Filed Pursuant to Rule 424(b)(3)
Registration No. 333-261383

PROSPECTUS SUPPLEMENT NO. 6
(to prospectus dated April 6, 2022)

Up to 20,406,908 Shares of Common Stock

This prospectus supplement no. 6 (this "prospectus supplement") amends and supplements the prospectus dated April 6, 2022 (as supplemented or amended from time to time, the "Prospectus") which forms a part of our Registration Statement on Form S-1, as amended (Registration Statement No. 333-261383). This prospectus supplement is being filed to update and supplement the information included or incorporated by reference in the Prospectus with the information contained in our Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission (the "SEC") on August 11, 2022 (the "Form 10-Q"). Accordingly, we have attached the Form 10-Q to this prospectus supplement.

This prospectus supplement updates and supplements the information in the Prospectus and is not complete without, and may not be delivered or utilized except in combination with, the Prospectus, including any amendments or supplements thereto. This prospectus supplement should be read in conjunction with the Prospectus and if there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement.

Our common stock is listed on The NASDAQ Stock Market LLC under the symbol "BTTX". On August 10, 2022, the closing price of our common stock was $1.79 per share.

Investing in our securities involves risks that are described in the "Risk Factors" section beginning on page 11 of the Prospectus.

Neither the SEC nor any state securities commission has approved or disapproved of the securities to be issued under the Prospectus or

determined if the Prospectus or this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is August 11, 2022.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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 June 30, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39864

BETTER THERAPEUTICS, INC.

Delaware	**85-3472546**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
548 Market St. #49404 **San Francisco, CA**	**94101**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 887-2311

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	BTTX	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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

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

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

As of August 5, 2022, the registrant had 23,743,037 shares of common stock, $0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

BETTER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)
(Unaudited)

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,685	$ 40,566
Prepaid expenses	2,380	4,409
Other current assets	72	276
Total current assets	32,137	45,251
Capitalized software development costs, net	4,364	5,077
Property and equipment, net	115	82
Other long-term assets	487	548
Total Assets	$ 37,103	$ 50,958
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,088	$ 1,523
Accrued payroll	2,074	1,352
Other accrued expenses	1,196	1,858
Current portion of long-term debt	1,783	—
Total current liabilities	6,141	4,733
Long-term debt, net of current portion and debt issuance costs	12,908	9,505
Total liabilities	19,049	14,238
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized as of June 30, 2022 and December 31, 2021 and 23,732,970 and 23,602,718 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	109,385	108,461
Accumulated deficit	(91,333)	(71,743)
Total Stockholders' Equity	18,054	36,720
Total Liabilities and Stockholders' Equity	$ 37,103	$ 50,958

The accompanying notes are an integral part of these Financial Statements.

BETTER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 4,241	$ 5,038	$ 7,914	$ 6,416
Sales and marketing	1,683	564	3,727	607
General and administrative	3,675	872	7,303	2,439
Total operating expenses	9,599	6,474	18,944	9,462
Loss from operations	(9,599)	(6,474)	(18,944)	(9,462)
Interest expense, net	(329)	(1)	(646)	(2)
Change in fair value of SAFEs	—	(2,821)	—	(5,313)
Gain on loan forgiveness	—	647	—	647
Loss before provision (benefit) from income taxes	(9,928)	(8,649)	(19,590)	(14,130)
Provision (benefit) from income taxes	—	1	—	(150)
Net loss	(9,928)	(8,650)	(19,590)	(13,980)
Cumulative preferred dividends allocated to Series A Preferred Shareholders	—	(394)	—	(782)
Net loss attributable to common shareholders, basic and diluted	$ (9,928)	$ (9,044)	$ (19,590)	$ (14,762)
Net loss per share attributable to common shareholders, basic and diluted	$ (0.42)	$ (0.84)	$ (0.83)	$ (1.38)
Weighted-average shares used in computing net loss per share	23,592,995	10,730,818	23,498,978	10,707,996

The accompanying notes are an integral part of these Financial Statements.

BETTER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2021	23,602,718	$ 2	$ 108,461	$ (71,743)	$ 36,720
Net loss	—	—	—	(9,662)	(9,662)
Issuance of common stock	5,882	—	1	—	1
Share based compensation	—	—	366	—	366
Balance as of March 31, 2022	23,608,600	$ 2	$ 108,828	$ (81,405)	$ 27,425
Net Loss	—	—	—	(9,928)	(9,928)
Issuance of common stock	124,370	—	145	—	145
Share based compensation	—	—	412	—	412
Balance as of June 30, 2022	23,732,970	$ 2	$ 109,385	$ (91,333)	$ 18,054

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2020, as adjusted	11,146,510	$ 1	$ 24,649	$ (31,408)	$ (6,758)
Net loss	—	—	—	(5,330)	(5,330)
Forfeiture of restricted stock	(444)	—	—	—	—
Share based compensation	—	—	34	—	34
Balance as of March 31, 2021, as adjusted	11,146,066	$ 1	$ 24,683	$ (36,738)	$ (12,054)
Net loss	—	—	—	(8,650)	(8,650)
Forfeiture of restricted stock	(51,818)	—	—	—	-
Share based compensation	—	—	28	—	28
Balance as of June 30, 2021, as adjusted	11,094,248	$ 1	$ 24,711	$ (45,388)	$ (20,676)

The accompanying notes are an integral part of these Financial Statements.

BETTER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Six months ended June 30,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (19,590)	$ (13,980)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,314	542
Change in fair value of SAFEs	—	5,313
Share based compensation expense	778	62
Deferred income taxes	—	(152)
Loss on write-off of property and equipment	9	—
Gain on loan forgiveness	—	(647)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	2,294	(1,308)
Accounts payable	(435)	890
Accrued expenses and other liabilities	60	1,181
Net cash used in operating activities	(15,570)	(8,099)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(69)	—
Capitalized internal-use software costs	(388)	(581)
Net cash used in investing activities	(457)	(581)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of SAFE notes	—	10,675
Proceeds from exercise of common stock options	21	—
Proceeds from the issuance of shares under the employee stock purchase plan	125	—
Proceeds from the issuance of long-term debt	5,000	—
Net cash provided by financing activities	5,146	10,675
Net change in cash and cash equivalents	(10,881)	1,995
Cash and cash equivalents, beginning of period	40,566	123
Cash and cash equivalents, end of period	$ 29,685	$ 2,118
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 462	$ —
Cash paid for taxes	$ —	$ —

The accompanying notes are an integral part of these Financial Statements.

Note 1. Description of Business and Summary of Significant Accounting Policies

Description of Business

Better Therapeutics, Inc. (“we”, “us”, “the Company”, or “Better”), a Delaware corporation, is a prescription digital therapeutics company developing nutritional cognitive behavioral therapy ("nCBT") to address the root causes of cardiometabolic diseases. We are developing a platform of FDA-regulated, software-based, prescription digital therapeutics ("PDTs") for treating diabetes, heart disease, and other cardiometabolic conditions that share lifestyle behaviors as common root causes. Our PDTs deliver a novel form of cognitive behavioral therapy that enables changes in neural pathways of the brain so that lasting changes in behavior become possible. Addressing the underlying causes of these diseases has the potential to dramatically improve patient health and lower healthcare costs. Our clinical development candidates are intended to treat cardiometabolic diseases, including type 2 diabetes ("T2D"), hypertension, hyperlipidemia, non-alcoholic fatty liver disease ("NAFLD"), non-alcoholic steatohepatitis ("NASH") and chronic kidney disease ("CKD"). Our lead product candidate for the treatment of patients with T2D, BT-001, completed a first-in-class randomized, controlled clinical trial of a prescription digital therapeutic for the treatment of in July 2022. The trial met both its primary and secondary endpoints showing statistically significant and clinically meaningful, durable decreases in blood sugar, when compared to a control group receiving standard of care. In addition, exploratory data revealed a host of cardiometabolic improvements as well as lower medication utilization compared to the control group.

On October 28, 2021, Mountain Crest Acquisition Corp. II, a Delaware corporation ("MCAD") merged with and into former Better Therapeutics, Inc. ("Legacy BTX") with Legacy BTX surviving as a wholly-owned subsidiary of the acquiring company with the new name Better Therapeutics, Inc. MCAD consummated the acquisition of all the issued and outstanding shares of Legacy BTX. Accordingly, for accounting purposes, the financial statements of the combined entity represent a continuation of the financial statements of Better with the business combination being treated as the equivalent of Legacy BTX issuing stock for the net assets of MCAD, accompanied by a recapitalization. The net assets of MCAD are stated at fair value with no goodwill or other intangible assets recorded. Operations prior to the merger are those of Legacy BTX.

As a result of the Business Combination, the shares and corresponding capital amounts and loss per share related to Legacy BTX's outstanding convertible preferred stock and common stock prior to the Business Combination have been retroactively restated to reflect the exchange ratio established in the Merger Agreement. For additional information on the Business Combination, refer to Note 2 of these financial statements.

We are a remote, "fully distributed" company, and do not have offices.

Basis of Presentation

The financial statements and accompanying notes have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and applicable rules and regulations of the Securities and Exchange Commission (“SEC”) regarding interim financial reporting. Certain information and disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments consisting of normal recurring accruals considered necessary for fair presentation have been included. Operating results for the three and six months ended June 30, 2022 are not necessarily indicative of the results that may be expected for the year ended December 31, 2022. Accordingly, these interim financial statements should be read in conjunction with the audited financial statements and accompanying notes for the years ended December 31, 2021 and 2020.

Reclassification

Certain prior year amounts have been reclassified for consistency with the current period presentation. An adjustment has been made to the Statement of Operations and Comprehensive Loss for the three and six months ended June 30, 2021 to reclassify $142 and $297 thousand of cost of sales into research and development expense to align with industry standards, respectively. This change in classification does not affect previously reported net loss in the Statement of Operations and Comprehensive Loss.

Emerging Growth Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until such time as those standards apply to private companies. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we do not adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies until required by private company accounting standards.

Liquidity and Capital Resources

The Company is in the development stage and our activities have consisted principally of raising capital and performing research and development. Since inception we have incurred significant losses from operations. As of June 30, 2022, we had cash of $29.7 million and an accumulated deficit of $91.3 million. We incurred a net loss of $19.6 million and used $15.6 million of cash in operating activities during the six months ended June 30, 2022. Our primary use of cash is to fund operating expenses, which consist of research and development expenses related to our lead product candidate, BT-001, preclinical programs and general and administrative expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We have incurred negative cash flows from operating activities and investing activities and significant losses from operations in the past. We expect to incur substantial expenses in the foreseeable future for the development and potential commercialization of our product candidates and ongoing internal research and development programs. At this time, we cannot reasonably estimate the nature, timing or aggregate amount of costs for our development, potential commercialization, and internal research and development programs. However, in order to complete our planned product development, and to complete the process of obtaining regulatory authorization or clearance for our product candidates, as well as to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding in the future. In the event that additional financing is required from outside sources, we may not be able to raise it on terms acceptable to us, or at all. If we are unable to raise additional capital when desired, our business, results of operations, and financial condition would be adversely affected. Under our current operating plan, we believe we have sufficient capital to fund our operations into the first quarter of 2023. These factors raise substantial doubt regarding the Company's ability to continue as a going concern.

Significant Risks and Uncertainties

The Company is subject to those risks common in its industry and also those risks common to early-stage companies including, but not limited to, the possibility of not being able to successfully develop or market its products, technological obsolescence, competition, dependence on key personnel, the successful protection of its proprietary technologies, compliance with government regulations, and the possibility of not being able to obtain additional financing when needed.

At this time, there remains uncertainty relating to the ongoing COVID-19 pandemic and the impact of related responses. Any impact of COVID-19 on our business, results of operations and financial condition will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make certain estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities and the related disclosures at the date of the financial statements, as well as the reported amounts of revenue and expenses during the periods presented. The estimates and assumptions used in the accompanying financial statements are based upon management's evaluation of the relevant facts and circumstances. Such estimates, judgments, and assumptions include estimated costs for capitalized internal-use software, fair values of stock-based awards, valuation allowance for deferred tax assets and fair value of SAFEs. Actual results could be different from these estimates. To the extent there are material differences between these estimates, judgments, or assumptions and actual results, our financial statements will be affected.

