Risk Factors Comparison 2024-03-15 to 2023-03-30 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

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. **On September 19, 2023, we announced the Plan of Dissolution and our intent to discontinue all clinical and preclinical development programs and reduce our workforce. In connection with the Plan of Dissolution, effective October 2, 2023, we discontinued all clinical and preclinical development programs and terminated most of our employees, except for certain employees, consultants, and advisors who will supervise or facilitate the dissolution and wind down of the Company. We held special meetings of stockholders on November 16, 2023, November 30, 2023, December 15, 2023, December 27, 2023, and February 15, 2024 (the " Special Meetings ") to seek stockholder approval of the Dissolution and the Plan of Dissolution. However, the Dissolution and Plan of Dissolution did not receive the affirmative vote of a majority of the outstanding shares of our common stock entitled to vote at the Special Meetings, and as a result, we intend to continue to seek approval to dissolve and distribute all remaining cash to stockholders over time. The following risks are related to the Dissolution:** • We ~~will need~~ **cannot assure you as** to **the timing, amount,** ~~raise substantial additional financing to fund our~~ **or** ~~operations~~ **number of distributions** , ~~including~~ **if any,** to ~~continue developing~~ **be made to our stockholders. • The Board of Directors (" Board ") may determine not to proceed with the Dissolution,** ~~our~~ **or** ~~lead development- stage program and~~ the **Company** ~~rest of our pipeline, which financing~~ may not ~~be available~~ **obtain the necessary approval** to **effect the Dissolution** ~~us on favorable terms or at all~~ . • Our **stockholders may be liable to third parties** ~~business depends on the successful continued financing, nonclinical and clinical development, regulatory approval, and commercialization of our pipeline assets. • Clinical drug development~~ for **part** ~~our~~ **or all of the amount received** ~~pipeline assets is expensive, time- consuming, and uncertain. Any data resulting~~ from **us in** our **liquidating distributions if cash reserves are inadequate** ~~trials may not be favorable for further development~~ . • Our **stockholders** ~~inability to regain and maintain compliance with continued listing requirements~~ of **record** ~~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 **buy** ~~obtain, afford, maintain, enforce, or protect our~~ **or sell shares** ~~intellectual property rights covering our product candidates and related technologies, that are~~ of **our common stock after** ~~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~~ **close** ~~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~~ **our** ~~technology, or~~ **stock transfer books at** ~~other~~ -- **the** ~~key aspects~~ **effective time** of ~~product development and / or commercialization, or increase our financial or other~~ -- **the Dissolution** ~~obligations to our licensors. • Our receipt of future payments from Botanix SB Inc.~~ (**the** " ~~Botanix~~ **Effective Time** ") ~~is contingent on various factors outside of our control, including~~ **. • We plan to initiate steps soon to exit from certain reporting requirements under** the **Securities Exchange Act** ~~successful development, regulatory approval, and commercialization~~ of **1934** ~~sofpironium bromide gel~~ , **as amended** ~~15 %, by Botanix outside of Japan, the successful continued commercialization of sofpironium bromide gel, 5 %~~ (**the** " ~~ECCLOCK ®~~ **Exchange Act** ") ~~by Kaken Pharmaceutical Co.~~ , **which may substantially reduce publicly available information about** ~~Ltd. (" Kaken ") in Japan, and the sufficiency of funds to pay~~ us ~~and Bodor Laboratories, Inc~~ . **If** ~~(" Bodor "),~~ the ~~licensor~~ **exit process is protracted, we will continue to bear the expense** of ~~this product~~ **being a public reporting company despite having no source of revenue. • The loss of key personnel could adversely affect our ability to efficiently dissolve, liquidate, and wind down** . 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~~ **On September 19, 2023, we announced the Plan of Dissolution and our intent to discontinue all clinical and preclinical development programs and reduce our workforce. Historically, we were** a clinical- stage pharmaceutical company striving to transform patient lives through the development of innovative and differentiated prescription therapeutics. Our pipeline ~~aims~~ **aimed** to disrupt existing treatment paradigms and ~~features~~ **featured** several new chemical entities that inhibit novel targets with first- in- class potential for autoimmune, inflammatory, and other debilitating diseases. Our **Board and** executive management team **conducted** ~~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 **alternatives with** ~~options to progress the development of our novel pipeline of potential treatments for autoimmune, inflammatory, and other~~ -- **the** ~~diseases~~ **goal of maximizing stockholder value** . Potential **alternatives that were under evaluation** ~~strategic options to be explored or evaluated as part of this process may include~~ **included** , but ~~are~~ **were** not limited to, a financing, **a merger or reverse merger, the** sale **of all** or **part of the Company,** licensing of assets, **a** ~~acquisition, merger,~~ business combination, and / or other strategic ~~transaction~~ **transactions** or series of related transactions involving ~~our~~ **the** Company. ~~MTS Health~~ **On September 18, 2023, after conducting an extensive, months- long potential strategic alternatives process, including four unsuccessful attempts to find a merger or reverse merger** ~~Partners~~ **partner due to the potential acquirer' s inability to secure its own necessary financing and / or inability to offer adequate value to consummate the transaction** , ~~LP has been retained~~ **and combined with the unsuccessful outreach to approximately 125 other possible counterparties and investors who operate or invest in both life sciences and other industry sectors, our Board unanimously approved the Dissolution and the Plan of Dissolution, subject to the approval of our stockholders. In connection with the Plan of Dissolution, effective October 2, 2023, we discontinued all clinical and preclinical development programs and terminated most of our employees, except for certain employees, consultants, and advisors who will supervise or facilitate the dissolution and wind down of the Company. We held Special Meetings on November 16, 2023, November 30, 2023, December 15, 2023, December 27, 2023, and February 15, 2024 to seek stockholder approval of the Dissolution and the Plan of Dissolution. However, the Dissolution and Plan of Dissolution did not receive the affirmative vote of a majority of the outstanding shares of our common stock entitled to vote at the Special Meetings, and** as ~~our exclusive financial advisor~~ **a result, we intend** to ~~assist in~~

