

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

or

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

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

FRESH TRACKS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

93-0948554

(I.R.S. Employer Identification No.)

5777 Central Avenue, Boulder, CO

(Address of principal executive offices)

80301

(Zip Code)

(720) 505-4755

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, \$0.01 par value per share	FRTX	The Nasdaq Stock Market LLC

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of May 4, 2023, there were 5,906,475 shares of the registrant's common stock outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (“Quarterly 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 Quarterly 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 Quarterly 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 our Annual Report on Form 10-K for the year ended December 31, 2022, in Part II, Item 1A, “Risk Factors” in this Quarterly 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 Quarterly 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 our Annual Report on Form 10-K for the year ended December 31, 2022, in Part II, Item 1A, “Risk Factors” in this Quarterly Report, and under a similar heading in any other periodic or current report we may file with the SEC 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.

FRESH TRACKS THERAPEUTICS, INC.
FORM 10-Q
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,764	\$ 8,680
Prepaid expenses and other current assets	1,049	1,403
Total current assets	11,813	10,083
Property and equipment, net	65	75
Contract asset, net of current portion	64	64
Operating lease right-of-use asset	25	49
Total assets	\$ 11,967	\$ 10,271
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 635	\$ 571
Accrued liabilities	1,438	2,457
Lease liability	28	49
Total current liabilities	2,101	3,077
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Common stock, \$0.01 par value, 300,000,000 shares authorized as of March 31, 2023 and December 31, 2022; 5,906,475 and 3,018,940 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	59	30
Additional paid-in capital	180,552	173,633
Accumulated deficit	(170,745)	(166,469)
Total stockholders' equity	9,866	7,194
Total liabilities and stockholders' equity	\$ 11,967	\$ 10,271

See accompanying notes to these condensed consolidated financial statements.

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

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

See accompanying notes to these condensed consolidated financial statements.

FRESH TRACKS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value			
Balance, December 31, 2021	2,652,828	\$ 27	\$ 170,247	\$ (145,367)	\$ 24,907
Stock-based compensation	—	—	551	—	551
Net loss	—	—	—	(9,410)	(9,410)
Balance, March 31, 2022	2,652,828	\$ 27	\$ 170,798	\$ (154,777)	\$ 16,048

	Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value			
Balance, December 31, 2022	3,018,940	\$ 30	\$ 173,633	\$ (166,469)	\$ 7,194
Common stock issued pursuant to ATM agreements, net of issuance costs of \$202	2,887,535	29	6,540	—	6,569
Stock-based compensation	—	—	379	—	379
Net loss	—	—	—	(4,276)	(4,276)
Balance, March 31, 2023	5,906,475	\$ 59	\$ 180,552	\$ (170,745)	\$ 9,866

See accompanying notes to these condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (4,276)	\$ (9,410)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	379	551
Non-cash operating lease expense	24	14
Depreciation	10	7
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets, including noncurrent portion of contract asset	354	(688)
Accounts payable	64	1,377
Accrued liabilities	(1,019)	(1,375)
Operating lease liability	(21)	(16)
Net cash used in operating activities	(4,485)	(9,540)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of common stock pursuant to ATM agreements, net of issuance costs	6,569	—
Payments of taxes related to net share settlement of equity awards	—	(55)
Net cash provided by (used in) financing activities	6,569	(55)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,084	(9,595)
CASH AND CASH EQUIVALENTS—BEGINNING	8,680	26,884
CASH AND CASH EQUIVALENTS—ENDING	\$ 10,764	\$ 17,289

See accompanying notes to these condensed consolidated financial statements.

FRESH TRACKS THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

NOTE 1. ORGANIZATION AND NATURE OF OPERATIONS

Fresh Tracks Therapeutics, Inc. (the “Company” or “Fresh Tracks”) is a clinical-stage pharmaceutical company striving to transform patient lives through the development of innovative and differentiated prescription therapeutics. The Company’s pipeline aims to disrupt existing treatment paradigms and features several new chemical entities that inhibit novel targets with first-in-class potential for autoimmune, inflammatory, and other debilitating diseases. This includes FRTX-02, a DYRK1A inhibitor for the treatment of certain autoimmune and inflammatory diseases; FRTX-10, a preclinical-stage Stimulator of Interferon Genes (“STING”) inhibitor candidate for the potential treatment of autoimmune, inflammatory, and rare genetic diseases; and a platform of next-generation kinase inhibitors with the potential to produce treatments for autoimmune, inflammatory, and other debilitating diseases.

Reverse Stock Split

On July 5, 2022, the Company effected a 1-for-45 reverse stock split of outstanding shares of its common stock. All common stock shares, per-share amounts, and other related balances and computations reported as of and for all periods presented in the condensed 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.

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 three months ended March 31, 2023, the Company had a net loss of \$4.3 million and net cash used in operating activities of \$4.5 million. As of March 31, 2023, the Company had cash and cash equivalents of \$10.8 million and an accumulated deficit of \$170.7 million. The Company believes that its cash and cash equivalents as of March 31, 2023 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 condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Brickell Subsidiary, Inc. (“Brickell Subsidiary”), and are presented in United States

(“U.S.”) dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and applicable rules and regulations of the SEC for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of the Company’s financial information. The results of operations for the three months ended March 31, 2023 are not necessarily indicative of the results to be expected for the full year ending December 31, 2023, for any other interim period, or for any other future period. The condensed consolidated balance sheet as of December 31, 2022 has been derived from audited financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. All intercompany balances and transactions have been eliminated in consolidation. The Company operates in one operating segment and, accordingly, no segment disclosures have been presented herein.