Net Loss Per Share Attributable to Common Stockholders

Basic and diluted net loss per share attributable to common stock is presented in conformity with the two-class method required for participating securities. Under the two-class method, the net loss attributable to common stock is not allocated to the preferred stock as the holders of our convertible preferred stock did not have a contractual obligation to share in our losses. Under the two-class method, net loss is attributed to common stock and participating securities based on their participation rights. Basic net loss per share attributable to common stock is computed by dividing the net loss attributable to common stock by the weighted-average number of shares of common stock outstanding during the period. Cumulative dividends attributable to participating securities are subtracted from net loss in determining net loss attributable to common stockholders. As we have reported net losses for all periods presented, all potentially dilutive securities are anti-dilutive and, accordingly, basic net loss per share equals diluted net loss per share.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which modifies lease accounting for lessees to increase transparency and comparability by recording lease assets and liabilities for operating leases and disclosing key information about leasing arrangements. In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases, and ASU No. 2018-11, Leases (Topic 842), Targeted Improvements, which affect certain aspects of the previously issued guidance. In December 2018, the FASB issued ASU No. 2018-20, Narrow-Scope Improvements for Lessor, Leases (Topic 842), which provides guidance on sales tax and other taxes collected from lessees. In December 2019, the FASB issued ASU No. 2019-01, Codification Improvements to Topic 842, Leases, which affect certain aspects of the previously issued guidance. Amendments include an additional transition method that allows entities to apply the new standard on the adoption date and recognize a cumulative effect adjustment to the opening balance of retained earnings, as well as a new practical expedient for lessors.

We adopted ASC 842 on January 1, 2022. The adoption of this guidance did not have any impact on our financial statements.

Note 2. Business Combination

On April 6, 2021, the Company entered into a merger agreement with MCAD, a special purpose acquisition company. In connection with the merger agreement, MCAD entered into subscription agreements (the "Subscription Agreements") dated as of April 6, 2021, with certain institutional and accredited investors, pursuant to which, among other things, MCAD agreed to issue and sell, in a private placement immediately prior to the closing of the Business Combination, an aggregate of 5.0 million shares of Common Stock for $10.00 per share (the "PIPE Shares").

On October 28, 2021, pursuant to the terms of the merger agreement, we completed the merger with MCAD. We raised $59 million in funding upon the completion of the merger with MCAD. Under the merger Agreement, MCAD acquired all of the outstanding shares of Legacy BTX in exchange for 15.2 million shares of MCAD. In connection with the merger, MCAD was renamed Better Therapeutics, Inc.

We accounted for the business combination as a reverse recapitalization, which is the equivalent of Legacy BTX issuing stock for the net assets of MCAD, accompanied by a recapitalization, with MCAD treated as the acquired company for accounting purposes. The determination of MCAD as the "acquired" company for accounting purposes was primarily based on the fact that subsequent to the business combination, Legacy BTX has a majority of the voting power of the combined company, Legacy BTX will comprise all of the ongoing operations of the combined entity, a majority of the governing body of the combined company and Legacy BTXs' senior management will comprise all of the senior management of the combined company. The net assets of MCAD were stated at historical cost with no goodwill or other intangible assets recorded. Reported results from operations included herein prior to the business combination are those of Legacy BTX. The shares and corresponding capital amounts and loss per share related to Legacy BTXs' outstanding redeemable convertible preferred stock, redeemable convertible common stock and common stock prior to the business combination have been retroactively restated to reflect the exchange ratio established in the business combination of .9475.

In connection with the business combination, we incurred underwriting fees and other costs considered direct and incremental to the transaction totaling $16.7 million consisting of legal, accounting, financial advisory and other professional fees.

PIPE Financing (Private Placement)

Concurrent with the execution of the Business Combination Agreement, we entered into subscription agreement with MCAD. Pursuant to the Subscription Agreements, each PIPE Investor subscribed for and purchased, and MCAD issued and sold to such investors an aggregate of 5 million shares of MCAD Common Stock for a purchase price of $10.00 per share, for aggregate gross proceeds of $50.0 million (the PIPE Financing).

We received $9,485 million of MCAD cash and cash held in trust for net proceeds of $42,761. In addition, we also assumed $43 thousand of prepaid assets and $245 thousand of accrued liabilities upon the closing of the business combination.

Note 3. Debt

On May 9, 2020 (the "Origination Date"), the Company received $640 thousand in aggregate loan proceeds (the "PPP Loan") from Celtic Bank Corporation (the "Lender") pursuant to the Paycheck Protection Program established under the CARES Act (the Coronavirus Aid, Relief, and Economic Security Act) of 2020. Payments of principal and interest were deferred for the first ten months following the Origination Date, and the PPP Loan was maturing in two years after the Origination Date. Following the deferral period, the Company was required to make payments of principal and interest accrued under the PPP Loan in monthly installments of $36 thousand and taking into consideration any portion of the PPP Loan that may be forgiven prior to that time. The PPP Loan bore interest at 1%. On December 30, 2020, the Company applied for loan forgiveness under the CARES Act and received approval of loan forgiveness in May 2021. As a result, the Company recorded a gain on loan forgiveness on the statements of operations and comprehensive loss and removed the balance from long-term debt on the balance sheet in the second quarter of 2021.

On August 18, 2021, we entered into a $50.0 million secured term loan agreement with Hercules Capital, Inc. (“Hercules Capital”). The term loan has a maturity date of August 1, 2025, which can be extended to February 1, 2026, and is secured by substantially all of our assets. Payments due for the term loan are interest-only until March 1, 2023 (subject to extension to September 1, 2023 or September 1, 2024 upon the achievement of certain milestones), after which principal shall be repaid in equal monthly installments. Interest is payable monthly in arrears. The outstanding principal bears interest at the greater of (a) 8.95% or (b) 8.95% plus the prime rate minus 3.25%. Prepayment of the outstanding principal is permitted under the secured term loan agreement and subject to certain prepayment fees. The Company incurred $518 thousand of debt issuance costs related to the borrowings under the secured term loan agreement. Debt issuance costs are being amortized through the maturity date of the secured loan and are reported as direct reduction of long-term debt on the balance sheet. In addition, we will be required to pay an end of term charge of the greater of (a) $893 thousand or (b) 5.95% of the aggregate outstanding principal upon repayment of the loan. The end of term charge is being accrued as additional interest expense using the effective interest method over the term of the loan. The secured term loan agreement contains customary representations, warranties, non-financial covenants, and events of default. We are permitted to borrow the loans in four tranches based on the completion of certain milestones which include, as set forth more fully in the secured term loan agreement: (i) $15.0 million upon the closing of the Business Combination, (ii) $10.0 million when we achieve certain positive clinical trial results sufficient to submit a de-novo classification request with respect to BT-001 and have initiated a second pivotal trial prior to September 15, 2022, (iii) $10.0 million when we have received FDA approval for such marketing of BT-001 for the improvement of glycemic control in people with T2D and received, prior to March 15, 2023, net cash proceeds of at least $40.0 million dollars from equity financings, and (iv) $15.0 million on or before June 15, 2023, subject to Hercules Capital's approval. In October 2021, we borrowed $10.0 million under our secured term loan agreement. In May 2022, we borrowed $5.0 million under our secured term loan agreement. As of June 30, 2022 and December 31, 2021 the outstanding debt balance, net of unamortized debt issuance costs was $14.7 million and $9.5 million, respectively. As of June 30, 2022 the interest rate was 10.45% and there was $127 thousand of accrued interest in other accrued liabilities.

Note 4. SAFE Agreements

Beginning in 2020, the Company issued Simple Agreements for Future Equity ("SAFEs") to fund its operations. The SAFEs included a provision allowing for cash redemption upon the occurrence of a change of control, the occurrence of which is outside the control of the Company. Therefore, the SAFEs were classified as marked-to-market liabilities, pursuant to ASC 480, in other long-term liabilities.

The SAFEs were marked to fair value as of June 30, 2021 resulting in a change in fair value reported as a loss of $2.8 million and $5.3 million for the three and six months ended June 30, 2021.

On October 28, 2021 in connection with the business combination all SAFEs were converted to common stock.

Note 5. Fair Value Measurements

The Company measures and reports certain financial instruments as assets and liabilities at fair value on a recurring basis.

The Company’s SAFE agreements were historically recorded at fair value in our balance sheet. The fair value of the Company’s SAFE agreements was based on significant inputs not observable in the market which cause the instrument to be classified as Level 3 measurements within the fair value hierarchy. We measured financial assets and liabilities at fair value at each reporting period using a fair value hierarchy that required the use of observable inputs and minimized the use of unobservable inputs. We define fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company assessed these assumptions and estimates on an on-going basis as additional data impacting the assumptions and estimates were obtained. Changes in the fair value of the SAFE agreements were recognized within the statement of operations and comprehensive loss. The fair value of the Company’s SAFE agreements was zero as of June 30, 2022 and December 31, 2021, respectively. As of June 30, 2022 and December 31, 2021, the Company did not have any other financial assets or liabilities measured at fair value.

Note 6. Net Loss Per Share Attributable to Common Stockholders

Series Seed Preferred Stock, Series A Preferred Stock, and common stock are participating securities in the calculation of loss per share as they participate in undistributed earnings on an as-if-converted basis. Basic and diluted earnings per share was the same for each period presented as the inclusion of all potential common stock outstanding would have been anti-dilutive.

The following table sets forth the computation of basic and diluted loss (in thousands, except for share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss	$ (9,928)	$ (8,650)	$ (19,590)	$ (13,980)
Less: Cumulative preferred dividends allocated to Series A preferred stockholders	—	(394)	—	(782)
Net loss attributable to common stockholders, basic and diluted	$ (9,928)	$ (9,044)	$ (19,590)	$ (14,762)
Weighted-average common stock outstanding	23,655,680	11,109,052	23,630,523	11,102,081
Less: weighted-average shares of common stock subject to vesting	(62,685)	(378,235)	(131,545)	(394,086)
Weighted-average shares of common stock outstanding used in the calculation of basic and diluted net loss per share attributable to shareholders	23,592,995	10,730,818	23,498,978	10,707,996
Loss per share attributable to common shareholders, basic and diluted	$ (0.42)	$ (0.84)	$ (0.83)	$ (1.38)

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	Three and Six Months Ended June 30,	
	2022	2021
SAFE agreements	—	3,013,815
Options to purchase common stock	2,718,290	227,125
	2,718,290	3,240,940

Note 7. Share-Based Compensation

In August 2020, we adopted the Better Therapeutics, Inc. 2020 Stock Option and Grant Plan (the “2020 Plan”) to grant equity-based incentives to officers, directors, consultants and employees. The equity-based incentives include Incentive Stock Options, Non-Qualified Stock Options, Restricted Stock Awards, Unrestricted Stock Awards, and Restricted Stock Units. A total of 807 thousand shares of our common stock have been reserved for issuance pursuant to the plan.

In October 2021, we adopted the Better Therapeutics Inc. 2021 Stock Option and Incentive Plan (the "2021 Plan") to grant equity based incentive to officers, directors, consultants and employees. The equity-based incentives include, Incentive Stock Options, Non-Qualified Stock Options, Stock appreciation rights, Restricted Stock Awards, Restricted Stock Units, Unrestricted Stock Awards, Cash-based Awards and Dividend Equivalent Rights. A total of 3.6 million shares of common stock were initially reserved for issuance. Additionally, on January 1, 2022 and each January 1 thereafter, the number of shares of Common Stock reserved and available for issuance under the Plan shall be cumulatively increased by five percent (5%) of the number of shares of Common Stock issued and outstanding on the immediately preceding December 31, or such lesser number of shares as approved by the Administrator (the “Annual Increase”). On January 1, 2022 the Company added 1.2 million shares to the plan for a total reserved for issuance of 4.8 million shares.

In October 2021, we adopted the Better Therapeutics, Inc. 2021 Employee Stock Purchase Plan (the "ESPP") to provide eligible employees with opportunities to purchase shares of the Company's common stock. A total of 280 thousand shares of common stock were initially been reserved for issuance. Additionally on January 1, 2022 and each January 1 thereafter, the number of shares of Common Stock reserved for issuance under the ESPP shall be cumulatively increased by the lesser of (i) 560 thousand shares of Common stock, (ii) one percent (1%) of the number of shares of Common Stock issued and outstanding on the immediately preceding December 31, or (iii) such lesser number of shares of Common Stock as determined by the Administrator. On January 1, 2022 the Company added 236 thousand shares to the plan for a total reserved for issuance of 516 thousand shares.

Stock Options

Stock options granted generally vest over four years with 25% of the option shares vesting one year from the vesting commencement date and then ratably on a monthly basis over the following 36 months. Options generally expire 10 years from the date of grant. Stock option activity under the Plans for the periods presented is as follows:

	Options Outstanding			
	Shares Subject to Options Outstanding	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance as of December 31, 2021	1,476,475	$ 9.35	9.4	—
Granted	1,515,413	2.20		
Exercised	(49,231)	0.50		
Forfeited	(224,367)	4.21		
Balance as of June 30, 2022	2,718,290	$ 5.94	9.4	$ 124

Aggregate intrinsic value represents the difference between the exercise price and the fair value of the shares underlying common stock.

The weighted-average grant date fair value of stock options granted to employees during the six months ended June 30, 2022, was $2.43 per share. As of June 30, 2022, total unrecognized compensation expense related to unvested stock options was $4.4 million which is expected to be recognized over a weighted-average period of 3.07 years.