this review process **continue to seek approval to dissolve and distribute all remaining cash to stockholders over time** . **Research and Development Assets** The following image summarizes our current pipeline **or previous research** and **development assets,** corresponding **stage of** development **, and potential therapeutic areas for each** programs **program** : Research & Development Programs FRTX- 02: A Potential First- in- Class Oral DYRK1A Inhibitor for the Treatment of Autoimmune and Inflammatory Diseases FRTX- 02 , **is** 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 **was** 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 **and clinical** models, including of **potentially for** 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 TH17 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 **FRTX- 10 is** In February 2022, we acquired exclusive, worldwide rights to research, develop, and **an early** 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 **and** , is a novel, potent, and orally bioavailable covalent STING inhibitor that specifically targets the palmitoylation site of STING. **STING is a well** This allows it to inhibit both wild - **known mediator** type STING and gain- of **innate immune responses. Excessive** - function mutants without competing with cGAMP binding, thus deactivating downstream signaling through IRF3 **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 IκBα and ultimately suppressing inflammation **could have orphan drug potential** . **Effective March 1, 2024, the license to develop** 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 **was terminated by mutual agreement** 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 **We have** ~~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. **Intellectual Property 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. Under the terms of the Voronoi License Agreement, the Company is responsible for the development and commercialization activities, including the first right to prosecute and maintain patents, related to all the licensed compounds. 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.** 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~~ **being managed directly by our licensor.** The **Company continues** ~~Phase 1 clinical trial of FRTX- 02 is a two-~~ **to** ~~- 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 ---- **assess prosecution deadlines** , 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 -- **the licensed** ~~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~~ **patents** ~~portfolio of product candidates that are safer~~ and **has so far elected** ~~/ or more effective than competing products. Intellectual Property Our success depends in large part upon our ability~~ to ~~secure proprietary~~ **transfer the** ~~protection~~ **prosecution** ~~for our products and technologies~~ , **maintenance** ~~including those in development~~ , and **costs** ~~to operate without infringing the proprietary rights~~ of ~~others~~ **managing such patents directly to our licensor** . 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 **any of** 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~~ **License** and ~~development~~ **Development** ~~agreement~~ **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 **the first right to prosecute and maintain** ~~patenting~~ **patents** , related to all the licensed compounds. **As of** ~~During the years ended~~ December 31, ~~2022~~ **2023** ~~and 2021~~ and through the date of this Annual Report, we ~~did~~ **have** not **yet** ~~make~~ **made** 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 **. The Voronoi License Agreement also provides that upon termination of the Voronoi License Agreement, Voronoi will be entitled to receive a non- exclusive license to any information and know- how independently developed by the Company for FRTX- 02 and other licensed assets in consideration for payment (s) at an arms'- length royalty rate on net sales that must be negotiated in good faith between the parties** . Exclusive License and Development Agreement with Carna In February 2022, we entered into an ~~exclusive~~ **Exclusive** ~~license~~ **License** ~~agreement~~ **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~~ **provided** that we ~~will~~ **would** 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~~ **provided** that we ~~will~~ **would** 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~~ **were** responsible for ~~, and bear the future costs of,~~ all development and commercialization activities, including patenting, related to all the licensed compounds. **As of** ~~During the years ended~~ December 31, ~~2022~~ **2023** ~~and 2021~~ and through the date of this Annual Report, we ~~did~~ **have** not ~~make~~ **made** 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 **. Effective March 1, 2024, the Carna License Agreement was terminated by mutual 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 **SB, Inc.** and Botanix Pharmaceuticals Limited **(" 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 us or Brickell Subsidiary (the " Assets "). Prior to the sale of the Assets, we had previously entered into a License Agreement with Bodor **Laboratories, Inc. (" 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 **became** ~~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 **Pharmaceutical Co., Ltd. (“ 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 **sofpironium bromide gel, 5 % (“** 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 **. On July 21, 2023, we and Brickell Subsidiary entered into Amendment No. 1 to the Asset Purchase Agreement (the “ Asset Purchase Agreement Amendment ”) with Botanix. The Asset Purchase Agreement Amendment provided that, in lieu of any remaining amounts potentially payable by Botanix to us pursuant to the Asset Purchase Agreement (collectively, the “ Post- Closing Payment Obligations ”), Botanix would pay $ 6. 6 million to us and $ 1. 7 million on behalf of us to Bodor. The payments from Botanix to the Company and Bodor were made on July 26, 2023. The Asset Purchase Agreement Amendment also provided that upon payment of the amounts by Botanix thereunder, all Post- Closing Payment Obligations under the Asset Purchase Agreement were terminated and of no further force or effect** . 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 **U. S. Food and Drug Administration (“** FDA **”)** in December 2022 of the filing of ~~an~~ **a new drug application (“** NDA **”)** for sofpironium bromide gel, 15 %, and (iv) ~~will~~ **would have been eligible to** receive **, prior to the Asset Purchase Agreement Amendment,** a contingent milestone payment of $ 4. 0 million if marketing approval in the U. S. for sofpironium bromide gel, 15 %, ~~is~~ **had been** received on or before September 30, 2023, or $ 2. 5 million if such marketing approval ~~is~~ **had been** 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 **for filing** by the FDA in December 2022. Under the Asset Purchase Agreement, we also ~~are~~ **would have been** eligible to receive **, prior to the Asset Purchase Agreement Amendment,** additional success- based regulatory and sales milestone payments of up to $ 168. 0 million. Further, we ~~will~~ **would have been eligible to** receive **, prior to the Asset Purchase Agreement Amendment,** 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~~ **provided** that Botanix ~~will~~ **would** pay ~~to~~ us a portion of the sales- based milestone payments and royalties that Botanix ~~receives~~ **received** from Kaken under the assigned Kaken Agreement (together, the “ Sublicense Income ”). Sublicense Income ~~represents~~ **represented** our estimate of payments that ~~will~~ **would** be earned by us in the applicable period from sales- based milestone payments and royalties Botanix ~~will~~ **would** receive from Kaken to the extent it ~~is~~ **was** probable that a significant reversal in the amount of cumulative revenue recognized ~~will~~ **would** 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~~ **was** contingent upon certain regulatory approvals and future sales subsequent to such regulatory approvals, or ~~is~~ **was** based upon future sales that we determined ~~are~~ **were** 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~~ **would** not be resolved for an extended period of time. Therefore, we determined that such variable consideration amounts ~~are~~ **were** fully constrained ~~as~~ **up through the date** of ~~December 31, 2022~~ **the Asset Purchase Agreement Amendment** , 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~~ **provide** 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. **As of the date of this Annual Report, we do not expect to provide any further services or receive any additional fees related to the TSA.** Contract Revenue under the Botanix Agreements During the year ended December 31, ~~2022~~ **2023** , we recorded contract revenue of $ **8** ~~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~~ **included** 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~~ **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. In connection with the Asset Purchase Agreement Amendment, on July 21, 2023, we, Brickell Subsidiary, and Bodor entered into a Second Amendment to Rights Agreement (the " RA Amendment "). The RA Amendment provides that in exchange for the one- time payment of $ 1. 