Significant Accounting Policies

The Company’s significant accounting policies are described in Note 2. “*Summary of Significant Accounting Policies*” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022. During the three months ended March 31, 2023, the Company did not adopt any additional significant accounting policies.

Reclassifications

Certain comparative figures in the prior year condensed 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 condensed 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 two financial institutions which, from time to time, are in excess of federally insured limits.

One third party individually accounted for all of the Company's revenue for the three months ended March 31, 2023 and 2022, as well as associated accounts receivable and contract asset balances as of March 31, 2023 and December 31, 2022. Refer to Note 3. "Strategic Agreements" for a detailed discussion of agreements with Botanix SB Inc. and Botanix Pharmaceuticals Limited ("Botanix").

Fair Value Measurements

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

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

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

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

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

	Level 1	
	March 31, 2023	December 31, 2022
Assets:		
Money market funds	\$ 7,946	\$ 7,680

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 condensed consolidated balance sheets approximate their fair values due to their short-term nature and market rates of interest.

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

Revenue Recognition

The Company has historically 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 sofipirionium bromide, as well as sublicense income and royalty fees on sales of sofipirionium bromide gel, 5% (ECCLOCK®) in Japan.

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

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

Contract Revenue

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

Licenses of Intellectual Property

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

Milestones

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

Sales-Based Payments

For license arrangements that include sales-based payments such as royalties or milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the sales-based payments relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the sales-based payment has been allocated has been satisfied (or partially satisfied). Sales-based payments received under license arrangements are recorded as royalty revenue in the Company's condensed 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 condensed consolidated balance sheets. The current portion of the contract asset is presented in prepaid expenses and other current assets on the Company's condensed consolidated balance sheets. Actual amounts paid or due by the customer are recorded as a reduction to the contract asset. Any revisions to the Company's estimated revenue based on actual results and future expectations are recognized as an adjustment to the contract asset.

Research and Development

Research and development costs are charged to expense when incurred and consist of costs incurred for independent and collaboration research and development activities. The major components of research and

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

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

	Three Months Ended March 31,	
	2023	2022
Outstanding warrants	621,063	621,063
Outstanding options	197,055	153,656
Unvested restricted stock units	141,250	—
Total	959,368	774,719

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 condensed 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 condensed 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.

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 condensed consolidated financial statements or disclosures.

NOTE 3. STRATEGIC AGREEMENTS

License and Development Agreement with Voronoi

On August 27, 2021, the Company entered into a License and Development Agreement (the "Voronoi License Agreement") with Voronoi Inc. ("Voronoi"), pursuant to which the Company acquired exclusive, worldwide rights to research, develop, and commercialize FRTX-02 and other next-generation kinase inhibitors.

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. As of March 31, 2023 and through the date of this Quarterly Report, the Company has not yet 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.

Exclusive License and Development Agreement with Carna

On February 2, 2022, the Company entered into an Exclusive License Agreement (the "Carna License Agreement") with Carna Biosciences, Inc. ("Carna"), pursuant to which the Company acquired exclusive, worldwide rights to research, develop, and commercialize Carna's portfolio of novel STING inhibitors. In accordance with the terms of the Carna License Agreement, in exchange for the licensed rights, the Company made a one-time cash payment of \$2.0 million, which was recorded as research and development expenses in the condensed consolidated statements of operations during the three months ended March 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. As of March 31, 2023 and through the date of this Quarterly Report, the Company has not yet 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.

Asset Purchase Agreement with Botanix

On May 3, 2022 (the “Effective Date”), the Company and Brickell Subsidiary entered into an asset purchase agreement with Botanix (the “Asset Purchase Agreement”), pursuant to which Botanix acquired and assumed control of all rights, title, and interests to assets primarily related to the proprietary compound sofipironium 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 sofipironium 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 sofipironium 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 sofipironium 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 three months ended March 31, 2022, prior to entering into the Asset Purchase Agreement, the Company recognized royalty revenue of \$0.1 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 U.S. Food and Drug Administration (“FDA”) in December 2022 of the filing of a new drug application (“NDA”) for sofipironium bromide gel, 15%, and (iv) will receive a contingent milestone payment of \$4.0 million if marketing approval in the U.S. for sofipironium 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 sofipironium 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 sofipironium 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 March 31, 2023, 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 March 31, 2023, and as such, did not recognize such amounts as contract revenue.

Transition Services Agreement with Botanix

In connection with the sale of the Assets, on the Effective Date, the Company and Botanix entered into a transition services agreement (the “TSA”) whereby the Company is providing consulting services as an independent contractor to Botanix in support of and through filing and potential approval of the U.S. NDA for sofipronium 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. During the three months ended March 31, 2023, the Company recognized \$9 thousand of contract revenue associated with consulting services provided under the TSA.