The fair value of each option award granted to employees is estimated on the grant date using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the input of subjective assumptions, including the fair value of the underlying common stock, the expected term of the option, the expected volatility of the price of our common stock, risk-free interest rates, and the dividend yield of our common stock. The assumptions used to determine the fair value of the option awards represent our best estimates. These estimates involve inherent uncertainties and the application of our judgment. The related stock-based compensation expense is recognized on a straight-line basis over the requisite service period of the awards, which is generally four years.

The Black-Scholes option pricing model assumptions used in evaluating our awards to employees are as follows:

	Six Months Ended June 30, 2022
Expected Term (Years)	6.03
Expected Volatility	40%
Risk-free interest rate	2.43%
Dividend Yield	—

Restricted Stock

During the six months ended June 30, 2022, 147 thousand were vested and converted into unrestricted common stock. As of June 30, 2022 there were 55 thousand shares of restricted stock outstanding.

Total stock-based compensation expense for time-based restricted stock of $24 thousand is expected to be recognized on a straight-line basis over approximately the next 1.0 years for the unvested restricted stock outstanding as of June 30, 2022.

Employee Stock Purchase Plan

The ESPP enables eligible employees to purchase the Company's common stock at a price per share equal to the lesser of 85% of the fair market value of the common stock at the beginning or end of each 24 month offering period. Each offering period will be divided into four purchase periods. The first offering period commenced on February 15, 2022. During the three months ended June 30, 2022 the Company issued 81 thousand shares in connection with the ESPP. The Company recorded $61 thousand of expense related to the ESPP in the six months ended June 30, 2022.

Equity-Based Compensation Expense

Equity-based compensation expense in the statement of operations is summarized as follows (in thousands):

	Six Months Ended June 30,	
	2022	**2021**
Research and development	$ 316	$ 28
Sales and marketing	31	-
General and administrative	420	34
Total equity-based compensation expense	$ 767	$ 62

For the six months ended June 30, 2022 and 2021, $11 thousand and $3 thousand of stock based compensation expense was included as part of capitalized internal-use software costs, respectively.

Note 8. Income Taxes

The effective tax rate was zero and 1.0% for the six months ended June 30, 2022 and 2021, respectively. The effective tax rate differs from our statutory tax rate of 21%, primarily due to a change in valuation allowance as of June 30, 2022.

Note 9. Commitments and Contingencies

From time to time, we become involved in claims, vendor disputes and other legal matters arising in the ordinary course of business. We investigate these claims as they arise. Although claims are inherently unpredictable, we are currently not aware of any matters that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial position or cash flows. We record liabilities for legal and other contingencies when losses are probable and estimable.

We enter into agreements in the normal course of business with various vendors, which are generally cancelable upon notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of service providers, up to the date of cancellation.

Note 10. Related Party Transactions

In the six months ended June 30, 2022 and 2021, the Company issued zero and $4.7 million in SAFEs to a significant shareholder, respectively. Upon the close of the Business Combination all SAFEs were converted to common stock.

In March 2021, Andrew Armanino, the former chief executive officer of Armanino LLP and close relative to the current chief executive officer of Armanino LLP joined the Company's board of directors. The company used Armanino LLP for tax, valuation and outsourced accounting services. During the six months ended June 30, 2022 and 2021, the Company incurred zero and $198 thousand in fees related to these services, respectively.

Note 11. Subsequent Events

Effective July 5, 2022 Frank Karbe was named Chief Executive Officer of the Company. Mr. Karbe was granted options to purchase 1,652,700 shares of the Company's common stock with various time, performance, and market conditions.

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains "forward-looking statements" which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this Quarterly Report may include, but are not limited to, statements about:

- our ability to obtain funding for our operations;
- our ability to successfully commercialize and market BT-001 and our other product candidates, if approved, and the timing of any commercialization and marketing efforts;
- the initiation, timing, progress, results, safety and efficacy, and cost of our research and development programs and our current and future preclinical studies and trials;
- the rate and degree of market acceptance of BT-001 and our other product candidates by physicians, patients, third-party payors and others in the medical community;
- the willingness of insurance companies to reimburse the use of prescription digital therapeutics ("PDTs");
- the potential benefits of our product candidates;
- our ability to build our own sales and marketing capabilities to commercialize our product candidates, if approved, and to advance awareness of PDTs for the treatment of disease among patients and providers;
- our expectations regarding the sufficiency of our existing cash and cash equivalents to fund our operating expenses and capital expenditure requirements;
- the pricing, reimbursement and cost-effectiveness of our product candidates, if approved;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the effect of the ongoing COVID-19 pandemic on the foregoing;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- regulatory developments in the United States and foreign countries;
- our financial performance; and
- other risks and uncertainties including those discussed in Part II, Item 1A - Risk Factors in this Quarterly Report.

The forward-looking statements contained in this Quarterly Report are based on current expectations and beliefs of the Company and its management concerning future developments and their potential effects on us, and are inherently subject to uncertainties and changes in circumstances. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in Part II, Item 1A - Risk Factors in the Quarterly Report. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of these risks and uncertainties may in the future be amplified by the ongoing COVID-19 pandemic and there may be additional risks that we consider immaterial or which are unknown. It is not possible to predict or identify all such risks. The forward-looking statements contained in this Quarterly Report speak only as of the date of such statement. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Overview

Better Therapeutics, Inc. ("we", "us", "the Company", or "Better") is a prescription digital therapeutics company developing nutritional cognitive behavioral therapy ("nCBT") to address the root causes of cardiometabolic diseases. Our mission is to address unmet needs for treatment of cardiometabolic diseases such as diabetes, liver disease and heart disease, which share lifestyle behaviors as common root causes. The U.S. spends approximately $4.0 trillion per year on healthcare, and approximately 90% of that spending is for the treatment of chronic diseases. Most chronic cardiometabolic diseases are caused predominantly by behaviors relating to diet, physical activity, and other lifestyle factors, yet current treatments are focused on reducing the effects of those diseases rather than addressing the root causes.

In response to addressing the root causes of cardiometabolic diseases, we are building a proprietary platform for the development of U.S. Food and Drug Administration ("FDA") regulated, software-based, prescription digital therapeutics ("PDTs"). Our investigational PDTs are designed to deliver a novel form of nCBT to enable changes in neural pathways of the brain so that lasting changes in behavior can become possible. Our lead prescription digital therapeutic product candidate for the treatment of patients with type 2 diabetes ("T2D"), BT-001, completed a first-in-class open label, randomized, controlled, parallel group clinical trial for the treatment of T2D in July 2022 and successfully met its primary and secondary endpoints as well as exploratory endpoints.

The clinical trial for BT-001 included a diverse, nationally representative population of 668 patients with T2D and a mean baseline A1c of 8.1%. Participants in the trial had long standing (mean 11 years), poorly controlled T2D, high cardiovascular risk, multiple comorbidities, multiple blood sugar lowering medications, representing a difficult to treat patient population. Prior to the start of the study, we discussed core aspects of the design of the trial with the FDA during several formal meeting interactions. During these formal meeting interactions, we aligned with the FDA that an appropriate endpoint is a clinically meaningful change in A1c as determined by the mean change in A1c in the BT-001 group compared to the mean change in the control group. Following these discussions, we determined that participants would be randomized to receive standard of care with or without BT-001and that the primary and secondary efficacy endpoints would be the difference in mean change from baseline in A1c at 90 and 180 days. The study was powered to detect a 0.4% or greater change in A1c at 90 days, between BT-001 and control and a statistically significant change ($p<0.05$) in A1c at 180 days. The study also assessed a safety endpoint (the occurrence, relatedness and severity of Adverse Events) at day 90 and 180.

Our clinical trial of BT-001 achieved statistically significant and clinically meaningful changes in both the primary and secondary endpoints. The primary efficacy endpoint was the difference in mean change from baseline in A1c after 90 days of treatment between the two groups and showed highly statistically significant improvement in A1c between the intervention and control groups (-0.4%, $p <0.001$). The secondary efficacy endpoint was the difference in mean change from baseline in A1c after 180 days of treatment between the two groups and showed statistically significant improvement in A1c between the intervention and control groups (-0.3%, $p <0.01$). The difference in A1c levels after 180 days of treatment between BT-001 treated patients and Standard of Care control group patients remained statistically significant even as more SOC patients increased blood sugar lowering medications. BT-001 also demonstrated sustained and improved A1c levels at 180 days with absolute A1c reduction improving from 0.3% at 90 days to 0.4% at 180 days, while half of the BT-001 patients achieved clinically meaningful improvements, with a mean A1c reduction of 1.3%. The improved A1c reduction from 90 days to 180 days suggests that BT-001 was durable. The clinical trial also provided evidence that beyond reductions in A1c: (1) there was a clear dose-response between greater engagement in nCBT and greater reductions in A1c, supporting nCBT as a mechanism of action, (2) measures of patient engagement, adherence, persistence, and satisfaction were all positive, (3) no meaningful differences in safety events were observed between groups and (4) exploratory endpoint data revealed a additional cardiometabolic improvements as well as lower medication utilization compared to the control group, supporting the potential for BT-001 to improve overall health of patients with T2D and potentially reduce the usage of increasingly costly T2D medication associated with the progression of the disease.

We will use the data from this study to submit a *de* novo classification request to the FDA in Q3 2022, seeking marketing authorization of BT-001 for the treatment of patients with T2D. We believe the successful clinical trial of BT-001, if viewed favorably by the FDA, will be sufficient for the FDA to grant marketing authorization of BT-001 for the treatment of T2D. We will also use the data from this study to inform the initiation of pivotal trials for the treatment of hypertension and hyperlipidemia.

We initiated a first-ever clinical study evaluating the feasibility of nCBT to reduce liver fat and improve liver disease biomarkers as a potential treatment for NAFLD and NASH. The study is being conducted in collaboration with Arizona Liver Health, a leading liver clinical research center. This single arm interventional cohort study is expected to enroll approximately 20 patients for a treatment period of 90 days. The primary endpoint is the mean change in percent liver fat, as measured by Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF). The study is expected to be completed in the fourth quarter of 2022. NAFLD/NASH affects over 64 million adults in the U.S., resulting in over $100 billion in direct healthcare costs annually. There are currently no FDA approved therapeutics for treating NASH/NAFLD.

We initiated a real world evidence study to evaluate the long-term effectiveness and healthcare utilization changes associated with the use of BT-001 for the treatment of T2D with Catalyst Heath Network, Mass General Brigham, Colorado Prevention Center Clinical Research, and Durham Veterans Administration Medical Center. The randomized, controlled, multi-site study is expected to enroll approximately 1,000 patients for a treatment period of at least 12 months. Change in A1c and healthcare resource utilization will be evaluated and compared to usual care. Interim study results are expected to be reported in 2023, once a sufficient number of patients has completed an incremental 90 days of treatment. The study is expected to generate evidence supporting payer coverage and reimbursement.

The unique characteristics of prescription digital therapeutics and cardiometabolic diseases ("CMDx") may make it possible for us to launch multiple products now in development for the treatment of other CMDx over the next few years.

We are building a fully integrated PDTs company focused on treating the root causes of cardiometabolic diseases. Our therapeutics are being developed to fill a known gap in the treatment of cardiometabolic diseases and integrate within the existing healthcare system. We expect primary care providers to prescribe our therapeutics and insurers to reimburse them, if authorized for marketing by the FDA, much like they would a drug, and for the patient to remain in the care of their provider while using them.

Impact of COVID-19

In March 2020, the World Health Organization declared COVID-19 a global pandemic. The ongoing COVID-19 pandemic has not had a significant impact on our operations. The ultimate impact of the ongoing COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trial, healthcare systems or the global economy as a whole. However, these effects could harm our operations, and we will continue to monitor the ongoing COVID-19 pandemic closely. Management is unable to estimate the future financial effects, if any, to our business as a result of COVID-19 because of the high level of uncertainties and unpredictable outcomes of this disease.

Components of Results of Operations

Revenue

We expect that our primary sources of revenue will be through reimbursement coverage for our treatments by commercial insurers, Medicare, and Medicaid in the U.S. and our near-term plan is to obtain broad reimbursement coverage for our first PDT for treating T2D, BT-001, if authorized for marketing by the FDA. We expect to be successful in obtaining a broad reimbursement coverage through demonstrating and generating a comprehensive set of evidence to substantiate the value of BT-001 based on its impact on clinical outcomes, total cost of care, and durability of effect. Obtaining a broad reimbursement coverage and timing of obtaining such coverage for BT-001, if authorized for marketing by the FDA, and our other product candidates is highly uncertain. As a result, the timing and the amount of revenue we expect to recognize from monetizing our product candidates may vary based on various factors.

We also may explore opportunities to partner with pharmaceutical companies marketing traditional drug therapies for cardiometabolic diseases that may benefit from an increase in efficacy and durability when combined with our prescription digital therapeutic.