7 million by Botanix on behalf of us to Bodor, we shall have no further payment obligations to Bodor under or in connection with the Rights Agreement or the Amended and Restated License Agreement. Except as explicitly amended by the RA Amendment, the Rights Agreement remains in full force and effect.** During the year ended December 31, ~~2022~~ **2023** , **we incurred** $ 1. ~~9~~ **7** million **of** ~~was incurred and reported as~~ general and administrative expenses ~~in the consolidated statements of operations~~ associated with **payments due** ~~achieved milestones related~~ to **Bodor** ~~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~~ **Because we discontinued all clinical and preclinical development programs in October 2023, we** currently **do not have any** ~~contract~~ **contracts** 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 **Although our operations** ~~FDA Drug Approval Process In the U. S., prescription human drugs~~ are **currently focused on winding down our operations in connection with our anticipated Dissolution, we remain** subject to **numerous** ~~extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act and other~~ federal ~~and~~ **,** state ~~statutes~~ **and local laws** 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 **securities** ~~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~~ , **tax** ~~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- **bribery** ~~kickbacks. States often impose strict legal requirements and prohibitions on a variety of post- approval drug marketing practices. We may market drugs holding an~~ **and privacy** ~~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 moiecule 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~~ **and** ~~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~~ **2023** , we had ~~13~~ **four** full- time employees **. In October 2023** , **we discontinued all clinical** ~~of which six were dedicated to research~~ and **preclinical** development **programs and terminated most** ~~activities. From time to time, we retain independent contractors. None~~ of our employees **, except** ~~is represented by a labor union or~~ **for certain** ~~covered by a collective bargaining agreement. We have not experienced any work stoppages, and we consider our relations with our~~ employees ~~to be excellent~~ **, consultants, and advisors who will supervise or facilitate the dissolution and wind down of the Company** . 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 **maintain our**

corporate offices at ~~occupy facilities totaling approximately 3, 000~~ **2000** ~~square feet~~ **Central Avenue, Suite 100, Boulder, CO 80301** under a **virtual office** lease **. We lease our corporate office premises under a monthly rental** agreement **at a nominal cost** ~~that expires in December 2025 and provides us an early termination option~~ . We ~~use~~ **consider** our current ~~facilities primarily~~ **office space adequate** for **our current operations** ~~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 TM 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. NameAgeTitleAndrew D. Sklawer39President and Chief Executive OfficerAlbert N. Marchio, II70Chief Financial OfficerDeepak Chadha53Chief Research and Development Officer and Chief Operating OfficerDavid McAvoy60General 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 ®, Bioenteries ®, 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 **the Dissolution We cannot predict the timing of the distributions, if any, to stockholders. We held Special Meetings on November 16, 2023, November 30, 2023, December 15, 2023, December 27, 2023, and February 15, 2024 to seek stockholder approval of the Dissolution and the Plan of Dissolution. However, the Dissolution and Plan of Dissolution did not receive the affirmative vote of a majority of the outstanding shares of our common stock entitled to vote at the Special Meetings, and as a result, we intend to continue to seek approval to dissolve and distribute all remaining cash to stockholders over time. The Board retains the discretion to determine not to proceed with the Dissolution in its sole discretion and, if it does proceed with the Dissolution, would have discretion as to the timing of the filing of the Certificate of Dissolution. However, if the Board determines that the Dissolution is not in our best interest or in the best interest of our stockholders, the Board may, in its sole discretion, abandon the Dissolution or may amend or modify the Plan of Dissolution to the extent permitted by the Delaware General Corporation Law (the " DGCL ") without the necessity of stockholder approval. After the Certificate of Dissolution has been filed, revocation of the Dissolution would require stockholder approval under the DGCL. Under Delaware law, utilizing the procedures of Section 281 (b) of the DGCL (which is contemplated by the Plan of Dissolution unless otherwise determined by the Board), before a dissolved corporation may make any distribution to its stockholders, it must: (i) pay or make reasonable provision to pay all of its claims and obligations, including all contingent, conditional or unmatured contractual claims known to the corporation, (ii) make such provision as will be reasonably likely to be sufficient to provide compensation for any claim against it which is the subject of a pending action, suit or proceeding to which it is a party, and (iii) make such provision as will be reasonably likely to be sufficient to provide compensation for claims that have not been made known to the corporation or that have not arisen but that, based on facts known to the corporation, are likely to arise or to become known to the corporation within ten years after the date it dissolves. Among other things, our potential liabilities that may require provision could include those relating to indemnification obligations, if any, to third parties or to our current and former officers and directors, and to resolve any stockholder or other litigation that may emerge. It might take significant time to resolve these matters, and as a result we are unable to predict the timing, amount, or number of distributions, if any are made, to our stockholders. We cannot predict with certainty the timing, amount, or number of distributions, if any, to our stockholders. Any such amounts may be paid in one or more distributions over a period of several years. Any such distributions will not occur until after the Certificate of Dissolution is filed, and we cannot predict the timing, amount, or number of any such distributions, or whether any such distributions will occur, as uncertainties as to the ultimate amount and scope of our liabilities, the operating costs and amounts to be set aside for claims, obligations, and provisions during the liquidation and winding- up process, and the related timing to complete such transactions, make it impossible to predict with certainty the actual net cash amount, if any, that will ultimately be available for distribution to stockholders or the timing of any such distributions. Examples of uncertainties that could reduce the value of distributions to our stockholders include: the incurrence by the Company of expenses relating to the Dissolution being different than estimated; the receipt of no, or lower than expected, proceeds in the course of our efforts to monetize our remaining assets and intellectual property; unanticipated costs relating to the defense, satisfaction or settlement of lawsuits or other claims that may be threatened against us or our current or former directors or officers; amounts necessary to resolve claims of any creditors or other third parties; and delays in the Dissolution or other winding- up process. In addition, as we wind down, we will continue to incur expenses from operations, including directors' and officers' insurance, severance payments, payments to service providers and any continuing employees or consultants, taxes, legal, accounting