Contract Assets under the Botanix Agreements

The following table presents changes in the value of the Company’s contract asset related to Sublicense Income for the three months ended March 31, 2023 (in thousands):

Contract asset as of January 1, 2023	\$	318
Amounts received or receivable		(34)
Contract asset as of March 31, 2023	\$	284
Contract asset, included in prepaid expenses and other current assets	\$	220
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 sofipironium 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, 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 three months ended March 31, 2023 and 2022, no expense was incurred or reported as general and administrative expenses in the condensed consolidated statements of operations associated with achieved milestones related to sofipironium bromide gel, 15%. 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):

	March 31, 2023	December 31, 2022
Prepaid insurance	\$ 496	\$ 521
Contract asset	220	254
Prepaid research and development expenses	159	254
Other prepaid expenses	122	117
Accounts receivable	45	250
Other current assets	7	7
Total	\$ 1,049	\$ 1,403

Accrued liabilities consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Accrued compensation	\$ 731	\$ 1,320
Accrued professional fees	404	705
Accrued research and development expenses	303	432
Total	\$ 1,438	\$ 2,457

NOTE 5. 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 is a summary of the contractual obligations related to operating lease commitments as of March 31, 2023 (in thousands):

Total maturities, through December 31, 2023	\$	29
Less imputed interest		(1)
Present value of lease liability	\$	<u>28</u>

On May 4, 2023, the Company entered into an amendment to the Boulder Lease, which will terminate the Boulder Lease, effective August 31, 2023.

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 6. CAPITAL STOCK***Common Stock***

Under the Company’s Restated Certificate of Incorporation, the Company’s Board has the authority to issue up to 300,000,000 shares of common stock with a par value of \$0.01 per share. Each share of the Company’s common stock is entitled to one vote, and the holders of the Company’s common stock are entitled to receive

dividends when and as declared or paid by its Board. The Company had reserved authorized shares of common stock for future issuance as of March 31, 2023 as follows:

	March 31, 2023
Common stock warrants	621,063
Common stock options outstanding	197,055
Unvested restricted stock units	141,250
Shares available for grant under the Employee Stock Purchase Plan	42,728
Shares available for grant under the 2020 Omnibus Long-Term Incentive Plan	18,854
Total	<u>1,020,950</u>

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

Public Offerings of Common Stock and Warrants

In October 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. No warrants associated with the October 2020 Offering were exercised during the three months ended March 31, 2023 or 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. No warrants associated with the June 2020 Offering were exercised during the three months ended March 31, 2023 or 2022.

At Market Issuance Sales Agreements

In March 2021, the Company entered into an At Market Issuance Sales Agreement (the “2021 ATM Agreement”) with Oppenheimer & Co. Inc. (“Oppenheimer”) and William Blair & Company, L.L.C. as the Company’s sales agents (the “Agents”). Pursuant to the terms of the 2021 ATM Agreement, the Company may sell from time to time through the Agents shares of its common stock having an aggregate offering price of up to \$50.0 million. Such shares are issued pursuant to the Company’s shelf registration statement on Form S-3 (Registration No. 333-254037). Sales of the shares are made by means of ordinary brokers’ transactions on The Nasdaq Capital Market at market prices or as otherwise agreed by the Company and the Agents. Under the terms of the 2021 ATM Agreement, the Company may also sell the shares from time to time to an Agent as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the shares to an Agent

as principal would be pursuant to the terms of a separate placement notice between the Company and such Agent. During the three months ended March 31, 2023, the Company sold 2,887,535 shares of common stock under the 2021 ATM Agreement at a weighted-average price of \$2.34 per share, for aggregate net proceeds of \$6.6 million, after giving effect to a 3% commission to the Agents. During the three months ended March 31, 2022, no sales of common stock under the 2021 ATM Agreement occurred. As of March 31, 2023, approximately \$38.0 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. As of March 31, 2023, 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. However, the shares that may be sold pursuant to the 2020 ATM Agreement are not currently registered under the Securities Act of 1933, as amended. During the three months ended March 31, 2023 and 2022, no sales of common stock under the 2020 ATM Agreement occurred.

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

Private Placement Offerings

In February 2020, the Company and Lincoln Park Capital Fund, LLC (“Lincoln Park”) entered into (i) a securities purchase agreement (the “Securities Purchase Agreement”); (ii) a purchase agreement (the “Purchase Agreement”); and (iii) a registration rights agreement (the “Registration Rights Agreement”). Pursuant to the Securities Purchase Agreement, Lincoln Park purchased, and the Company sold, (i) an aggregate of 21,111 shares of common stock (the “Common Shares”); (ii) a warrant to initially purchase an aggregate of up to 13,476 shares of common stock at an exercise price of \$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 \$2.20 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 three months ended March 31, 2023 or 2022.

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 three months ended March 31, 2023 and 2022, no sales of common stock under the Purchase Agreement occurred. As of March 31, 2023, 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 has the right to terminate the Purchase Agreement at any time, at no cost or penalty.