Operating Expenses

We classify operating expenses into three main categories: (i) research and development, (ii) sales and marketing and (iii) general and administrative.

Research and Development

Our research and development expenses consist of external and internal expenses incurred in connection with our research activities and development programs. These expenses include external expenses, including expenses associated with contract research organizations engaged to manage and conduct clinical trials; and other research and development expenses associated with software development and licenses, and other external development spend. Additionally, our research and development expenses include internal personnel expenses, including expenses for salaries, benefits and stock-based compensation, and allocation of certain overhead expenses.

We capitalize our research and development internal use software costs related to our digital therapeutic platform incurred during the application development stage and separately present these costs on the balance sheet as capitalized software development costs. Research and development costs incurred during the preliminary planning and evaluation stage of the project were expensed as incurred. To date, the majority of these expenses have been incurred to advance our lead product candidate, BT-001.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our platform and our product candidates, as our product candidates advance into later stages of development, and as we continue to conduct clinical trials. The successful development of our platform and our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Sales and Marketing

Sales and marketing expenses consist primarily of advertising and public relations costs and consulting services. We expect our sales and marketing expenses to increase for the foreseeable future as we prepare to prepare for commercialization of BT-001. Our sales and marketing efforts are expected to focus on targeting patients and primary care physicians through general awareness and branded promotional activities. We expect to incur significant investments in building a primary care sales force, and our plan and expectation is to have recruited and deployed such sales force during the first year of commercialization of our initial product candidate.

General and Administrative

General and administrative expenses consist primarily of personnel-related costs and professional services including legal, audit and accounting services. Personnel-related costs consist of salaries, benefits, and stock-based compensation. We expect our general and administrative expenses to increase for the foreseeable future due to anticipated increases in headcount to advance our product candidates and as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, additional insurance expenses, investor relations activities and other administrative and professional services.

Interest Expense, Net

Interest expense, net primarily consists of interest expense related to long-term debt entered into in 2021.

Results of Operations

Comparisons of the three and six months ended June 30, 2022 and 2021.

The following table summarizes our results of operations for the periods presented (in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022	2021	Change	% Change	2022	2021	Change	% Change
Operating expenses:								
Research and development	$ 4,241	$ 5,038	$ (797)	(16)%	$ 7,914	$ 6,416	$ 1,498	23 %
Sales and marketing	1,683	564	1,119	198 %	3,727	607	3,120	N/M
General and administrative	3,675	872	2,803	321 %	7,303	2,439	4,864	199 %
Total operating expenses	9,599	6,474	3,125	48 %	18,944	9,462	9,482	100 %
Loss from operations	(9,599)	(6,474)	(3,125)	48 %	(18,944)	(9,462)	(9,482)	100 %
Interest expense, net	(329)	(1)	(328)	N/M	(646)	(2)	(644)	N/M
Change in fair value of SAFEs	—	(2,821)	2,821	N/M	—	(5,313)	5,313	N/M
Gain on loan forgiveness	—	647	(647)	N/M	—	647	(647)	N/M
Loss before provision (benefit) from income taxes	(9,928)	(8,649)	(1,279)	15 %	(19,590)	(14,130)	(5,460)	39 %
Provision (benefit) from income taxes	—	1	(1)	N/M	—	(150)	150	N/M
Net loss	$ (9,928)	$ (8,650)	$ (1,278)	15 %	$ (19,590)	$ (13,980)	$ (5,610)	40 %

N/M – The percentage change is not meaningful

Research and Development Expenses

Research and development expenses were $4.2 million for the three months ended June 30, 2022, compared to $5.0 million for the three months ended June 30, 2021. The decrease was primarily due to a $2.0 million decrease in clinical trial related costs as we are winding down the trial related to BT-001, offset by a $1.2 million increase in personnel and consulting costs related preparing the *de* novo submission for BT-001 and expanding our clinical research and software development capabilities.

Research and development expenses were $7.9 million for the six months ended June 30, 2022 compared to $6.4 million for the six months ended June 30, 2021. The increase was primarily due to a $3.3 million increase in personnel and consulting costs related to preparing the *de* novo submission for BT-001 and expanding our clinical research and software development capabilities. This was offset by a $2.3 million decrease in clinical trial related costs as we are winding down the pivotal trial related to BT-001.

Sales and Marketing Expenses

Sales and marketing expenses were $1.7 million for the three months ended June 30, 2022, compared to $564 thousand for the three months ended June 30, 2021. The increase was primarily due to an increase in personnel, marketing and consulting expenses associated with commercial readiness activities to support he potential launch of BT-001.

Sales and marketing expenses were $3.7 million for the six months ended June 30, 2022, compared to $607 thousand for the six months ended June 30, 2021. The increase was primarily due to an increase in personnel, marketing and consulting expenses associated with commercial readiness activities to support the potential launch of BT-001.

General and Administrative Expenses

General and administrative expenses were $3.7 million for the three months ended June 30, 2022, compared to $872 thousand for the three months ended June 30, 2021. The overall increase in general and administrative expenses was primarily related to an increase of $1.0 million in personnel related costs and $1.1 million in business insurance related to the cost of being a public company.

General and administrative expenses were $7.3 million for the six months ended June 30, 2022, compared to $2.4 million for the six months ended June 30, 2021. The overall increase in general and administrative expenses was primarily related to an increase of $2.1 million in personnel related costs and $2.3 million in business insurance related to the cost of being a public company.

Interest Expense, Net

Interest expense, net was $329 thousand for the three months ended June 30, 2022 compared to $1 thousand for the three months ended June 30, 2021. The increase in interest expense, net was the result of the interest incurred on our secured term loan agreement with Hercules Capital.

Interest expense, net was $646 thousand for the six months ended June 30, 2022 compared to $2 thousand for the six months ended June 30, 2021. The increase in interest expense, net was the result of the interest incurred on our secured term loan agreement with Hercules Capital, Inc. ("Hercules Capital").

Change in Fair Value of SAFEs

The expense related to the change in fair value of our SAFEs was zero for the three and six months ended June 30, 2022, compared to a loss of $2.8 million and $5.3 million for the three and six months ended June 30, 2021, respectively. The change was a result of the business combination and the conversion of SAFEs to common stock.

Gain on Loan Forgiveness

On May 9, 2020 (the “Origination Date”), the Company received $640 thousand in aggregate loan proceeds (the “PPP Loan”) from Celtic Bank Corporation (the “Lender”) pursuant to the Paycheck Protection Program established under the CARES Act (the Coronavirus Aid, Relief, and Economic Security Act) of 2020. In May 2021, the Company received approval of loan forgiveness and recorded a gain on loan forgiveness of $647 thousand.

Liquidity and Capital Resources

We have primarily funded our operations through the sale of preferred stock, convertible notes, SAFEs and funding from the merger with Mountain Crest Acquisition Corp. II ("MCAD").

On April 6, 2021, we entered into a merger agreement with MCAD. In connection with the merger agreement, MCAD entered into Subscription Agreements with certain institutional and accredited investors, pursuant to which, among other things, MCAD agreed to issue and sell, in a private placement immediately prior to the closing of the Business Combination, an aggregate of 5.0 million PIPE Shares. On October 28, 2021, we completed the merger with MCAD. We raised $59.0 million in funding upon the completion of the merger with MCAD. Under the merger Agreement, MCAD acquired all of the outstanding shares of Legacy BTX in exchange for 15.2 million shares of MCAD.

On August 18, 2021, we entered into a $50.0 million secured term loan agreement with Hercules Capital. The term loan has a maturity date of August 1, 2025, which can be extended to February 1, 2026, and is secured by substantially all of our assets. Payments due for the term loan are interest-only until March 1, 2023 (subject to extension to September 1, 2023 or September 1, 2024 upon the achievement of certain milestones), after which principal shall be repaid in equal monthly installments. Interest is payable monthly in arrears. The outstanding principal bears interest at the greater of (a) 8.95% or (b) 8.95% plus the prime rate minus 3.25%. Prepayment of the outstanding principal is permitted under the secured term loan agreement and subject to certain prepayment fees. The Company incurred $518 thousand of debt issuance costs related to the borrowings under the secured term loan agreement. Debt issuance costs are being amortized through the maturity date of the secured term loan and are reported as a direct reduction of long-term debt on the balance sheet. Amortization expense, included in interest expense, net on the accompanying statements of operations and comprehensive loss totaled $186 thousand and zero for the six months ended June 30, 2022 and 2021, respectively. In addition, we will be required to pay an end of term charge of the greater of (a) $893 thousand or (b) 5.95% of the aggregate outstanding principal upon repayment of the loan. The secured term loan agreement contains customary representations, warranties, non-financial covenants, and events of default. We are permitted to borrow the loans in four tranches based on the completion of certain milestones which include, as set forth more fully in the secured term loan agreement: (i) $15.0 million upon the closing of the Business Combination, (ii) $10.0 million when we achieve certain positive clinical trial results sufficient to submit a de-novo classification request with respect to BT-001 and have initiated a second pivotal trial prior to September 15, 2022, (iii) $10.0 million when we have received FDA approval for such marketing of BT-001 for the improvement of glycemic control and initiated a pivotal trial for a new indication in people with T2D and received, prior to March 15, 2023, net cash proceeds of at least $40.0 million from equity financings, and (iv) $15.0 million on or before June 15, 2023, subject to Hercules Capital's approval. In October 2021, we borrowed $10.0 million under the secured term loan agreement. In May 2022, we borrowed $5.0 million under the term loan agreement.

As of June 30, 2022, we had $29.7 million in cash, and an accumulated deficit of $91.3 million. Our primary use of cash is to fund operating expenses, which consist of research and development expenses related to our lead product candidate, BT-001, and preclinical programs and general and administrative expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We have incurred negative cash flows from operating activities and investing activities and significant losses from operations in the past. We expect to incur substantial expenses in the foreseeable future for the development and potential commercialization of our product candidates and ongoing internal research and development programs. At this time, we cannot reasonably estimate the nature, timing or aggregate amount of costs for our development, potential commercialization, and internal research and development programs. However, in order to complete our planned product development, and to complete the process of obtaining regulatory authorization or clearance for our product candidates, as well as to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding in the future. In the event that additional financing is required from outside sources, we may not be able to raise it on terms acceptable to us, or at all. If we are unable to raise additional capital when desired, our business, results of operations, and financial condition would be adversely affected. Under our current operating plan, we believe we have sufficient capital to fund our operations into the first quarter of 2023. These factors raise substantial doubt regarding the Company's ability to continue as a going concern.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash, cash equivalents and restricted cash for the periods presented below (in thousands):

	Six Months Ended June 30,	
	2022	**2021**
Cash used in operating activities	$ (15,570)	$ (8,099)
Cash used in investing activities	(457)	(581)
Cash provided by financing activities	5,146	10,675
Net increase (decrease) in cash and cash equivalents	$ (10,881)	$ 1,995

Cash Used in Operating Activities

During the six months ended June 30, 2022, net cash used in operating activities was $15.6 million, which consisted of a net loss of $19.6 million, a net change of $1.9 million in our net operating assets and liabilities and $2.1 million in non-cash charges. The net change in our operating assets and liabilities was primarily due a net increase in accounts payable and accrued expenses of $375 thousand, offset by a decrease in prepaid expenses and other assets of $2.3 million. The non-cash charges of $2.1 million consisted of depreciation and amortization expense, share-based compensation expense, and loss on fixed asset disposal.

During the six months ended June 30, 2021, net cash used in operating activities was $8.1 million, which consisted of a net loss of $14.0 million and a net change of $763 thousand in our net operating assets and liabilities and $5.1 million in non-cash charges. The net change in our operating assets and liabilities was primarily due a net increase in accounts payable and accrued expenses of $2.1 million, offset by an increase in prepaid expenses and other assets of $1.3 million. The non-cash charges of $5.1 million consisted of the change in fair value of SAFEs, depreciation and amortization expense, share-based compensation expense, deferred income taxes and gain on loan forgiveness.

Cash Used in Investing Activities

During the six months ended June 30, 2022, cash used in investing activities was $457 thousand and was primarily related to capitalized internal-use software cost and capital expenditures.

During the six months ended June 30, 2021, cash used in investing activities was $581 thousand and was primarily related to capitalized internal-use software costs.

Cash Provided by Financing Activities

During the six months ended June 30, 2022, cash provided by financing activities was $5.1 million related to proceeds received from the issuance of long-term debt, the issuance of shares under the employee stock purchase plan and the exercise of common stock options.

During the six months ended June 30, 2021, cash provided by financing activities was $10.7 million consisting of net proceeds from the issuance of SAFEs.

Contractual Obligations and Commitments

Contractual obligations are cash amounts that we are obligated to pay as part of certain contracts that we have entered into during the normal course of business. We do not have any contractual obligations and other commitments as of June 30, 2022.

Off-Balance Sheet Arrangements

Since the date of our incorporation, we have not engaged in any off-balance sheet arrangements, as defined in Regulation S-K, Item 303(a)(4)(ii).