and consulting fees, costs associated with patent prosecution and transitioning this responsibility back to our licensors, expenses related to our filing obligations with the SEC and / or others, and costs associated with continuing to seek approval to dissolve, which will reduce any amounts available for distribution to our stockholders. As a result, we cannot assure you as to any amounts, if any, to be distributed to our stockholders if the Board proceeds with the Dissolution. Because our stockholders did not approve the Dissolution and the Plan of Dissolution, we are not currently able to proceed with the Dissolution and no liquidating distributions will be made in connection therewith, until and unless the Company is able to obtain stockholder or judicial approval to dissolve the Company. It is the current intent of the Board, assuming approval of the Dissolution, that any cash will first be used to pay our outstanding current liabilities and obligations, and then will be retained to pay ongoing corporate and administrative costs and expenses associated with winding down the Company, liabilities and potential liabilities relating to or arising out of any litigation matters and potential liabilities relating to our indemnification obligations, if any, to our service providers, or to our current and former officers and directors, before such cash, if any remains, will be available for distribution to stockholders. The Board will determine, in its sole discretion, the timing and number of the distributions of the remaining amounts, if any, to our stockholders in the Dissolution. We can provide no assurance as to if or when any such distributions will be made, and we cannot provide any assurance as to the amount to be paid to stockholders in any such distributions, if any are to be made. Stockholders may receive substantially less than the amount that we currently estimate that they may receive, or they may receive no distribution at all. The Board may determine not to proceed with the Dissolution. The Board may determine in its sole discretion not to proceed with the Dissolution, especially if some other alternative emerges, which we do not expect, that would provide greater value to the stockholders than Dissolution and the Plan of Dissolution. If our**

Board elects to pursue any alternative to the Plan of Dissolution, our stockholders may not receive any of the funds that might otherwise have been available now or in the future for distribution to our stockholders. After the Certificate of Dissolution has been filed, revocation of the Dissolution would require stockholder approval under the DGCL. If the Dissolution becomes effective, we are required to establish a cash reserve designed to satisfy any additional claims and obligations that may arise. Any reserve may not be adequate to cover all of our claims and obligations. Under the DGCL, if we fail to create an adequate reserve for payment of our expenses, claims, and obligations, each stockholder could be held liable for payment to our creditors for claims brought prior to or after the Effective Time (or such longer period as the Delaware Court of Chancery may direct) (the " Survival Period ") (or, if we choose the Safe Harbor Procedures under DGCL Section 280 and 281 (a), for claims brought prior to the expiration of the Survival Period), up to the lesser of (i) such stockholder' s pro rata share of amounts owed to creditors in excess of the reserve and (ii) the amounts previously received by such stockholder in the Dissolution from us and from any liquidating trust or trusts. Accordingly, in such event, a stockholder could be required to return part or all of the distributions previously made to such stockholder, and a stockholder could ultimately receive nothing from us under the Plan of Dissolution. Moreover, if a stockholder has paid taxes on amounts previously received, a repayment of all or a portion of such amount could result in a situation in which a stockholder may incur a net tax cost if the repayment of the amount previously distributed does not cause a commensurate reduction in taxes payable in an amount equal to the amount of the taxes paid on amounts previously distributed. Our ~~Business~~ **stockholders of record will not be able to buy or sell shares of our common stock after we close our stock transfer books at the Effective Time of the Dissolution. If the Board determines to proceed with the Dissolution, we intend to close our stock transfer books and discontinue recording transfers of our common stock at the Effective Time of the Dissolution. After we close our stock transfer books, we will not record any further transfers of our common stock on our books except at our sole discretion by will, intestate succession, or** ~~Operations~~ **operation** ~~The successful development, regulatory approval, and commercialization~~ of **law. Therefore, shares of our common stock will not be freely transferable after the Effective Time. As a result of the closing of the stock transfer books, all liquidating distributions in the Dissolution will likely be made to the same stockholders of record as the stockholders of record as of the Effective Time. We plan to initiate steps to exit from certain reporting requirements under the Exchange Act, which may substantially reduce publicly available information about us. If the exit process is protracted, we will continue to bear the expense of being a public reporting company despite having no source of revenue. Our common stock is currently registered under the Exchange Act, which requires that we, and our officers and director with respect to Section 16 of the Exchange Act, comply with certain public reporting and proxy statement requirements thereunder. Compliance with these requirements is costly and time- consuming. We plan to initiate steps to exit from such reporting requirements in order to curtail expenses; however, such process may be protracted and we may be required to file Current Reports on Form 8- K** ~~our~~ **or** ~~pipeline~~ **other reports to disclose material events, including those related to the Dissolution. Accordingly, we will continue to incur expenses that will reduce any amount available for distribution, including expenses of complying with public company reporting requirements and paying our service providers, among others. If our reporting obligations cease, publicly available information about us will be substantially reduced. We intend to rely on a few individuals in key management roles and as contractor support to dissolve, liquidate our remaining** assets **, and wind- down operations, which** will ~~require significant additional financing and depend~~ **continue for at least three years during the Survival Period. Loss of** ~~on~~ **one** ~~a number~~ **or more** of ~~factors~~ **these key individuals, or inability to contract with essential personnel, could hamper the efficiency or effectiveness of these processes. We may not be able to find a purchaser for our remaining non- cash assets during the Dissolution. We own several non- cash assets** , including but not limited to **preclinical** ~~the following: • timely~~ and ~~successful initiation and completion of~~ clinical **data packages** ~~trials for our product candidate portfolio, which may be significantly costlier than~~ **that** 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** **generated** ~~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 development for our pipeline assets is expensive, time- consuming, difficult to design and implement, and its outcome is inherently uncertain. Most~~ product candidates **. We may try to find a buyer** ~~that commence clinical trials are never approved by regulatory authorities~~ for ~~commercialization, and of those~~ **these assets but** ~~that are approved, many do not cover their~~ - **there** ~~costs of development or ever generate a profit. In addition, we, any partner with which we currently or~~ may **be no buyers forthcoming** ~~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~~ - **or the offers for the** ~~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 **adequate** ~~favorable for further development, either due to the results themselves or because funding to continue additional development based on these results is not forthcoming~~ . **As** ~~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 **there may** ~~as AD, remains to~~ be **no opportunity** ~~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 **stockholders** ~~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 **retained** ~~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,~~ **including during the Survival Period or thereafter. Stockholders** may not be able to ~~compete effectively~~ **recognize a loss** ~~or~~ **for** ~~achieve significant~~ **U. S. federal income tax purposes until they receive a final distribution from us. As a result of the Dissolution, for U. S. federal**