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

Preferred Stock

Under the Company's Restated Certificate of Incorporation, the Company's Board has the authority to issue up to 5,000,000 shares of preferred stock with a par value of \$0.01 per share, at its discretion, in one or more classes or series and to fix the powers, preferences and rights, and the qualifications, limitations, or restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, without further vote or action by the Company's stockholders. As of March 31, 2023, there were no shares of preferred stock outstanding.

NOTE 7. 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 March 31, 2023, 25,047 and 1,684 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 19,377 shares. As of March 31, 2023, 323,364 shares were authorized, and 338,305 shares were subject to outstanding awards under the Omnibus Plan. As of March 31, 2023, 18,854 shares remained available for grant under the Omnibus Plan.

Employee Stock Purchase Plan

On April 19, 2021, the Company's stockholders approved the Fresh Tracks Therapeutics, Inc. Employee Stock Purchase Plan (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 March 31, 2023, 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 condensed consolidated statements of operations was allocated as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Research and development	\$ 92	\$ 103
General and administrative	287	448
Total stock-based compensation expense	<u>\$ 379</u>	<u>\$ 551</u>

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

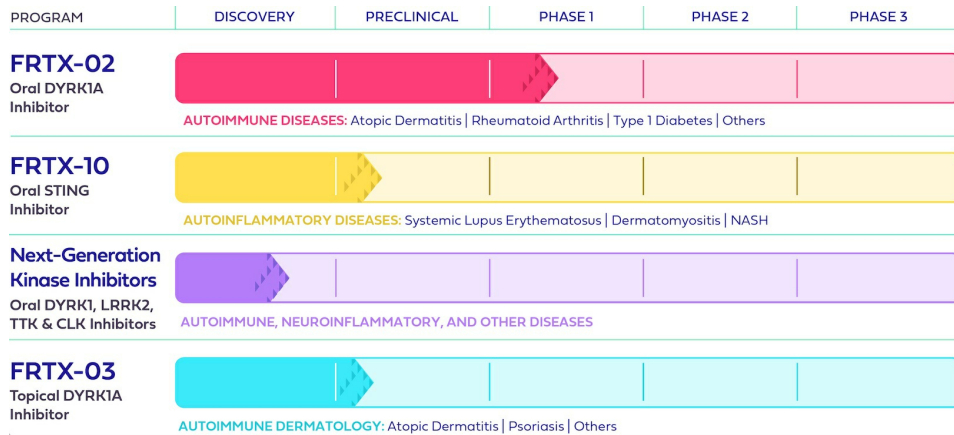
We are a clinical-stage pharmaceutical company striving to transform patient lives through the development of innovative and differentiated prescription therapeutics. Our pipeline aims to disrupt existing treatment paradigms and features several new chemical entities that inhibit novel targets with first-in-class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

Exploration of Strategic Options

Our Board and executive management team are conducting a comprehensive process to explore and evaluate strategic options to progress the development of our novel pipeline of potential treatments for autoimmune, inflammatory, and other diseases. Potential strategic options to be explored or evaluated as part of this process may include, but are not limited to, a financing, sale or licensing of assets, acquisition, merger, business combination, and/or other strategic transaction or series of related transactions involving our Company. MTS Health Partners, LP has been retained as our exclusive financial advisor to assist in this review process.

Research and Development Programs

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



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

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

FRTX-02 is our lead development-stage program and has demonstrated promising results in various preclinical models, including of atopic dermatitis (“AD”) and rheumatoid arthritis. In these models, FRTX-02 showed encouraging decreases in disease severity and reduction of pro-inflammatory cytokines compared to current standard-of-care agents, such as Janus kinase (JAK) inhibitors and anti-tumor necrosis factor (“TNF”) biologics. Notably, many current therapies for autoimmune disorders are broadly immunosuppressive, which may lead to severe side effects, such as increased infection risk. Preclinical data have shown FRTX-02 to drive regulatory T-cell differentiation while dampening pro-inflammatory 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 Quarterly Report.

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

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

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

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

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

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

In August 2021, we acquired exclusive global rights to a cutting-edge platform of next-generation kinase inhibitors. This library of new chemical entities includes next-generation DYRK1 inhibitors, as well as other molecules that specifically inhibit Leucine-Rich Repeat Kinase 2 (“LRRK2”), CDC2-like kinase (“CLK”), and TTK protein kinase (“TTK”), also known as Monopolar spindle 1 (Mps1) kinases. A number of these drug candidates have the potential to penetrate the blood-brain barrier, presenting an opportunity to address neuroinflammatory conditions of high unmet need, such as Down Syndrome, Alzheimer’s Disease, and Parkinson’s Disease, while other peripherally acting novel LRRK2, TTK, and CLK kinase inhibitors could be developed in additional therapeutic areas within autoimmunity, inflammation, and oncology.

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

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

Study Design

The Phase 1 clinical trial of FRTX-02 is a two-part, randomized, double-blinded, placebo-controlled study designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of FRTX-02 capsules in both healthy subjects and patients with AD. Part 1A of the study was a single ascending dose (“SAD”) assessment, which enrolled a total of 56 healthy subjects across seven cohorts (single oral dose of 10 to 600 mg FRTX-02 or placebo). Part 1B of the study was a multiple ascending dose (“MAD”) assessment, which enrolled a total of 33 healthy subjects across three cohorts (75, 150, and 300 mg FRTX-02 or placebo, once-daily for 14 days). Part 2 of the study is planned to compare once-daily oral doses of FRTX-02 to placebo in subjects with moderate-to-severe AD and include an exploratory evaluation of efficacy.