Reclassification

Certain prior year amounts have been reclassified for consistency with the current period presentation. These reclassifications had no effect on the reported results of operations. An adjustment has been made to the Statement of Operations and Comprehensive Loss for three and six months ended June 30, 2021 to reclassify $142 thousand and $297 thousand of cost of sales into research and development expense to align with industry standards, respectively. This change in classification does not affect previously reported net loss in the Statement of Operations and Comprehensive Loss.

Critical Accounting Policies and Estimates

There have been no significant changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations," disclosed in our 2021 Annual Report, except for the significant accounting policies related to the adoption of FASB ASC Topic 842, Leases, effective January 1, 2022. There was no material impact to our financial statements due to the adoption of the lease guidance.

The preparation of financial statements in conformity with U.S. GAAP requires management to make certain estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities and the related disclosures at the date of the financial statements, as well as the reported amounts of revenue and expenses during the periods presented. The estimates and assumptions used in the accompanying financial statements are based upon management’s evaluation of the relevant facts and circumstances. Such estimates, judgments, and assumptions include estimated costs and useful life for capitalized internal-use software, fair values of stock-based awards and valuation allowance for deferred tax assets. Actual results could be different from these estimates. To the extent there are material differences between these estimates, judgments, or assumptions and actual results, our financial statements will be affected. We believe the following critical accounting policies involve the most significant estimates and judgements used in the preparation of our financial statements.

Fair Value Measurements

The carrying value of our financial instruments, including cash equivalents, accounts payable, accrued liabilities and notes payable approximates fair value due to their short-term nature. The Company's investment portfolio consists of money market funds, which are carried at fair value. The company has determined the carrying value to be equal to the fair value and has classified these investments as Level 1 financial instruments.

We measure financial assets and liabilities at fair value at each reporting period using a fair value hierarchy that requires the use of observable inputs and minimizes the use of unobservable inputs. We define fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value is estimated by applying the following hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs other than quoted prices in active markets for identical assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Inputs that are generally unobservable and typically reflect management's estimate of assumptions that market participants would use in pricing the asset or liability.

Property and Equipment, Net

Property and equipment, net, which include computer, equipment and software are stated at cost, less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful life of 3 years. Expenditures for repairs and maintenance are expensed in the period incurred.

Capitalized Internal-Use Software Costs

Costs incurred to develop software and our platform for internal use consist primarily of direct employee-related and third-party contractor costs and are accounted for pursuant to ASC 350-40, Internal Use Software. Costs incurred during the preliminary planning and evaluation stage of the project are expensed as incurred. Costs incurred during the application development stage of the project are capitalized and amortized over an estimated useful life of 3 years.

Impairment of Long-Lived Assets

We review long-lived assets for impairment when circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of these assets is measured by a comparison of the carrying amounts to the sum of the future un-discounted cash flows the assets are expected to generate over the remaining useful lives of the assets. If a long-lived asset fails a recoverability test, we measure the amount by which the carrying value of the asset exceeds its fair value. There were no events or changes in business circumstances during the six months ended June 30, 2022 that indicated the carrying amounts of any long-lived assets were not fully recoverable.

Equity-Based Compensation

We account for equity-based compensation arrangements granted to employees in accordance with ASC 718, "Compensation: Stock Compensation", by measuring the grant date fair value of the award and recognizing the resulting expense over the period during which the employee is required to perform service in exchange for the award. Equity-based compensation expense is only recognized for awards subject to performance conditions if it is probable that the performance condition will be achieved.

We account for equity-based compensation arrangements issued to non-employees using the fair value approach prescribed by ASU 2018-07, "Compensation-Stock Compensation (ASC 718): Improvements to Non-employee Share-Based Payment Accounting". The value of non-employee equity-based compensation is measured at the grant date using a fair value-based measure.

We estimate the fair value of each equity-based award on the date of grant using the Black-Scholes option-pricing model. The determination of the fair value of each stock award using this option-pricing model is affected by our assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the fair value of the common stock at the date of grant, the expected term of the awards, the expected stock price volatility over the term of the awards, risk-free interest rate, and dividend yield as follows:

Fair Value of Common Stock — We determined the fair value of common stock based on the closing price of our common stock on the date of the grant.

Expected Term — The expected term represents the period that the equity-based awards are expected to be outstanding. We determine the expected term using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the options. For stock options granted to non-employees, the expected term equals the remaining contractual term of the option from the vesting date.

Expected Volatility — As we had no trading history for our common stock when we granted our option awards prior to the Business Combination, the expected volatility was estimated by taking the average historic price volatility for industry peers, consisting of several public companies in our industry that are either similar in size, stage, or financial leverage, over a period equivalent to the expected term of the awards. Due to our limited trading history, we will continue to determine expected volatility using estimate of industry peers.

Risk-Free Interest Rate — The risk-free interest rate is calculated using the average of the published interest rates of U.S. Treasury zero-coupon issues with maturities that are commensurate with the expected term.

Dividend Yield — The dividend yield assumption is zero, as we have no history of, or plans to make, dividend payments.

We account for forfeitures when they occur. For awards forfeited before completion of the requisite service period, previously recognized compensation cost is reversed in the period the award is forfeited.

Income Taxes

We account for income taxes using the asset and liability method under which deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities with consideration given to net operating losses and tax credit carryforwards. Deferred tax assets and liabilities are measured using the enacted tax rates that are expected to be in effect when the differences are expected to reverse.

We assess the likelihood that deferred tax assets will be recovered from future taxable income and a valuation allowance is established when necessary to reduce deferred tax assets to the amounts more likely than not expected to be realized. We adopted Accounting Standards Update (“ASU”) No. 2015-17, Income Taxes — Balance Sheet Classification of Deferred Taxes, and classified our deferred income taxes as non-current in the balance sheets.

We recognize and measure uncertain tax positions using a two-step approach. The first step is to evaluate the tax position taken or expected to be taken by determining if the weight of available evidence indicates that it is more likely than not that the tax position will be sustained in an audit, after resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. Significant judgment is required to evaluate uncertain tax positions. We evaluate our uncertain tax positions on a regular basis. Our evaluations are based on a number of factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues.

Net Loss Per Share Attributable to Common Stockholders

Basic and diluted net loss per share attributable to common stock is presented in conformity with the two-class method required for participating securities. Under the two-class method, the net loss attributable to common stock is not allocated to the preferred stock as the holders of our convertible preferred stock did not have a contractual obligation to share in our losses. Under the two-class method, net loss is attributed to common stock and participating securities based on their participation rights. Basic net loss per share attributable to common stock is computed by dividing the net loss attributable to common stock by the weighted-average number of shares of common stock outstanding during the period. Cumulative dividends attributable to participating securities are subtracted from net loss in determining net loss attributable to common stockholders. As we have reported net losses for all periods presented, all potentially dilutive securities are antidilutive and, accordingly, basic net loss per share equals diluted net loss per share.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act of 1933, as amended, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As such, we are eligible for and intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), (ii) the exemptions from say-on-pay, say-on- frequency and say-on-golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a "large accelerated filer" under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which would occur if the market value of our common equity held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter; or (ii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we may adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies instead of the dates required for other public companies.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our ordinary shares held by non-affiliates exceeds $250 million as of the prior June 30, or (ii) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our ordinary shares held by non-affiliates exceeds $700 million as of the prior June 30.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a "smaller reporting company", we are not required to provide the information otherwise required by this Item 3.

Item 4. Controls and Procedures.

Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures , as such term is defined in Rules 13a-115(e) and 15d-15(e) under the Exchange Act, as of the end of the fiscal quarter ended June 30, 2022. Based on this evaluation, our principal executive officer and principal financial and accounting officer have concluded that during the period covered by this report, our disclosure controls and procedures were effective at a reasonable assurance level and, accordingly, provided reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

Our business is subject to numerous material and other risks. You should carefully consider the following risks and uncertainties, those risks and uncertainties discussed in "Part I, Item 1A, Risk Factors" in our 2021 Annual Report together with all of the other information contained in this Quarterly Report, including our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report. If any of the risks described below actually occur, our business, prospects, operating results and financial condition could suffer materially. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Summary of Risk Factors

Risks Related to Our Business

- We are a clinical-stage digital therapeutics company with a limited operating history and have incurred significant financial losses since our inception. We anticipate that we will continue to incur significant financial losses for the foreseeable future.
- We have never generated revenue from product sales and may never be profitable.
- We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or terminate our product discovery and development programs or commercialization efforts.
- Our business is highly dependent on the success of our lead product candidate, BT-001. If we are unable to successfully complete clinical development, obtain regulatory marketing authorization for or commercialize BT-001, or if we experience delays in doing so, our business will be materially harmed.
- The failure of our products, if authorized for marketing, to achieve and maintain market acceptance would cause our business, financial condition and results of operation to be materially and adversely affected.
- Competitive products may reduce or eliminate the commercial opportunity for our product candidates, if authorized for marketing. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.
- If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates, if authorized for marketing.
- Any failure to offer high-quality patient support may adversely affect our relationships with our existing and prospective patients, and in turn our business, results of operations and financial condition.
- We may in the future enter into collaborations, in-licensing arrangements, joint ventures, or strategic alliances with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.

Risks Related to our Intellectual Property and Potential Litigation

- Failure to protect or enforce our intellectual property rights could harm our business and results of operations.

Risks Related to Discovery and Development

- Our current product candidates are in various stages of development. Our product candidates may fail in development or suffer delays that adversely affect their commercial viability. If we fail to obtain or maintain FDA de novo classification or clearance to market and sell our BT-001 digital therapeutic, or other product candidates, or if such classification or clearance is delayed, our business will be materially harmed.

- The clinical trial process required to obtain marketing authorizations for our product candidates is lengthy and expensive with uncertain outcomes. If clinical trials of any of our digital therapeutic applications in development fail to produce results necessary to support regulatory marketing authorization or clearance in the United States or, with respect to our current or future products, elsewhere, we will be unable to commercialize these products and may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of those products.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.
- If patients or physicians are not willing to change current practices to adopt our BT-001 digital therapeutic, if granted authorization for marketing, our future product candidates may fail to gain increased market acceptance, and our business will be adversely affected.
- Our long-term growth depends on our ability to enhance our digital therapeutic products, expand our indications and develop and commercialize additional products once granted marketing authorization and clearance.

Risk Related to Government Regulation

- Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.
- We may not receive the necessary de novo classification grant for our BT-001 digital therapeutic or clearances for future expanded indications of our BT-001 digital therapeutic product candidate, and failure to timely obtain these regulatory authorizations would adversely affect our ability to grow our business.

Risks Related to Healthcare Laws and Regulations

- The insurance coverage and reimbursement status of newly-authorized products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for any of our product candidates, if authorized for marketing, could limit our ability to market those products and decrease our ability to generate revenue.

Risk Related to our Legal and Regulatory Environment

- Failure to comply with anti-bribery, anti-corruption and anti-money laundering laws could subject us to penalties and other adverse consequences.
- Federal, state and local employment-related laws and regulations could increase our cost of doing business and subject us to fines and lawsuits.

Risk Related to Our Common Stock

- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.
- The price of our common stock may be volatile.

Risk Related to Our Business

We are a clinical-stage digital therapeutics company with a limited operating history and have incurred significant financial losses since our inception. We anticipate that we will continue to incur significant financial losses for the foreseeable future.

We are a clinical-stage digital therapeutics company with a limited operating history. We were formed in April 2015 and our operations to date have been limited. We have not yet demonstrated an ability to generate revenues, obtain regulatory marketing authorizations, manufacture any product on a commercial scale or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

We have no products authorized for commercial sale and have not generated any revenue from product sales to date, nor do we expect to generate any revenue until sometime in 2023 upon commercialization. We will continue to incur significant research and development and other expenses related to our preclinical and clinical development, pre-commercialization activities and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net loss was $10.0 million and $19.6 million for the three and six months ended June 30, 2022. As of June 30, 2022, we had an accumulated deficit of $91.3 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory authorizations for, our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- advance our lead product candidate, BT-001, through clinical development;
- advance our pilot stage product candidates into clinical development;
- seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our clinical operations;
- expand our operational, financial and management systems and increases personnel to support our operations;
- meet the requirements and demands of being a public company;
- maintain, expand and protect our intellectual property portfolio;
- seek regulatory authorizations for any product candidates that successfully complete clinical trials; and
- continue to undertake pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory authorization.

Digital therapeutic product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy, gain regulatory marketing authorization, secure market access and reimbursement and become commercially viable and therefore any investment in our company is highly speculative. Additionally, our expenses could increase beyond our expectations if we are required by the FDA, or other regulatory authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate arrangements for or in completing our clinical trials or the development of any of our product candidates.

You should consider our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage digital therapeutics companies such as us. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing digital therapeutics products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

We have never generated revenue from product sales and may never be profitable.