income tax purposes, a stockholder that is a U. S. person generally will recognize gain or loss on a share- by- share basis equal to the difference between (1) the sum of the amount of cash and the fair market ~~penetration. The pharmaceutical industry~~ **value of property, if any, distributed to the stockholder with respect to each share, less any known liabilities assumed by the stockholder or to which the distributed property (if any)** is **subject** ~~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~~ **and** ~~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~~ (**2** ~~" CROs ")~~ and other -- **the stockholder** ~~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 **adjusted tax basis in each** ~~regulations and good clinical practice (" GCP ") requirements, which are~~ **share** ~~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~~ **our** ~~any of~~ **common stock. A liquidating distribution pursuant to** ~~these~~ -- **the Plan of Dissolution** ~~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~~ **occur** ~~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~~ **times** ~~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 **and** 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 **tax year. Any loss generally will be recognized by a stockholder only in the tax year in which the stockholder receives our final liquidating distribution,** and marketed product **then only if the aggregate value of all liquidating distributions with respect** to sustain employing **a share of our common stock is less than the stockholder' s tax basis for that share. Stockholders are urged to consult with their own tax advisors as to the specific tax consequences to them of the Dissolution pursuant to the Plan of Dissolution. The tax treatment of any liquidating distribution may vary from stockholder to stockholder, and the discussions in this proxy statement regarding tax consequences are general in nature. We have not requested a ruling from the Internal Revenue Service with respect to the anticipated tax consequences of the Dissolution, and we will not seek** an **opinion of counsel** internal sales force. We may choose to collaborate with **respect to** third parties in various countries, including the **anticipated tax consequences of any liquidating** U. S., that have direct sales forces, commercial and regulatory capacities, and established distribution **distributions** 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 **If any of the anticipated tax consequences described in this Annual Report prove** to enter into and pay for such arrangements, and / or we may not be **incorrect** 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 -- **the** 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 **increased taxation at** delayed. We may be adversely affected by natural disasters and other -- **the corporate** catastrophic events and by man- made problems such as war or terrorism or labor disruptions that could disrupt our - **or** business operations **stockholder level** , **thus reducing the benefit to our stockholders** and **/** our - **or** 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 -- **the Dissolution. Tax** event occurred that prevented us from using all or a significant portion of our office, that damaged critical infrastructure, or that otherwise disrupted operations **considerations** , it **applicable to particular stockholders** may **vary with and** be difficult or, in certain cases, impossible for us to continue **contingent on the stockholder** our business for a period of time. Our contract manufacturers ' **s individual circumstances** 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.~~ 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 **in** ~~between Russia~~ and **around** Ukraine **, Israel, the broader Middle East, and other areas of the world** . 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~~ **these geopolitical** ~~conflict~~ **conflicts** ~~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 **in** ~~between Russia~~ and **around** Ukraine **, Israel, the broader Middle East, and other areas of the world** . Although the length and impact of ~~the~~ ongoing military ~~conflict~~ **conflicts** ~~is~~ **are** highly unpredictable, ~~the~~ **these** ~~conflict~~ **conflicts have** ~~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 **geopolitical conflict in and around** ~~the ongoing COVID- 19 pandemic, the Russian invasion of~~ Ukraine **, Israel, the broader Middle East,** and ~~related sanctions~~ **other areas of the world** , global IT threats, and ~~rising~~ **elevated** 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 **occurs** ~~, 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 **operate** ~~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: • **the payment of any distribution** ~~our need for additional potential financings~~ to ~~raise funds to further develop and commercialize~~ **stockholders as part of the Dissolution while** our ~~pipeline assets, which could result in significant additional share dilution~~ **outstanding common stock continues to be listed on the OTC Pink market** ; • 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 **geopolitical conflicts** ~~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, **and** 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 **maximize intended distributions** ~~fund the development and growth~~ of **all remaining cash to stockholders, pending stockholder** ~~our~~ **or judicial approval** ~~business. As a result, capital appreciation, if any,~~ of ~~our shares will be your sole source of gain, if any, for~~ the ~~foreseeable future~~ **Dissolution and the Plan of Dissolution** . 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~~ **2023** , we had approximately $ ~~454~~ **432** . ~~5~~ **7** million of federal and $ ~~444~~ **452** . ~~4~~ **3** million of state net operating loss (" NOL ") carryforwards available to offset **any** future taxable income, of which $ ~~210~~ **217** . ~~3~~ **4** million will carryforward indefinitely and the remainder will expire in varying amounts beginning in ~~2023~~ **2024** 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 **any** 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