Safety

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

Pharmacokinetics (“PK”)

A dose-proportional increase in exposure was observed through all SAD and MAD cohorts. PK data from the 75 mg and 150 mg MAD cohorts achieved maximum plasma concentrations (C_{max}) 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 (T_{max}) 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 IFN γ , IL-23, IL-10, IL-6, and TNF α . Additionally, maximum individual subject cytokine reductions from baseline were shown to be >90% for IFN γ , >50% for IL-23, IL-10, and TNF α , and approximately 40% for IL-6.

Strategic, Licensing, and Other Arrangements

License and Development Agreement with Voronoi

In August 2021, we entered into a License and Development Agreement (the “Voronoi License Agreement”) with Voronoi Inc. (“Voronoi”), pursuant to which we acquired exclusive, worldwide rights to research, develop, and commercialize FRTX-02 and other next-generation kinase inhibitors.

With respect to FRTX-02, the Voronoi License Agreement provides that we will make payments to Voronoi of up to \$211.0 million in the aggregate contingent upon achievement of specified development, regulatory, and commercial milestones. With respect to the compounds arising from the next-generation kinase inhibitor platform, we will make payments to Voronoi of up to \$107.5 million in the aggregate contingent upon achievement of specified development, regulatory, and commercial milestones. Further, the Voronoi License Agreement provides that we will pay Voronoi tiered royalty payments ranging from low-single digits up to 10% of net sales of products arising from the DYRK1A inhibitor programs and next-generation kinase inhibitor platform. All of the contingent payments and royalties are payable in cash in U.S. Dollars, except for \$1.0 million of the development and regulatory milestone payments, which amount is payable in equivalent shares of our common stock. Under the terms of the Voronoi License Agreement, we are responsible for, and bear the future costs of, all development and commercialization activities, including patenting, related to all the licensed compounds. As of March 31, 2023 and through the date of this Quarterly Report, we have not yet 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.

Exclusive License and Development Agreement with Carna

In February 2022, we entered into an Exclusive License Agreement (the “Carna License Agreement”) with Carna Biosciences, Inc. (“Carna”), pursuant to which we acquired exclusive, worldwide rights to research, develop, and commercialize Carna’s portfolio of novel STING inhibitors. In accordance with the terms of the Carna License Agreement, in exchange for the licensed rights, we made a one-time cash payment of \$2.0 million, which was recorded as research and development expenses in the condensed consolidated statements of operations during the three months ended March 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. As of March 31, 2023 and through the date of this Quarterly Report, we have not yet 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.

Agreements with Botanix

Asset Purchase Agreement with Botanix

On May 3, 2022 (the “Effective Date”), we and 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 sofipironium 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 sofipironium 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 sofipironium 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 sofipironium 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 sofipironium 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. During the three months ended March 31, 2022, prior to entering into the Asset Purchase Agreement, we recognized royalty revenue of \$0.1 million under the Kaken Agreement.

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

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

The Asset Purchase Agreement also provides that Botanix will pay to us a portion of the sales-based milestone payments and royalties that Botanix receives from Kaken under the assigned Kaken Agreement (together, the “Sublicense Income”). Sublicense Income represents our estimate of payments that will be earned by us in the applicable period from sales-based milestone payments and royalties Botanix will receive from Kaken to the

extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Royalties vary based on net sales that are impacted by a wide variety of market and other factors. We have recorded a contract asset equal to the amount of revenue recognized related to the Sublicense Income, less the amount of payments received from or due by Botanix in relation to the Sublicense Income.

All other consideration due under the Asset Purchase Agreement is contingent upon certain regulatory approvals and future sales subsequent to such regulatory approvals, or is based upon future sales that we determined are not yet probable due to such revenues being highly susceptible to factors outside of our influence and uncertainty about the amount of such consideration that will not be resolved for an extended period of time. Therefore, we determined that such variable consideration amounts are fully constrained as of March 31, 2023, and, as such, did not recognize such amounts as contract revenue.

Transition Services Agreement with Botanix

In connection with the sale of the Assets, on the Effective Date, we and Botanix entered into a transition services agreement (the “TSA”) whereby we are providing consulting services as an independent contractor to Botanix in support of and through filing and potential approval of the U.S. NDA for sofipironium 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 are receiving 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. During the three months ended March 31, 2023, we recognized \$9 thousand of contract revenue associated with consulting services provided under the TSA.

Agreements with Bodor

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

Pursuant to the terms of the Asset Purchase Agreement, we retained our obligation under the Amended and Restated License Agreement to issue \$1.0 million in shares of our common stock to Bodor upon the FDA’s acceptance of an NDA filing for sofipironium 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, 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 three months ended March 31, 2023 and 2022, no expense was incurred or reported as general and administrative expenses in the condensed consolidated statements of operations associated with achieved milestones related to sofipironium bromide gel, 15%. 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 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. No warrants associated with the October 2020 Offering were exercised during the three months ended March 31, 2023 or 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. No warrants associated with the June 2020 Offering were exercised during the three months ended March 31, 2023 or 2022.