Our ability to become and remain profitable depends on our ability to generate revenue or execute other business development arrangements. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory authorization for, and successfully commercialize the product candidates we are developing or may develop. Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory authorization for these product candidates, developing, marketing and selling those products for which we may obtain regulatory authorization, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payers. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have since inception, investors may not receive any return on their investment and may lose their entire investment.

We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or terminate our product discovery and development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical and preclinical development of our product candidates, including the program for our leading product candidate BT-001, and for pre-commercialization activities for BT-001. We will need to raise additional capital to complete our currently planned clinical trials and any future clinical trials for our product candidates. Other unanticipated costs may arise in the course of our development efforts. If we are able to gain marketing authorization for product candidates that we develop, we will require significant additional amounts of funding in order to launch and commercialize such product candidates. We cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop and we may need substantial additional funding to complete the development and commercialization of our product candidates.

Our future need for additional funding depends on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;
- the timing of, and the costs involved in, obtaining marketing authorizations for our product candidates and any other additional product candidates we may develop and pursue in the future;
- the number of future product candidates that we may pursue and their development requirements;
- the costs of commercialization activities for our product candidate, if authorized, including the costs and timing of establishing product sales, marketing, and distribution capabilities;
- subject to receipt of regulatory authorization, revenue, if any, received from commercial sales of our product candidates;
- the extent to which we in-licenses or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, reduce or terminate our product development programs or plans for commercialization.

We believe that we will be able to fund our operating expenses and capital expenditure requirements into the first quarter of 2023. Our estimate may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. We may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.

We currently have one clinical-stage product candidate as well as several other product candidates that are at various earlier stages of development. We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively pursuing our more advanced clinical-stage product candidate, BT-001, and ensuring the development of additional potential product candidates. Due to the significant resources required for the development of our product candidates, we must decide which product candidates to pursue and advance and the amount of resources to allocate to each.

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, in particular for cardiometabolic disorders, our business, financial condition, and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect management's ability to oversee the development of our product candidates.

If we raise additional capital through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, reduce or terminate our product discovery and development programs or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourself.

The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly or fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of our clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners or as a result of the ongoing COVID-19 pandemic or increasing global economic instability;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts, including as a result of the ongoing COVID-19 pandemic;
- our ability to obtain marketing authorization for our product candidates and the timing and scope of any such authorizations we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive marketing authorization, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if authorized for marketing, and existing and potential future therapeutics that compete with our product candidates;

- the changing and volatile U.S. and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results or revenue fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

Our business is highly dependent on the success of our lead product candidate, BT-001. If we are unable to successfully complete clinical development, obtain regulatory marketing authorization for or commercialize BT-001, or if we experience delays in doing so, our business will be materially harmed.

To date, we as an organization have not completed any clinical trials or development of any product candidates. Our future success and ability to generate revenue from our lead product candidates, is dependent on our ability to successfully develop, obtain regulatory marketing authorization for and commercialize BT-001. We completed our potentially pivotal clinical trial for BT-001 in July 2022 and announced primary endpoint data in March 2022 with secondary endpoint data in July 2022. If BT-001 encounters safety or efficacy problems, development delays or regulatory issues or other problems, the development plans for our other product candidates and business would be materially harmed.

We may not have the financial resources to continue development of our product candidates if BT-001 experiences any issues that delay or prevent regulatory authorization of, or our ability to commercialize, BT-001, including:

- our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that BT-001 is safe and effective;
- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- negative or inconclusive results or differing interpretations with regulatory authorities from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials, including unexpected results, or by individuals using products similar to BT-001;
- delays in enrolling subjects in clinical trials;
- high drop-out rates of subjects from clinical trials;
- poor effectiveness of BT-001 during clinical trials;
- greater than anticipated clinical trial or manufacturing costs;
- delays in submitting a de novo application, or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA, the European Medicines Agency ("EMA"), or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or
- varying interpretations of data by the FDA, EMA and comparable foreign regulatory authorities.

The failure of our products, if authorized for marketing, to achieve and maintain market acceptance would cause our business, financial condition and results of operation to be materially and adversely affected.

Our current business strategy is highly dependent on our products potentially achieving FDA authorization for commercial distribution and maintaining market acceptance. Market acceptance and adoption of our products depends on educating people with cardiometabolic conditions, as well as payers, health plans and government entities, as to the distinct features, clinical impact, cost savings, and other benefits of our products. If we are not successful in demonstrating to physicians who treat potential patients the benefits of our products, if authorized for marketing, or if we are not able to achieve the support of insurance carriers for our products, our business, financial condition and results of operation would be materially and adversely affected.

In addition, our products may be perceived by patients and healthcare providers to be more complicated or less effective than traditional approaches, and people may be unwilling to change their current health regimens. Moreover, we believe that healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third-party reimbursement. Accordingly, healthcare providers may not recommend our products until there is sufficient evidence to convince them to alter their current approach.

Competitive products may reduce or eliminate the commercial opportunity for our product candidates, if authorized for marketing. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.

The clinical and commercial landscapes for the treatment of cardiometabolic diseases are highly competitive and subject to rapid and significant technological change. We face competition with respect to our indications for our product candidates from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies and potentially other technology companies. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drug candidates for the treatment of the indications that we are pursuing.

Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. In addition, technology companies are increasingly exploring the potential for digital products to manage and treat cardiometabolic diseases that could compete with our product candidates, if approved.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals or marketing authorizations and reimbursement and marketing commercialized products than we do. Accordingly, our competitors may be more successful than we may be in obtaining regulatory marketing authorization for therapies and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our therapies obsolete or non-competitive before we can recover development and commercialization expenses. If any of our product candidates, including BT-001, is authorized for marketing, it could compete with a range of therapeutic treatments that are in development.

If we obtain marketing authorization for any of our product candidates, we may face competition based on many different factors, including the efficacy, safety and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory marketing authorizations for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, less expensive or marketed and sold more effectively than any product we may develop. Competitive products may make any product we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

In addition, our competitors may obtain patent protection or FDA approval and commercialize products more rapidly than we do, which may impact future authorizations or clearances we may seek or sales of any of our product candidates that receive regulatory marketing authorization or clearance. If the FDA approves the commercial sale of any of our product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory authorizations or clearances, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payers, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receive regulatory marketing authorization but cannot compete effectively in the marketplace.

Additionally, mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly as the develop disruptive therapies through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our programs.

Acquisitions and investments could result in operating difficulties, dilution and other harmful consequences that may adversely impact our business, results of operations and financial condition.

We may in the future make acquisitions to add complementary companies, products, technologies, or revenue. These transactions could be material to our results of operations and financial condition. We may also evaluate and enter into discussions regarding a wide array of potential strategic transactions. The identification of suitable acquisition candidates can be difficult, time-consuming and costly, and we may not be able to complete acquisitions on favorable terms, if at all. The process of integrating an acquired company, business or technology may create unforeseen operating difficulties and expenditures. The areas where we face risks include:

- loss of key employees of the acquired company and other challenges associated with integrating new employees into our culture, as well as reputational harm if integration is not successful;
- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- implementation or remediation of controls, procedures, and policies at the acquired company;
- difficulties in integrating and managing the combined operations, technologies, technology platforms and products of the acquired companies and realizing the anticipated economic, operational and other benefits in a timely manner, which could result in substantial costs and delays or other operational, technical or financial problems;
- integration of the acquired company's accounting, human resource and other administrative systems, and coordination of products, engineering and sales and marketing function;
- assumption of contractual obligations that contain terms that are not beneficial to us, require us to license or waive intellectual property rights, or increase our risk for liabilities;
- failure to successfully further develop the acquired technology or realize our intended business strategy;
- uncertainty of entry into markets in which we have limited or no prior experience or in which competitors have stronger market positions;
- unanticipated costs associated with pursuing acquisitions;
- failure to find commercial success with the products or services of the acquired company;
- difficulty of transitioning the acquired technology onto our existing platforms and maintaining the security standards for such technology consistent with our other products;
- failure to successfully onboard patients or maintain brand quality of acquired companies;
- responsibility for the liabilities of acquired businesses, including those that were not disclosed to us or exceed our estimates, as well as, without limitation, liabilities arising out of their failure to maintain effective data protection and privacy controls and comply with applicable regulations;
- inability to maintain our internal standards, controls, procedures, and policies;
- failure to generate the expected financial results related to an acquisition on a timely manner or at all;
- difficulties in complying with antitrust and other government regulations;
- challenges in integrating and auditing the financial statements of acquired companies that have not historically prepared financial statements in accordance with GAAP;
- potential accounting charges to the extent intangibles recorded in connection with an acquisition, such as goodwill, trademarks, patient relationships or intellectual property, are later determined to be impaired and written down in value; and
- failure to accurately forecast the impact of an acquisition transaction.

Future acquisitions could also result in expenditures of significant cash, dilutive issuances of our equity securities, the incurrence of debt, restrictions on our business, contingent liabilities, amortization expenses or write-offs of goodwill, any of which could harm our financial condition. In addition, any acquisitions we announce could be viewed negatively by patients.

Additionally, competition within our industry for acquisitions of business, technologies and assets may become intense. Even if we are able to identify an acquisition that we would like to consummate, we may not be able to complete the acquisition on commercially reasonable terms or the target may be acquired by another company. We may enter into negotiations for acquisitions that are not ultimately consummated.

Those negotiations could result in diversion of management time and significant out-of-pocket costs. If we fail to evaluate and execute acquisitions successfully, we may not be able to realize the benefits of these acquisitions, and our operating results could be harmed. If we are unable to successfully address any of these risks, our business, financial condition or operating results could be harmed.

If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates, if authorized for marketing.

We are currently commencing pre-commercialization activities but have not completed the build-out of our marketing, sales or distribution capabilities. We intend to establish a sales and marketing organization, to commercialize our product candidates, if authorized for marketing. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates, if authorized for marketing.

Factors that may inhibit our efforts to commercialize our product candidates, if authorized for marketing, include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products, if authorized for marketing;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if authorized for marketing. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any products authorized for marketing, our future product revenue will suffer and we may incur significant additional losses.

If we are unable to achieve widespread acceptance of our products, if authorized for marketing, our revenue growth could be slower than we expect, and our business may be adversely affected.

We expect to generate revenue from physicians prescription of our products, if authorized for marketing, for patients. As a result, widespread acceptance, prescription and use of our products, if authorized for marketing, is critical to our future growth and success. If the market fails to grow or grows more slowly than we currently anticipate, demand for any of our marketed products could be negatively affected and our revenue may grow more slowly than we expect and our business may be adversely affected. Demand for any products we market is affected by a number of factors, many of which are beyond our control. Some of these potential factors include:

- awareness of our products and the adoption of prescription CBT;
- ease of adoption and use;
- platform experience;
- performance;
- brand;
- security and privacy; and

- pricing.

Any failure to offer high-quality patient support may adversely affect our relationships with our existing and prospective patients, and in turn our business, results of operations and financial condition.

In implementing and using our products, our patients will depend on our patient support to resolve issues in a timely manner. We may be unable to respond quickly enough to accommodate short-term increases in demand for patient support. Increased patient demand for support could increase costs and adversely affect our results of operations and financial condition. Any failure to maintain high-quality patient support, or a market perception that we do not maintain high-quality patient support, could adversely affect patient satisfaction or the willingness of physicians to prescribe our products, and in turn our business, results of operations, and financial condition.

We may in the future enter into collaborations, in-licensing arrangements, joint ventures, or strategic alliances with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, or strategic alliances to develop proposed products and to pursue new markets.

In the future, proposing, negotiating, and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all, and may not realize the anticipated benefits of any such transaction or arrangement.

Additionally, with respect to current and future collaborations, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals.

It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' or our future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

We could suffer disruptions, outages, defects, and other performance and quality problems with our platform or with the cloud and internet infrastructure on which it relies.

Our business depends on our platform to be available without disruption. We have experienced, and may in the future experience, disruptions, outages, defects, and other performance and quality problems with our platform. We have also experienced, and may in the future experience, disruptions, outages, defects, and other performance and quality problems with the cloud and internet infrastructure on which our platform relies. These problems can be caused by a variety of factors, including introductions of new functionality, vulnerabilities and defects in proprietary and open source software, human error or misconduct, capacity constraints, design limitations, or denial of service attacks or other security-related incidents.

Further, if our contractual and other business relationships with our cloud service providers are terminated, suspended, or suffer a material change to which we are unable to adapt, such as the elimination of services or features on which we depend, we could be unable to provide our platform and could experience significant delays and incur additional expense in transitioning patients to a different cloud service provider.

Any disruptions, outages, defects, and other performance and quality problems with our platform or with the cloud and internet infrastructure on which it relies, or any material change in our contractual and other business relationships with our cloud services providers, could result in reduced use of our platform, increased expenses, including service credit obligations, and harm to our brand and reputation, any of which could have a material adverse effect on our business, financial condition, and results of operations.