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** ~~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~~ **cloud** ~~- approval activities~~ **based software to provide the functionality necessary to operate our company** , ~~including commercialization~~ **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 ~~. 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 **protect confidential** ~~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 **sensitive** ~~control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export, and reporting of safety and other post- market~~ information ~~related to~~ **from unauthorized disclosure across all** our **platforms, and similar efforts** ~~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 cloud service provider** ~~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) **and** ~~for which the product may be marketed or~~ **our** ~~on the~~ **other third** ~~conditions of approval. A product candidate' s approval may contain requirements for potentially costly post-~~ **party contractors** ~~approval studies and surveillance~~ , **consultants** ~~including Phase 4 clinical trials~~ , ~~to monitor the safety~~ and **vendors** ~~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~~ , **whether** ~~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 **technology (" IT ") providers** ~~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~~ **or otherwise** ~~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 **law firms accountants, and government** ~~the FDA' s Office of Prescription Drug Promotion' s regulation~~ **regulators** ~~of promotional activities~~ **, this information,** and ~~direct~~ **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** ~~to~~ **attacks or cyber intrusion** ~~consumer advertising~~, ~~fraud and abuse~~ **or other illegal acts**, ~~antikickback~~ **including by computer hackers**, ~~product sampling~~ **foreign governments**, ~~debarment, scientific speaker engagements~~ and ~~activities~~ **cyber- terrorists**, ~~formulary interactions~~ **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, malicious cyber actors may increase malware and ransom campaigns and phishing emails targeting teleworkers** as well as ~~interactions~~ **company systems, global conflicts like** with **Ukraine** ~~healthcare practitioners~~, **Israel, and the broader Middle East,** ~~including various conflict- of- interest reporting requirements for~~ **or other world trends and events, which exposes us to additional cybersecurity risks, or may try to illegally obtain material 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 business operations. In addition, since we have sponsored clinical trials,** any **breach** ~~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~~ **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. For example, the loss or theft of clinical trial data** from ~~participating~~ **completed clinical trials could result** in ~~federal reimbursement programs like Medicare~~ **stock manipulation and significantly increase** ~~or~~ **our** ~~Medicaid~~ **costs to recover or reproduce the data**. To the extent that **any disruption** ~~a product candidate is approved for~~ **or security breach were** ~~sale in other countries, it may be subject~~ to ~~similar~~ **result in a loss of, or damage to,** ~~or~~ **our** ~~more onerous (e. g.~~ **data or applications or inappropriate disclosure of confidential or proprietary information**, **we could incur liability or suffer from stock** ~~prohibition on direct- to- consumer advertising and~~ price **volatility** ~~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~~ **or decline** ~~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 **or product candidates** ~~and will face an even greater risk if~~ we ~~commercialize any products~~ **have previously sub- licensed, sold, and / or assigned** . 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 **, past and present,** 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~~ - **or** ~~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, **and** operating results ~~,~~ and **lessen** ~~prospects. Healthcare reform measures, including price controls or restricted access, could hinder or prevent~~ the **amount, timing, and number** ~~commercial success of our product candidates. The enactment~~ of any **distributions** ~~new healthcare initiatives or pharmaceutical industry regulations could have significant impacts on our ability~~ to **stockholder pursuant** ~~advance the development of our product candidates and eventually~~ to ~~commercialize them~~ - **the Plan** ~~, if at all. Specifically, on August 16, 2022, President Biden signed into law the Inflation Reduction Act~~ of **Dissolution** ~~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, **and** operating results ~~, and prospects~~ . Certain federal and state healthcare laws and regulations pertaining to ~~fraud and abuse and~~ patients' rights and privacy **, as well as other rights and obligations,** are and ~~will~~ **may** be applicable to our business. We are subject to regulation by ~~both~~ the federal government and the states **where** ~~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 **, fluctuation in our stock price,** 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, **and** 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 **or have collaborated** may engage **or may have engaged** 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 **or have collaborated** may engage **or may have engaged** 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~~ **on** data **and patient** 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, **and** operating results ~~,~~ and ~~prospects~~ **ability to implement the Dissolution and Plan of Dissolution** . We incur costs and demands upon management **because** ~~as a result~~ of complying with the laws and regulations affecting public companies. We incur significant legal, accounting, and other expenses **and management demands** 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, **and** ~~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, 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 **and** 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 -- **implement** , 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 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 -- **the Dissolution** , or third parties with access to their facilities and **Plan** 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 **Dissolution** 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~~ --- **litigation** ~~under~~ **related to** 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~~ **for** ~~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~~ **infringement under** ~~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 **circumstances** ~~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, **assignees,** and partners ~~and will continue to do so in the future,~~ around the world, if one of our licensors, licensees **, assignees** , or partners is sued for infringing a third party' s intellectual property rights, this could expose us to liability, and our business, financial condition, **and** 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, **assignees,** 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 **, assignees** , 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 or in- licensed** 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, **and** 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 **or some or all of our assets** 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~~ **, reverse merger, licensing,** acquisition **, or other strategic transaction** 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 **the sole** ~~members~~ **member** 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 **the sole** ~~members~~ **member** 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. 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 TH17 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 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. 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. 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. 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. 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. 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) Pharmacodynamics (PD) 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. 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. 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. 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. 