For additional information regarding the offerings described above, see Note 6. "Capital Stock" of the notes to our condensed consolidated financial statements included in this Quarterly 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 three months ended March 31, 2023, we sold 2,887,535 shares of

common stock under the 2021 ATM Agreement at a weighted-average price of \$2.34 per share, for aggregate net proceeds of \$6.6 million, after giving effect to a 3% commission to the Agents. During the three months ended March 31, 2022, no sales of common stock under the 2021 ATM Agreement occurred. As of March 31, 2023, approximately \$38.0 million of shares of common stock were remaining, but had not yet been sold 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. As of March 31, 2023, approximately \$2.6 million of shares of common stock were remaining, but had not yet been sold under the 2020 ATM Agreement, however, the shares that may be sold pursuant to the 2020 ATM Agreement are not currently registered under the Securities Act of 1933, as amended. During the three months ended March 31, 2023 and 2022, no sales of common stock under the 2020 ATM Agreement occurred.

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 three months ended March 31, 2023 or 2022.

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 three months ended March 31, 2023 and 2022, no sales of common stock under the Purchase Agreement occurred. As of March 31, 2023, 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 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 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 ECLOCK 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 \$4.3 million and \$9.4 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of \$170.7 million. We expect to continue incurring significant expenses and operating losses for at least the next several years as we:

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

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

Our Board and executive management team are conducting a comprehensive process to explore and evaluate strategic options to progress the development of our novel pipeline of potential treatments for autoimmune, inflammatory, and other diseases. Potential strategic options to be explored or evaluated as part of this process

may include, but are not limited to, a financing, sale or licensing of assets, acquisition, merger, business combination, and/or other strategic transaction or series of related transactions involving our Company. To continue developing FRTX-02 and the rest of our pipeline, we need to raise additional funds. If such financing or a strategic partnership is not forthcoming in a timely manner, we will be unable to conduct certain additional research and development activities.

Key Components of Operations

Revenue

Revenue generally consists of revenue recognized under our strategic agreements for the development and commercialization of our product candidates. Our strategic agreements generally outline overall development plans and include payments we receive at signing, payments for the achievement of certain milestones, sublicense income, earnout payments on net product sales, and royalties on net product sales. For these activities and payments, we utilize judgment to assess the nature of the performance obligations to determine whether the performance obligations are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. Prior to entering into the Asset Purchase Agreement, we recognized royalty revenue earned on a percentage of net sales of ECCLOCK in Japan. Beginning in the second quarter of 2022, we began recognizing contract revenue pursuant to the terms of the Asset Purchase Agreement. After March 31, 2023, 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. 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.

Total Other Income (Expense), Net

Other income (expense), 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 condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). The preparation of these condensed 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 condensed 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.

There were no changes during the three months ended March 31, 2023 to our critical accounting estimates as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022. For information on our significant accounting policies, please refer to Note 2 of the notes to our condensed consolidated financial statements included elsewhere in this Quarterly Report.

Recent Accounting Pronouncements

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 condensed consolidated financial statements upon adoption.

Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

	Three Months Ended March 31,		Change
	2023	2022	
	(in thousands)		
Revenue	\$ 9	\$ 92	\$ (83)
Research and development expenses	(1,936)	(6,013)	4,077
General and administrative expenses	(2,414)	(3,486)	1,072
Other income (expense), net	65	(3)	68
Net loss attributable to common stockholders	<u>\$ (4,276)</u>	<u>\$ (9,410)</u>	<u>\$ 5,134</u>

Revenue

Revenue decreased by approximately \$0.1 million for the three months ended March 31, 2023 compared to the three months ended March 31, 2022. Revenue for the three months ended March 31, 2023 primarily consisted of contract revenue recognized for services provided under the TSA with Botanix, while revenue for the three months ended March 31, 2022 was driven by royalty revenue earned on a percentage of net sales of ECCLOCK in Japan under the Kaken Agreement.

Research and Development Expenses

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

	Three Months Ended March 31,		Change
	2023	2022	
(in thousands)			
Direct program expenses related to			
Sofpironium bromide	\$ —	\$ 2,168	\$ (2,168)
DYRK1A inhibitor program (FRTX-02)	936	728	208
STING inhibitor program (FRTX-10)	102	2,010	(1,908)
Personnel and other unallocated expenses	898	1,107	(209)
Total research and development expenses	<u>\$ 1,936</u>	<u>\$ 6,013</u>	<u>\$ (4,077)</u>

Research and development expenses decreased by \$4.1 million for the three months ended March 31, 2023 compared to the three months ended March 31, 2022, driven primarily by lower clinical expenses of \$2.2 million related to sofipironium bromide, decreased costs of \$1.9 million related to our STING inhibitor program, and lower personnel and other unallocated expenses of \$0.2 million, partially offset by increased costs of \$0.2 million related to our DYRK1A inhibitor program. Additional detail on our programs is as follows:

- *Sofpironium bromide.* In the fourth quarter of 2021, we completed our Phase 3 pivotal clinical program for sofipironium bromide gel, 15%. While we incurred \$2.2 million during the three months ended March 31, 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 sofipironium bromide subsequent to the Effective Date, when we sold the assets primarily related to sofipironium bromide that we previously owned and/or licensed to Botanix, which is responsible for all further research, development, and commercialization of sofipironium bromide.
- *DYRK1A inhibitor program.* In May 2022, we initiated a Part 1 of a two-part Phase 1 clinical trial in Canada for FRTX-02 that was completed in December 2022, and we reported topline results in March 2023, described above under the heading “*Topline Results of FRTX-02 (Phase 1 Part A and B) Clinical Trial.*”
- *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 incurred during the three months ended March 31, 2022.
- *Personnel and other unallocated expenses.* Personnel and other expenses include operating expenses related to research and development activities not specifically attributable to a specific program. Other expenses include travel, office supplies, license fees, and other miscellaneous expenses. These expenses vary over time depending on the development phase of the assets, the timing of acquisition or disposition of the assets, and other variables inherent in carrying out preclinical and clinical studies.

General and Administrative Expenses

General and administrative expenses decreased by \$1.1 million for the three months ended March 31, 2023, compared to the three months ended March 31, 2022. The decrease of \$1.1 million was primarily related to

decreased expenses in the 2023 period of \$0.6 million for legal and compliance fees, \$0.3 million for other expenses, and \$0.2 million for compensation-related expenses.

Total Other Income (Expense), Net

Total other income (expense), net increased by \$0.1 million for the three months ended March 31, 2023 compared to the three months ended March 31, 2022. The increase was primarily due to higher interest rates associated with interest income earned on money market funds and interest-bearing accounts.

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 three months ended March 31, 2023 and 2022, we had a net loss of \$4.3 million and \$9.4 million, respectively. As of March 31, 2023, we had an accumulated deficit of \$170.7 million. As of March 31, 2022, we had cash and cash equivalents of \$10.8 million compared to \$8.7 million as of December 31, 2022. 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 March 31, 2023 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. 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:

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (4,485)	\$ (9,540)
Financing activities	6,569	(55)
Total	<u>\$ 2,084</u>	<u>\$ (9,595)</u>

Operating Activities

Net cash used in operating activities of \$4.5 million during the three months ended March 31, 2023 decreased compared to \$9.5 million during the three months ended March 31, 2022, primarily as a result of 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 \$5.1 million decrease was impacted by the net effect of a decrease in net loss of \$5.1 million and the net effect of changes in working capital of \$0.1 million, partially offset by a decrease in non-cash operating expenses of approximately \$0.1 million.

Financing Activities

Net cash provided by financing activities during the three months ended March 31, 2023 increased by \$6.6 million compared to the three months ended March 31, 2022. The increase primarily resulted from net proceeds received during the three months ended March 31, 2023 of \$6.6 million from sales of our common stock under the 2021 ATM Agreement.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and are not required to provide the information under this item.

ITEM 4. CONTROLS AND PROCEDURES

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 Quarterly Report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective and were operating at a reasonable assurance level as of March 31, 2023.

Changes in Internal Control over Financial Reporting

Management has determined that there were no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. 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 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 in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022 under the heading “Risk Factors.” 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. There have been no changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2022, except as set forth below.

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 “2022 Notice”) from the Listing Qualifications Department of the Nasdaq Stock Market (“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 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 two independent members.

The 2022 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.

On April 21, 2023, Mr. Lyons informed us that he will resign from the Board on the date of our 2023 annual meeting of stockholders due to overboarding concerns under proxy advisor and other institutional investor policies. The date of our 2023 annual meeting of stockholders has not yet been determined.

In addition, on April 24, 2023, we received a notice from the Listing Qualifications Department of Nasdaq informing us that because the closing bid price for our common stock listed on Nasdaq was below \$1.00 per share for 30 consecutive business days, we do not comply with the minimum closing bid price requirement for continued listing on The Nasdaq Capital Market under Nasdaq Marketplace Rule 5550(a)(2). In accordance with Nasdaq’s Listing Rules, we have a period of 180 calendar days, or until October 23, 2023, to regain compliance with such rule.

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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Because we are filing this Quarterly Report within four business days after the triggering event, we are making the following disclosure under this Item 5 instead of filing a Current Report on Form 8-K under Item 1.02, Termination of a Material Definitive Agreement:

On May 4, 2023, we entered into an amendment to the Boulder Lease with BRE-BMR Flatiron VII, LLC, which amendment will terminate the Boulder Lease, effective August 31, 2023, in exchange for a termination fee of \$5,051. The Boulder Lease, which would have expired in December 2025, is a multi-year lease for our corporate headquarters in Boulder, Colorado, occupying approximately 3,000 square feet. Pursuant to the Boulder Lease, we currently pay base rent of \$7,089 per month, plus our pro rata share of operating expenses. We are terminating the Boulder Lease to reduce our operating expenses.