Our business could be disrupted by catastrophic events and man-made problems, such as power disruptions, data security breaches, and terrorism.

Our platform and the cloud-based infrastructure on which our platform relies are vulnerable to damage or interruption from the occurrence of any catastrophic event, including earthquake, fire, flood, tsunami, or other weather event, power loss, telecommunications failure, software or hardware malfunction, cyber- attack, war, terrorist attack, incident of mass violence or disease, such as the COVID-19 pandemic, and similar events, which could result in lengthy interruptions in access to our platform. In addition, acts of terrorism, including malicious internet-based activity, could cause disruptions to the internet or the economy as a whole. Even with our disaster recovery arrangements, access to our platform could be interrupted. If our systems were to fail or be negatively impacted as a result of a natural disaster or other event, our ability to deliver our platform and products to our patients would be impaired or we could lose critical data. If we are unable to develop adequate plans to ensure that our business functions continue to operate during and after a disaster, and successfully execute on those plans in the event of a disaster or emergency, our business, financial condition, and results of operations would be harmed.

We have implemented a disaster recovery program that allows us to move website traffic to a backup data center in the event of a catastrophe. This allows us the ability to move traffic in the event of a problem, and the ability to recover in a short period of time. However, to the extent our disaster recovery program does not effectively support the movement of traffic in a timely or complete manner in the event of a catastrophe, our business and results of operations may be harmed.

We do not carry business interruption insurance sufficient to compensate us for the potentially significant losses, including the potential harm to our business, financial condition and results of operations that may result from interruptions in access to our platform as a result of system failures.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn may cause extreme volatility and disruptions in the capital and credit markets and could result in a variety of risks to our business and our ability to raise additional capital when needed on acceptable terms, if at all. Additionally, our obligations to repay principal and interest on our indebtedness make us vulnerable to economic or market downturns.

Geopolitical developments, or the perception that any of them could occur, may lead to worldwide economic and legal uncertainty, including significant volatility in global stock markets and currency exchange rates, and increasingly divergent laws and regulations.

In February 2022, armed conflict escalated between Russia and Ukraine. The sanctions announced by the U.S. and other countries against Russia since February 2022 include restrictions on selling or importing goods, services, or technology in or from affected regions and travel bans and asset freezes impacting connected individuals and political, military, business, and financial organizations in Russia. The U.S. and other countries could impose wider sanctions and take other actions should the conflict further escalate. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, prolonged periods of higher inflation, geopolitical shifts, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, all of which could have a material adverse effect on our business, financial condition, and results of operations.

Any of the foregoing could harm our business, and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our Loan Agreement with Hercules Capital contains restrictions that limit our flexibility in operating our business.

In August 2021, we entered into a loan and security agreement (the "Loan Agreement") with Hercules Capital as agent and lender. The Loan Agreement provides for an up to $50.0 million senior secured term loan facility (the "Term Loan Facility"). The Loan Agreement is secured by a lien on substantially all of our assets, including, but not limited to, shares of our subsidiaries, our current and future intellectual property, insurance, trade and intercompany receivables, inventory and equipment and contract rights. The Loan Agreement requires us to meet specified minimum cash requirements, as described below, and contains various affirmative and negative covenants that limit our ability to engage in specified types of transactions. These covenants, which are each subject to customary exceptions, limit our ability to, without Hercules Capital's prior written consent, effect any of the following, among other things:

- sell, lease, transfer or otherwise dispose of certain assets;

- acquire another company or business or enter into a merger or similar transaction with third parties;
- incur additional indebtedness;
- make investments;
- enter into certain outbound licenses of intellectual property;
- encumber or permit liens on certain assets; and
- pay dividends and make other restricted payments with respect to our capital stock.

Our board of directors (the "Board") or management team could believe that taking any one of these actions would be in our best interests and the best interests of our stockholders. If that were the case and if we were unable to complete any of these actions because Hercules Capital does not provide its consent, that could adversely impact our business, financial condition and results of operations.

In addition, on or after July 1, 2023, we are required to maintain a minimum aggregate balance of $10.0 million in cash in one or more controlled accounts. Such requirement terminates if we reach certain valuation requirements. These accounts are required to be maintained as cash collateral accounts securing our obligations under the Loan Agreement. While such requirements apply under the Loan Agreement, our ability to use the cash amounts held in these controlled accounts in the operation of our business will be limited.

On October 28, 2021, we drew down on $10 million of the Term Loan Facility. Our ability to draw on the remaining Term Loan Facility is contingent on our compliance with the covenants described above and certain other covenants and milestones. Even if we meet these conditions, we may elect not to draw on the remaining Term Loan Facility.

In the event of a default under the Loan Agreement, including, among other things, our failure to make any payment when due or our failure to comply with any provision of the Loan Agreement, subject to customary grace periods, Hercules Capital could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit. If we are unable to repay the amounts due under the Loan Agreement, Hercules Capital could proceed against the collateral granted to it to secure this indebtedness, which could have an adverse effect on our business, financial condition and results of operations.

Hercules Capital interests as a lender may not always be aligned with our interests. If our interests come into conflict with those of Hercules Capital, including in the event of a default under the Loan Agreement, Hercules Capital may choose to act in its self-interest, which could adversely affect the success of our current and future collaborative efforts with Hercules Capital.

Risks Related to our Intellectual Property and Potential Litigation

We may be subject to legal proceedings and litigation, including intellectual property and privacy disputes, which are costly to defend and could materially harm our business and results of operations.

We may be party to lawsuits and legal proceedings in the normal course of business. These matters are often expensive and disruptive to normal business operations. We may face allegations, lawsuits and regulatory inquiries, audits and investigations regarding data privacy, security, labor and employment, consumer protection and intellectual property infringement, including claims related to privacy, patents, publicity, trademarks, copyrights and other rights. A portion of the technologies we use incorporates open source software, and we may face claims claiming ownership of open source software or patents related to that software, rights to our intellectual property or breach of open source license terms, including a demand to release material portions of our source code or otherwise seeking to enforce the terms of the applicable open source license. We may also face allegations or litigation related to our acquisitions, securities issuances or business practices, including public disclosures about our business. Litigation and regulatory proceedings, and particularly the patent infringement and class action matters we could face, may be protracted and expensive, and the results are difficult to predict. Certain of these matters may include speculative claims for substantial or indeterminate amounts of damages and include claims for injunctive relief. Additionally, our litigation costs could be significant. Adverse outcomes with respect to litigation or any of these legal proceedings may result in significant settlement costs or judgments, penalties and fines, or require us to modify our products or require us to stop offering certain products, all of which could negatively impact our revenue growth. We may also become subject to periodic audits, which would likely increase our regulatory compliance costs and may require us to change our business practices, which could negatively impact our revenue growth. Managing legal proceedings, litigation and audits, even if we achieve favorable outcomes, is time-consuming and diverts management’s attention from our business.

The results of regulatory proceedings, litigation, claims, and audits cannot be predicted with certainty, and determining reserves for pending litigation and other legal, regulatory and audit matters requires significant judgment. There can be no assurance that our expectations will prove correct, and even if these matters are resolved in our favor or without significant cash settlements, these matters, and the time and resources necessary to litigate or resolve them, could harm our reputation, business, financial condition, results of operations and the market price of our common stock.

Furthermore, our business exposes us to potential product liability claims if our products fail to properly perform due to undetected errors or similar problems. There can be no assurance that, despite testing we undertake, errors will not be found in new products after commencement of commercial use. In addition, the misuse of our products, or the failure of patients to adhere to operating guidelines, could cause significant harm to patients, including death, which could result in product liability claims. Product liability lawsuits and claims, with or without merit, could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, harm our reputation and adversely affect our ability to attract and retain patients, any of which could have a material adverse effect on our business, financial condition and results of operations.

Although we maintain third-party product liability insurance coverage, it is possible that claims against us may exceed the coverage limits of our insurance policies. Even if any product liability loss is covered by an insurance policy, these policies typically have substantial deductibles for which we are responsible.

Product liability claims in excess of applicable insurance coverage could have a material adverse effect on our business, financial condition and results of operations. In addition, any product liability claim brought against us, with or without merit, could result in an increase of our product liability insurance premiums. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all.

Failure to protect or enforce our intellectual property rights could harm our business and results of operations.

We believe that our intellectual property is an essential asset of our business. If we do not adequately protect our intellectual property, our brand and reputation could be harmed and competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our platform and delay or render impossible our achievement of profitability. A failure to protect our intellectual property in a cost-effective and meaningful manner could have a material adverse effect on our ability to compete. We regard the protection of our trade secrets, copyrights, trademarks, trade dress, databases, domain names and patents as critical to our success. We strive to protect our intellectual property rights by relying on federal, state and common law rights and other rights provided under foreign laws. These laws are subject to change at any time and could further restrict our ability to protect or enforce our intellectual property rights. In addition, the existing laws of certain foreign countries in which we operate may not protect our intellectual property rights to the same extent as do the laws of the United States. We also have a practice of entering into confidentiality and invention assignment agreements with our employees and contractors, and often enter into confidentiality agreements with parties with whom we conduct business in order to limit access to, and disclosure and use of, our proprietary information. In addition, from time to time we make our technology and other intellectual property available to others under license agreements, including open source license agreements and trademark licenses under agreements with any development collaborators for the purpose of co-branding or co-marketing our products or services. However, these contractual arrangements and the other steps we have taken to protect our intellectual property rights may not prevent the misappropriation of our proprietary information, infringement of our intellectual property rights, disclosure of trade secrets and other proprietary information, or deter independent development of similar or competing technologies, duplication of our technologies or efforts to design around our patents by others, and may not provide an adequate remedy in the event of such misappropriation or infringement.

Obtaining and maintaining effective intellectual property rights is expensive, including the costs of defending our rights. We make business decisions about when to seek patent protection for a particular technology and when to rely upon trade secret protection, and the approach we select may ultimately prove to be inadequate. We are seeking to protect certain of our intellectual property rights through filing applications for copyrights, trademarks, patents and domain names in a number of jurisdictions, a process that is expensive and may not be successful in all jurisdictions. We are continuing to monitor and evaluate our intellectual property protection in various jurisdictions as we expand our business. Even in cases where we seek patent protection, there is no assurance that the resulting patents will effectively protect every significant feature of our products, technology, or proprietary information, or provide us with any competitive advantages. Moreover, we cannot guarantee that any of our pending patent applications will issue or be approved. The United States Patent and Trademark Office, or the USPTO, also requires compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs, our competitors might be able to enter the market, which would have a material adverse effect on our business. Even where we have intellectual property rights, they may later be found to be unenforceable or have a limited scope of enforceability. In addition, we may not seek to pursue such protection in every jurisdiction. In particular, we believe it is important to maintain, protect and enhance our brands. Accordingly, we pursue the registration of domain names and our trademarks and service marks in the United States and in some jurisdictions outside of the United States.

Third parties may challenge our use of our trademarks, oppose our trademark applications or otherwise impede our efforts to protect our intellectual property in certain jurisdictions. In the event that we are unable to register our trademarks in certain jurisdictions, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. We have already and may, over time, increase our investment in protecting innovations through investments in patents and similar rights, and this process is expensive and time-consuming.

In order to protect our intellectual property rights, we may be required to spend significant resources to monitor and protect these rights. We may not always detect infringement of our intellectual property rights, and defending or enforcing our intellectual property rights, even if successfully detected, prosecuted, enjoined or remedied, could result in the expenditure of significant financial and managerial resources.

Litigation may be necessary to enforce our intellectual property rights, protect our proprietary rights or determine the validity and scope of proprietary rights claimed by others. Any litigation of this nature, regardless of outcome or merit, could result in substantial costs and diversion of management and technical resources, any of which could adversely affect our business and results of operations. We may also incur significant costs in enforcing our trademarks against those who attempt to imitate our brand and other valuable trademarks and service marks. Furthermore, our efforts to enforce our intellectual property rights may be met with defenses, counterclaims, countersuits and adversarial proceedings such as oppositions, inter partes review, post-grant review, re-examination or other post-issuance proceedings, that attack the validity and enforceability of our intellectual property rights. An adverse determination of any litigation proceedings could put our patents at risk of being invalidated or interpreted narrowly and could put our related pending patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

If we fail to maintain, protect and enhance our intellectual property rights, our business, results of operations and financial condition may be harmed and the market price of our common stock could decline.

Risks Related to Discovery and Development

Our current product candidates are in various stages of development. Our product candidates may fail in development or suffer delays that adversely affect their commercial viability. If we fail to obtain or maintain FDA de novo classification or clearance to market and sell our BT-001 digital therapeutic, or other product candidates, or if such classification or clearance is delayed, our business will be materially harmed.