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. We recognized the following as contract revenue during the year ended December 31, 2022 (in thousands): Year EndedDecember 31, 2022Upfront consideration $ 3, 000 Milestone payment received upon acceptance by FDA of NDA filing2, 000 Consulting services provided under the TSA794 Reimbursed development expenditures under the Asset Purchase Agreement624 Sublicense Income433 Total contract revenue $ 6, 851 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 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. Key Components of Operations 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 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. Comparison of the Year Ended December 31, 2022 and 2021 Year EndedDecember 31, 20222021 (in thousands) Revenue $ 6, 943 $ 404 Research and development expenses (14, 043) (28, 231) General and administrative expenses (14, 434) (12, 417) Other income, net432 770 Net loss $ (21, 102) $ (39, 474) 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. Below is a summary of our research and development expenses by period related to our programs: Year EndedDecember 31, 20222021Change (in thousands) Direct program expenses related toSofpironium 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 expenses3, 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 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 EndedDecember 31, 20222021 (in thousands) Net cash provided by (used in): Operating activities $ (19, 335) $ (36, 148) Investing activities (47) (36) Financing activities1, 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 INDEX PageReport of Independent Registered Public Accounting Firm (PCAOB ID No. 42) 68Consolidated Balance Sheets70Consolidated Statements of Operations71Consolidated Statements of Redeemable Preferred Stock and Stockholders' Equity72Consolidated Statements of Cash Flows73Notes to Consolidated Financial Statements74 To the Stockholders and the Board of Directors of Fresh Tracks Therapeuties, Inc. Opinion on the Financial Statements We have audited the accompanying consolidated balance sheets of Fresh Tracks Therapeuties, 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 costsDescription of the MatterThe 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 WeAddressed the Matter in Our AuditTo 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 LLPWe have served as the Company' s auditor since 2017. Denver, ColoradoMarch 30, 2023 FRESH TRACKS THERAPEUTICS, INC. CONSOLIDATED BALANCE SHEETS (in thousands, except share and per share data) December 31, 20222021AssetsCurrent assets: Cash and cash equivalents $ 8, 680 $ 26, 884 Prepaid expenses and other current assets1, 403 2, 716 Total current assets10, 083 29, 600 Property and equipment, net75 58 Contract asset, net of current portion64 — Operating lease right- of- use asset49 59 Total assets $ 10, 271 $ 29, 717 Liabilities and stockholders' equityCurrent liabilities: Accounts payable $ 571 $ 1, 605 Accrued liabilities2, 457 3, 136 Lease liability49 69 Total current liabilities3, 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, respectively30 27 Additional paid- in capital173, 633 170, 247 Accumulated deficit (166, 469) (145, 367) Total stockholders' equity7, 194 24, 907 Total liabilities and stockholders' equity $ 10, 271 $ 29, 717 See accompanying notes to these consolidated financial statements. CONSOLIDATED STATEMENTS OF OPERATIONS Year EndedDecember 31, 20222021RevenueContract revenue $ 6, 851 $ — Royalty revenue92 404 Total revenue6, 943 404 Operating expenses: Research and development14, 043 28, 231 General and administrative14, 434 12, 417 Total operating expenses28, 477 40, 648 Loss from operations (21, 534) (40, 244) Other income441 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 diluted2, 808, 075 1, 784, 791 See accompanying notes to these consolidated financial statements. CONSOLIDATED STATEMENTS OF REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (in thousands, except share data) Series A Redeemable Preferred StockCommon StockAdditional Paid- In- CapitalAccumulated DeficitTotal Stockholders' EquitySharesPar ValueSharesPar ValueBalance, 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 stock1 — — — — — — — — 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 CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands) Year EndedDecember 31, 20222021CASH FLOWS FROM OPERATING ACTIVITIES: Net loss $ (21, 102) $ (39, 474) Adjustments to reconcile net loss to net cash used in operating activities: Stock- based compensation2, 156 2, 263 Non- cash operating lease expense59 15 Depreciation30 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 asset1, 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 costs1, 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 program37 29 Proceeds from the exercise of warrants — 8, 969 Net cash provided by financing activities1, 178 32, 953 NET DECREASE IN CASH AND CASH EQUIVALENTS (18, 204) (3, 231) CASH AND CASH EQUIVALENTS — BEGINNING26, 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 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. 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 1December 31, 20222021Assets: 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. 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. 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 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 EndedDecember 31, 20222021Outstanding warrants621, 063 621, 063 Outstanding options215, 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. 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 the consolidated 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 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. 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. 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. 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): 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 recognized433 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, 20222021Prepaid insurance521 921 Contract asset254 — Prepaid research and development expenses254 1, 443 Accounts receivable250 125 Other prepaid expenses117 168 Other current assets7 59 Total $ 1, 403 $ 2, 716 Accrued liabilities consisted of the following (in thousands): December 31, 20222021Accrued compensation $ 1, 320 $ 1, 861 Accrued professional fees705 452 Accrued research and development expenses432 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 of 1. 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 EndedDecember 31, 20222021Operating lease cost $ 62 $ 62 Variable lease cost $ 39 $ 37 Cash outflows from operating leases $ 111 $ 88 Weighted- average remaining lease term0. 5 years1. 0 yearWeighted- average discount rate11. 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 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 Therapeuties, 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. 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, 2022Common stock warrants621, 063 Common stock options outstanding 215, 316 Shares available for grant under the 2020 Omnibus Long- Term Incentive Plan141, 843 Shares available for grant under the ESPP42, 728 Total1, 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. 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. 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. 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 $ 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 "). 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. 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 by 119, 377 shares. As of December 31, 2022, 323, 364 shares were authorized, and 188, 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 generally four 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 EndedDecember 31, 20222021Expected term6. 0 years6. 0 yearsExpected volatility97. 8 % 99. 3 % Risk- free interest rate3. 0 % 1. 0 % Expected dividend yield — % — % A summary of stock option activity under the Company' s incentive plans is as follows: SharesWeighted- Average Exercise PriceTotalIntrinsic ValueWeighted- Average Remaining Contractual Life (In Years) Outstanding as of December 31, 2021156, 765 $ 143. 15 $ — 8. 53Granted86, 204 $ 10. 95 Forfeited (19, 361) $ 28. 74 Expired (8, 292) $ 569. 23 Outstanding as of December 31, 2022215, 316 $ 84. 10 $ — 8. 21Options vested and exercisable as of December 31, 202278, 751 $ 185. 91 $ — 7. 19Options outstanding as of December 31, 2022 and expected to vest197, 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. 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

