining to the Stock Incentive Plan of Vical Incorporated,
(5) Registration Statement (Form S-8 No. 333-107581) pertaining to the Stock Incentive Plan of Vical Incorporated,
(6) Registration Statement (Form S-8 No. 333-116951) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
(7) Registration Statement (Form S-8 No. 333-135266) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
(8) Registration Statement (Form S-8 No. 333-143885) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
(9) Registration Statement (Form S-8 No. 333-169344) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
(10) Registration Statement (Form S-8 No. 333-183215) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
(11) Registration Statement (Form S-8 No. 333-190343) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
(12) Registration Statement (Form S-8 No. 333-213034) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
(13) Registration Statement (Form S-8 No. 333-219804) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
(14) Registration Statement (Form S-8 No. 333-233698) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated and the Equity Incentive Plan of Brickell Biotech, Inc.,
(15) Registration Statement (Form S-3 No. 333-236757) of Brickell Biotech, Inc.,
(16) Registration Statement (Form S-3 No. 333-236353) of Brickell Biotech, Inc.,
(17) Registration Statement (Form S-1 No. 333-237568) of Brickell Biotech, Inc.,
(18) Registration Statement (Form S-8 No. 333-237859) pertaining to the 2020 Omnibus Long-Term Incentive Plan of Brickell Biotech, Inc., the Equity Incentive Plan of Brickell Biotech, Inc., and the Amended and Restated Stock Incentive Plan of Vical Incorporated,
(19) Registration Statement (Form S-1 No. 333-238298) of Brickell Biotech, Inc.,
(20) Registration Statement (Form S-8 No. 333-248688) pertaining to the 2020 Omnibus Long-Term Incentive Plan of Brickell Biotech, Inc.,
(21) Registration Statement (Form S-1 No. 333-249441) of Brickell Biotech, Inc.,
(22) Registration Statement (Form S-3 No. 333-254037) of Brickell Biotech, Inc.,
(23) Registration Statement (Form S-8 No. 333-256113) pertaining to the 2020 Omnibus Long-Term Incentive Plan of Fresh Tracks Therapeutics, Inc.,
(24) Registration Statement (Form S-8 No. 333-256114) pertaining to the Employee Stock Purchase Plan of Fresh Tracks Therapeutics, Inc.,
(25) Registration Statement (Form S-8 No. 333-265183 pertaining to the 2020 Omnibus Long-Term Incentive Plan of Brickell Biotech, Inc.,
(25) Registration Statement (Form S-8 No. 333-237859 pertaining to the 2020 Omnibus Long-Term Incentive Plan of Brickell Biotech, Inc.,
(26) Registration Statement (Form S-8 No. 333-233698) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated and the Equity Incentive Plan of Brickell Biotech, Inc., and
(27) Registration Statement (Form S-1 No. 333-267254) of Brickell Biotech, Inc.

of our report dated March 30, 2023, with respect to the consolidated financial statements of Fresh Tracks Therapeutics, Inc., included in this Annual Report (Form 10-K) of Fresh Tracks Therapeutics, Inc. for the year ended December 31, 2022.

/s/ Ernst & Young LLP

Denver, Colorado
March 30, 2023

Exhibit 31.1

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Andrew D. Sklawer, certify that:

1. I have reviewed this Annual Report on Form 10-K of Fresh Tracks Therapeutics, Inc., a Delaware corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2023

By: /s/ Andrew D. Sklawer
Andrew D. Sklawer
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Albert N. Marchio, II, certify that:

1. I have reviewed this Annual Report on Form 10-K of Fresh Tracks Therapeutics, Inc., a Delaware corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2023

By: /s/ Albert N. Marchio, II
Albert N. Marchio, II
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

SECTION 1350 CERTIFICATION

Each of the undersigned, Andrew D. Sklawer, Chief Executive Officer of Fresh Tracks Therapeutics, Inc., a Delaware corporation (the "Company"), and Albert N. Marchio, II, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge (1) the Annual Report on Form 10-K of the Company for the annual period ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Andrew D. Sklawer
Andrew D. Sklawer
Chief Executive Officer
(Principal Executive Officer)
Date: March 30, 2023

/s/ Albert N. Marchio, II
Albert N. Marchio, II
Chief Financial Officer
(Principal Financial Officer)
Date: March 30, 2023

This certification accompanies and is being "furnished" with this Report, shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.