ITEM 6. EXHIBITS

Exhibit Number	Description of Exhibit	Form	Date of Filing	Exhibit Number	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation, as amended through September 6, 2022	8-K	9/8/2022	3.2	
3.2	Amended and Restated Bylaws, as amended through September 6, 2022	10-Q	11/14/2022	3.2	
10.1+	Transition and Release Agreement, by and between Fresh Tracks Therapeutics, Inc. and Robert B. Brown, dated as of February 1, 2023	8-K	2/7/2023	10.1	

10.2	Consulting Agreement, by and between Fresh Tracks Therapeutics, Inc. and Dancing Bear Consulting, LLC, effective as of January 31, 2023	8-K	1/27/2023	10.1	
10.3+	Amended and Restated Employment Agreement by and between Fresh Tracks Therapeutics, Inc. and Brickell Subsidiary, Inc., on the one hand, and Andrew D. Sklawer, on the other hand, including the form of Non-Competition Agreement with Andrew D. Sklawer, dated as of February 21, 2023	8-K	2/24/2023	10.1	
10.4+	Amended and Restated Employment Agreement by and between Fresh Tracks Therapeutics, Inc. and Brickell Subsidiary, Inc., on the one hand, and Deepak Chadha, on the other hand, including the form of Non-Competition Agreement with Deepak Chadha, dated as of February 21, 2023	8-K	2/24/2023	10.2	
10.5+	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-K	3/30/2023	10.27	
10.6+	Form of Employee Retention Bonus Agreement	8-K	2/24/2023	10.3	
10.7+	Form of Indemnification Agreement by and between the Company and its directors and executive officers	10-K	3/30/2023	10.21	
10.8+	Separation and Release Agreement, by and between Fresh Tracks Therapeutics, Inc. and Brickell Subsidiary, Inc., on the one hand, and Monica Luchi, on the other hand, dated as of January 19, 2023	10-K/A	5/1/2023	10.29	
10.9	Letter Agreement, dated as of May 4, 2023, by and between Fresh Tracks Therapeutics, Inc. and BRE-BMR Flatiron VII LLC (f/k/a GPIF 5777 Flatiron LLC and BMC Properties, LLC)				×
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended				×
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended				×
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				×
101.INS	Inline XBRL Instance Document				×
101.SCH	Inline XBRL Taxonomy Extension Schema Document				×
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				×
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				×
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				×

101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	×
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	×

+ Indicates a management contract or compensatory plan.

* 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Quarterly Report to be signed on its behalf by the undersigned thereunto duly authorized.

Fresh Tracks Therapeutics, Inc.

Date: May 10, 2023

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

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

BRE-BMR Flatiron VII LLC

4570 Executive Drive, Suite 400 • San Diego, CA 92121
Phone: (858) 485-9840 • Facsimile: (858) 485-9843

May 4, 2023

Fresh Tracks Therapeutics, Inc. 5777 Central Avenue, Suite 102
Boulder, CO 80301

Re: Letter Agreement

Dear Andy:

This letter agreement (this "Letter Agreement") is made in connection with that certain Fifth Amendment to Lease dated as of December 29, 2022 (the "Fifth Amendment"), by and between BRE-BMR FLATIRON VII LLC ("BMR") and FRESH TRACKS THERAPEUTICS, INC. ("Fresh Tracks"), with respect to certain premises at 5777 Central Avenue in Boulder, Colorado. Capitalized terms used, but not defined, in this Letter Agreement shall have the meanings ascribed to them in the Fifth Amendment.

By executing this Letter Agreement, BMR and Fresh Tracks hereby agree that Article 13 of the Fifth Amendment is hereby amended as follows:

- Termination Date: The Termination Date is amended to be **August 31, 2023**.
- Exercise of Termination Option: Fresh Tracks is hereby deemed to have irrevocably exercised the Termination Option, and BMR is hereby deemed to have accepted Fresh Tracks' irrevocable exercise of the Termination Option. Accordingly, the Lease shall terminate on the Termination Date pursuant to the terms, conditions and provisions of Section 13.3 of the Fifth Amendment.
- Termination Fee: Fresh Tracks shall pay to BMR the Termination Fee, which Termination Fee shall equal \$5,050.68, within 10 business days after the date of this Letter Agreement. Fresh Tracks' obligation to pay the Termination Fee shall survive the expiration or earlier termination of the Lease.

Except as expressly set forth above, all other terms, conditions and provisions of Article 13 of the Fifth Amendment shall remain unmodified and in full force and effect. In the event of any conflict between the terms of this Letter Agreement and the terms of Article 13 of the Fifth Amendment, the terms of this Letter Agreement shall control.

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Andrew D. Sklawer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Fresh Tracks Therapeutics, Inc., a Delaware corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2023

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

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Albert N. Marchio, II, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Fresh Tracks Therapeutics, Inc., a Delaware corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2023

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

SECTION 1350 CERTIFICATION

Each of the undersigned, Andrew D. Sklawer, Chief Executive Officer of Fresh Tracks Therapeutics, Inc., a Delaware corporation (the “Company”), and Albert N. Marchio, II, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Andrew D. Sklawer

Andrew D. Sklawer
Chief Executive Officer
(Principal Executive Officer)
Date: May 10, 2023

/s/ Albert N. Marchio, II

Albert N. Marchio, II
Chief Financial Officer
(Principal Financial Officer)
Date: May 10, 2023

This certification accompanies and is being “furnished” with this Report, shall not be deemed “filed” by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.