EndedDecember 31, 20222021Research and development $ 425 $ 478 General and administrative1, 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 EndedDecember 31, 20222021Federal statutory income tax rate21. 00 % 21. 00 % State taxes, net of federal benefit2. 88 4. 93 Research and development tax credits1. 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 EndedDecember 31, 20222021NOL carryforwards $ 104, 278 $ 100, 831 Research and development and other tax credits17, 247 16, 881 Depreciable assets4, 812 6, 481 Capitalized research and development costs2, 347 — Intangible assets1, 797 1, 470 Stock- based compensation1, 505 1, 238 Other82 110 Net deferred tax asset132, 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 NOLsState NOLsFederal R & D CreditFederal Orphan Drug CreditState R & D Credit202322, 398 — 322 929 — 202425, 032 — 213 663 — 202527, 190 — 456 507 — 2026 and thereafter224, 441 383, 032 8, 374 13, 306 — Indefinite148, 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 Subsequent to December 31, 2022 and through March 30, 2023, the Company sold 2, 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 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 ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS 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 ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES 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 page 67 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 ExhibitNumberDescription of ExhibitFormDate of FilingExhibit NumberFiled Herewith3. 1Amended and Restated Certificate of Incorporation, as amended through September 6, 20228- K9 / 8 / 20223. 23. 2Amended and Restated Bylaws, as amended through September 6, 202210- Q11 / 14 / 20223. 24. 1Specimen Common Stock Certificate S- 89 / 10 / 20194. 14. 2Form of Senior IndentureS- 33 / 9 / 20214. 34. 3Form of Subordinated IndentureS- 33 / 9 / 20214. 44. 4Form of Warrant to Purchase Common Stock issued in connection with the Company' s October 2020 OfferingS- 110 / 13 / 20204. 24. 5Form of Warrant

Agency Agreement issued in connection with the Company' s October 2020 OfferingS- 110 / 13 / 20204. 44. 6Form of Warrant Agency Agreement between Brickell Biotech, Inc. and American Stock Transfer & Trust Company, LLC in connection with the Company' s June 2020 OfferingS- 1 / A6 / 17 / 20204. 44. 7Form of Warrant to Purchase Common Stock issued in connection with the Company' s June 2020 Offering S- 1 / A6 / 17 / 20204. 24. 8Description 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- K9 / 1 / 202110. 110. 2 † Exclusive License Agreement, dated as of February 2, 2022, by and between Carna Biosciences, Inc. and Brickell Biotech, Inc. 8- K2 / 2 / 202210. 110. 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 Limited8- K5 / 3 / 202210. 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- Q11 / 14 / 202210. 610. 5 † Transition Services Agreement, dated as of May 3, 2022, by and between Botanix SB Inc. and Brickell Biotech, Inc. 8- K5 / 3 / 202210. 210. 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- K9 / 3 / 201910. 210. 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 / A6 / 8 / 202010. 210. 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- K9 / 3 / 201910. 310. 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, 2019S- 1 / A6 / 8 / 202010. 410. 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 / A6 / 8 / 202010. 510. 11 † Letter Agreement, dated as of September 3, 2020, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd. S- 110 / 13 / 202010. 610. 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- K3 / 9 / 202110. 710. 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- Q8 / 12 / 202110. 410. 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. Bodor8- K2 / 18 / 202010. 110. 15 † Settlement Agreement, dated February 17, 2020, by and among Brickell Biotech, Inc., Brickell Subsidiary, Inc., Bodor Laboratories, Inc., and Dr. Nicholas S. Bodor8- K2 / 18 / 202010. 210. 16 † Rights Agreement, dated as of May 3, 2022, by and among Brickell Biotech, Inc., Brickell Subsidiary, Inc., and Bodor Laboratories, Inc. 8- K5 / 3 / 202210. 310. 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- Q11 / 14 / 202210. 7 10. 18Boulder Lease Agreement, as amended, dated August 4, 2016, by and between Brickell Biotech, Inc. and BMC Properties, LLC8- K9 / 3 / 201910. 1010. 19Fourth 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- Q8 / 12 / 202110. 110. 20Fifth 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, 20238- K2 / 7 / 202310. 110. 23Consulting Agreement, by and between Fresh Tracks Therapeutics, Inc. and Dancing Bear Consulting, LLC, effective as of January 31, 20238- K1 / 27 / 202310. 110. 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, 20238- K2 / 24 / 202310. 110. 25 Consulting Agreement by and between Brickell Biotech, Inc. and Danforth Advisors LLC, effective as of December 1, 20208- K11 / 24 / 202010. 210. 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, 20238- K2 / 24 / 202310. 210. 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, 202210- Q11 / 14 / 202210. 110. 29 Form of Restricted Stock Unit Award Agreement under the Fresh Tracks Therapeutics, Inc. 2020 Omnibus Long- Term Incentive Plan10- Q11 / 14 / 202210. 310. 30 Form of Incentive Stock Option Award Agreement under the Fresh Tracks Therapeutics, Inc. 2020 Omnibus Long- Term Incentive Plan10- Q11 / 14 / 202210. 410. 31 Form of Non- Qualified Stock Option Award Agreement under the Fresh Tracks Therapeutics, Inc. 2020 Omnibus Long- Term Incentive Plan10- Q11 / 14 / 202210. 510. 32 Amended and Restated Stock Incentive Plan of Vical Incorporated8- K6 / 1 / 201799. 110. 33 Amended and Restated 2009 Equity Incentive Plan of Brickell Biotech, Inc. S- 89 / 10 / 201999. 2 10. 34Fresh Tracks Therapeutics, Inc. Employee Stock Purchase Plan × 10. 35Securities Purchase Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC8- K2 / 18 / 202010. 310. 36Series A Warrant issued by Brickell Biotech, Inc. to Lincoln Park Capital Fund, LLCS- 32 / 28 / 20204. 310. 37Series B Warrant issued by Brickell Biotech, Inc. to Lincoln Park Capital Fund, LLCS- 32 / 28 / 20204. 410. 38Purchase Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC8- K2 / 18 / 202010. 610. 39Registration Rights Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC8- K2 / 18 / 202010. 710.

40At Market Issuance Sales Agreement, dated April 14, 2020, by and between Brickell Biotech, Inc. and Oppenheimer & Co. Inc. 8- K4 / 14 / 20201. 110. 41At Market Issuance Sales Agreement, dated March 9, 2021, by and among the Company, Oppenheimer & Co. Inc. and William Blair & Company, L. L. C. S- 33 / 9 / 20211. 210. 42 Form of Employee Retention Bonus Agreement8- K2 / 24 / 202310. 321. 1List of Subsidiaries × 23. 1Consent of Ernst & Young LLP × 31. 1Certification 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. 2Certification 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. INSInline XBRL Instance Document × 101. SCHInline XBRL Taxonomy Extension Schema Document × 101. CALInline XBRL Taxonomy Extension Calculation Linkbase Document × 101. DEFInline XBRL Taxonomy Extension Definition Linkbase Document × 101. LABInline XBRL Taxonomy Extension Label Linkbase Document × 101. PREInline XBRL Taxonomy Extension Presentation Linkbase Document × 104Cover 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 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, 2023By: / s / Andrew D. SklawerAndrew D. SklawerChief Executive Officer (Principal Executive Officer) By: / s / Albert N. Marchio, IIAlbert N. Marchio, IIChief 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. SignatureTitleDate / s / Andrew D. SklawerPresident and Chief Executive Officer (Principal Executive Officer) March 30, 2023Andrew D. Sklawer / s / Albert N. Marchio, IIChief Financial Officer (Principal Financial Officer) March 30, 2023Albert N. Marchio, II / s / Aaron Fox- CollisVP of Finance and Chief Accounting Officer (Principal Accounting Officer) March 30, 2023Aaron Fox- Collis / s / Reginald L. HardyCo- Founder and Chairman of the Board of DirectorsMarch 30, 2023Reginald L. Hardy / s / Robert B. BrownDirectorMarch 30, 2023Robert B. Brown / s / Vijay B. Samant DirectorMarch 30, 2023Vijay B. Samant / s / Gary A. LyonsDirectorMarch 30, 2023Gary A. Lyons Exhibit 4. 8 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. 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).