The process of seeking regulatory de novo classification or clearance to market a medical device is expensive and time consuming. There can be no assurance that marketing authorization will be granted. If we are not successful in obtaining timely de novo classification granting marketing authorization of our BT- 001 digital therapeutic, or any of our other product candidates, we may never be able to generate significant revenue and may be forced to cease operations. Specifically, we hope to pursue additional regulatory marketing clearances for our BT-001 digital therapeutic for additional uses if our first de novo classification is granted. The FDA de novo classification process requires an applicant to demonstrate the safety and efficacy based, in part, on extensive data, including, but not limited to preclinical, clinical trial, technical, manufacturing and labeling data. The FDA regulatory clearance process requires an applicant to demonstrate the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device and the de novo classification process requires an applicant to demonstrate the safety and effectiveness of a new device. The FDA can delay, limit or deny de novo classification or clearance of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our product candidates are safe and effective for their intended use;
- the FDA may disagree that our clinical data supports the label and use that we are seeking; and
- the FDA may disagree that the data from our preclinical or pilot studies and clinical trials is sufficient to support marketing authorization.

Obtaining de novo classification and clearance from the FDA or any foreign regulatory authority could result in unexpected and significant costs for us and consume management's time and other resources. The FDA could ask us to supplement our submissions, collect additional non-clinical data, conduct additional clinical trials, prepare additional manufacturing data or information or engage in other time-consuming actions, or it could simply deny our applications. In addition, if granted marketing authorization, we may be required to obtain additional FDA marketing authorizations or clearances prior to marketing certain modifications to our devices, and the FDA may revoke the marketing authorization or clearance or impose other restrictions if post-market data demonstrates safety issues or lack of efficacy. If we are unable to obtain and maintain the necessary regulatory authorizations and clearances to market our products, our financial condition may be adversely affected, and our ability to grow domestically and internationally would likely be limited. Additionally, even if authorized or cleared for marketing, our BT-001 digital therapeutic may not receive marketing authorization for the indications that are necessary or desirable for successful commercialization or profitability.

We are substantially dependent on the FDA's de novo classification of our BT-001 digital therapeutic, as well as market acceptance in the United States of BT-001, and our failure to receive FDA de novo classification of our BT- 001 digital therapeutic or the failure to gain such market acceptance for it would negatively impact our business.

Since our inception, we have devoted substantially all of our efforts to the development of our BT-001 digital therapeutic application that we believe, if granted de novo classification, will serve as the basis for future marketing clearances for additional uses in other indications. We have not yet received de novo classification from the FDA to market and sell our BT-001 digital therapeutic in the United States. However, we have begun incurring costs, including costs to build our commercial team and sales force, in anticipation of potential FDA de novo classification being granted. If we are unable to obtain the necessary grant from the FDA to market and sell our BT-001 digital therapeutic in the United States and then to achieve significant market acceptance in the United States, our results of operations will be adversely affected as the United States is expected to be the principal market for our BT-001, if authorized. Further, because we have incurred costs prospectively in advance of FDA de novo classification, we would be unable to recoup these costs if the BT-001 is not granted marketing authorization by the FDA or if it is granted de novo classification but fails to obtain market acceptance. We have other digital therapeutic candidates in development that depend on marketing clearance to be obtained under FDA's 510(k) clearance pathway, enabled by the de novo classification of our first BT- 001 product candidate; thus, if we are unsuccessful in obtaining de novo classification of our initial BT-001 digital therapeutic, we would need to seek de novo classification for the next BT-001 digital therapeutic indication we seek to market. Unexpected or serious complications or other unforeseen negative effects related to the development or market acceptance of any BT-001 digital therapeutic we seek to market could materially and adversely affect our business.

The clinical trial process required to obtain marketing authorizations for our product candidates is lengthy and expensive with uncertain outcomes. If clinical trials of any of our digital therapeutic applications in development fail to produce results necessary to support regulatory marketing authorization or clearance in the United States or, with respect to our current or future products, elsewhere, we will be unable to commercialize these products and may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of those products.

We recently completed a potentially pivotal clinical trial and plan to seek de novo classification for our BT-001 digital therapeutic application for the treatment of T2D. The virtual aspects of the trial design included recruitment of participants using email and social media and conducting the study using telemedicine visits. In order to obtain de novo classification, we must submit clinical data demonstrating the safety and effectiveness of the product candidate. Conducting clinical trials is a complex and expensive process, can take many years, and outcomes are inherently uncertain. For example, we announced results from our potentially pivotal clinical trial of BT-001 in July 2022, but the FDA will ultimately determine whether these results, together with earlier clinical data, provide adequate support to grant our de novo classification request. We may incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the trials will ever result in commercial revenue. We may experience significant setbacks in clinical trials, even after earlier clinical trials showed promising results, and failure can occur at any time during the clinical development process. Any of our products may malfunction or may produce undesirable adverse effects that could cause us, IRBs, or regulatory authorities to interrupt, delay or halt clinical trials. We, IRBs, the FDA, or another regulatory authority may suspend or terminate clinical trials at any time to avoid exposing trial participants to unacceptable health risks. In addition, successful results of earlier pilot studies are not necessarily indicative of future clinical trial results, and predecessor pilot study or clinical trial results may not be replicated in subsequent clinical trials.

Moreover, interim results or topline results may be subject to change upon full review of the data from a clinical trial. Additionally, the FDA may disagree with our interpretation of the data from our pilot studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to demonstrate safety or efficacy, and may require us to pursue additional clinical trials, which could further delay the de novo classification grant or clearance of our product candidates. The data we collect from our pilot studies and clinical trials may not be sufficient to support FDA de novo classification or clearance, and if we are unable to demonstrate the safety and efficacy of our future products in our clinical trials, we will be unable to obtain the regulatory authorizations we need to commercialize our products.

In addition, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which are often referred to as milestones. These milestones could include: the submission to the FDA of a meeting request to discuss product development pathways or submission of an IDE, if applicable, to commence clinical trials of our product candidates; the enrollment of patients in clinical trials; the release of data from clinical trials; the obtainment of the right to affix the CE mark in the European Union. The actual timing of these milestones could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot assure you that we will meet our projected milestones and if we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

Clinical trials are necessary to support de novo classification requests and certain 510(k) premarket notifications and may be necessary to support subsequent 510(k) submissions for modified versions of any digital therapeutic devices for which we obtain marketing authorization. This requires the enrollment of large numbers of suitable subjects, which may be difficult to identify, recruit and maintain as participants in the clinical trial. Adverse outcomes in our potentially pivotal trials or post-market studies could also result in restrictions on or withdrawal of marketing clearances we obtain. We will likely need to conduct additional clinical studies in the future for the authorization of the use of our products in some foreign countries. Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. The initiation and completion of any of these trials may be prevented, delayed, or halted for numerous reasons. We may experience a number of events during the conduct of our clinical trials that could adversely affect the costs, timing or successful completion, including:

- if we are required to submit an IDE application to FDA, which must become effective prior to commencing human clinical trials, the FDA may reject our IDE application and notify us that we may not begin investigational trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, ("CROs"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may have disagreements with CROs and clinical trial sites about the terms of our contracts with them and the amounts owed thereunder, and as a result, the costs of our clinical trials may be higher than anticipated;

- clinical trials may produce negative or inconclusive results, or we may not agree with regulatory authorities on the interpretation of our clinical trial results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials, including to effectively test and demonstrate the effect of our product candidates, may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites or trial subjects;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in our ability to supply our product candidates;
- marketing authorization policies, pathways or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for marketing authorization; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

Clinical trials must be conducted in accordance with the applicable laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. We may in the future have to terminate a clinical trial site or investigator which is found through our clinical trial monitoring activities to be noncompliant with our clinical trial protocols or with applicable laws, regulations, requirements and guidelines for the conduct of our clinical trials.

Furthermore, we rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our CROs to support the conduct of our clinical trials in compliance with good clinical practice ("GCP"), requirements. To the extent our CROs fail to help oversee the conduct the study in compliance with GCP standards or are delayed for a significant time in the execution of the trial, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Failure can occur at any stage of clinical testing. Our clinical trials may produce negative or inconclusive results or may demonstrate a lack of effect of our product candidates. We may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned. Our failure to adequately demonstrate the safety and effectiveness of any product candidates we may develop or may develop in the future would prevent receipt of regulatory marketing authorization and, ultimately, the commercialization of that product or indication for use. Even if our future products are granted de novo classification or cleared in the United States, commercialization of our products in foreign countries would require marketing authorization by regulatory authorities in those countries.

Marketing authorization procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including the conduct of additional pilot studies or clinical trials. Any of these occurrences could have an adverse effect on our business, financial condition and results of operations.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays or difficulties in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials on our current timelines, or at all, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Slow enrollment in our clinical trials may lead to delays in our development timelines and milestones.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the ability of patients to continue to receive medical care, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved or authorized for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, make our data more difficult to interpret, affect the powering of our trial, or result in the failure of the clinical trial.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. In addition, we rely on clinical trial sites to ensure timely conduct of our clinical trials and, while we have entered into agreements governing their services, we are limited in our ability to compel their actual performance.

Interim, "topline," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our pilot studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and treatment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing authorization or clearance or commercialization of the particular product candidate, the commercial success of any product for which we may have already obtained authorization or clearance, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differs from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain marketing authorization for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

If patients or physicians are not willing to change current practices to adopt our BT-001 digital therapeutic, if granted authorization for marketing, our future product candidates may fail to gain increased market acceptance, and our business will be adversely affected.

Our primary strategy to grow our revenue is to drive the adoption of our BT-001 digital therapeutic, if granted marketing authorization, by physicians to assist their patients in improving glycemic control by lowering HbA1c. Physicians may choose not to adopt our digital therapeutic products for a number of reasons, including:

- lack of availability of adequate third-party payer coverage or reimbursement;
- lack of experience with our product;
- our inability to convince key opinion leaders to recommend our products;
- perceived inadequacy of evidence supporting clinical benefits, safety or cost-effectiveness of our product;
- liability risks generally associated with the use of new products; and
- the training required to use new products.

For our lead product candidate, BT-001, if authorized for marketing, we intend to focus our sales, marketing and training efforts primarily on primary care physicians. However, physicians from other disciplines, such as endocrinologists, as well as other medical professionals, such as nurse practitioners and physician assistants, are often the initial point of contact for patients with diabetes management needs. We believe that educating physicians in these disciplines and other medical professionals about the clinical merits, patient benefits and safety profile of our digital therapeutic products is an element of increasing product adoption. If additional primary care physicians or other medical professionals do not appreciate and recommend the benefits of our digital therapeutic for any reason, including those listed above, our ability to execute our growth strategy will be impaired, and our business may be adversely affected.

In addition, patients may not be able to adopt or may choose not to adopt our digital therapeutic if, among other potential reasons, they are worried about potential adverse effects of use of our digital therapeutic or they are unable to obtain adequate third-party coverage or reimbursement.

Our long-term growth depends on our ability to enhance our digital therapeutic products, expand our indications and develop and commercialize additional products once granted marketing authorization and clearance.

It is important to our business strategy that we continue to enhance our BT-001 digital therapeutic with additional functionalities and, in the future, additional indications, as well as develop, seek authorization or clearance for and introduce new products. Developing products is expensive and time-consuming and could divert management's attention away from our core business. The success of any new product offering or product enhancements will depend on several factors, including our ability to:

- properly identify and anticipate physician and patient needs;
- develop and introduce new functionalities, uses, products and product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and effectiveness of new products with data from preclinical and pilot studies and clinical trials;
- obtain the necessary regulatory clearances, authorizations or approvals for expanded indications, new products or product modifications;
- be fully FDA-compliant with marketing of new products or modified products;
- provide adequate training to potential patients prescribed our products;
- receive adequate coverage and reimbursement for procedures performed with our products; and
- develop an effective and dedicated sales and marketing team.

If we are not successful in expanding our indications and developing and commercializing new products and product enhancements, our ability to increase our revenue may be impaired, which could have a material adverse effect on our business, financial condition and results of operations.

Our product candidates represent novel and innovative potential therapeutic areas, and negative perception of any product candidate that we develop could adversely affect our ability to conduct our business, obtain regulatory marketing authorizations or identify alternate regulatory pathways to market for such product candidate.

Certain of our product candidates are considered relatively new and novel therapeutic approaches. Our and their success will depend upon physicians who specialize in the treatment of diseases targeted by our and their product candidates prescribing potential treatments that involve the use of our and their product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Access will also depend on consumer acceptance and adoption of products that are commercialized. In addition, responses by the U.S., state or foreign governments to negative public perception or ethical concerns may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory authorization, identify alternate regulatory pathways to market or otherwise achieve profitability.

For example, in the United States, no prescription digital therapeutic candidates designed to deliver cognitive behavioral therapy for treating diabetes, heart disease, and other cardiometabolic conditions have been authorized, to date. We are developing a platform of FDA-regulated, software-based, prescription digital therapeutic candidates for treating such conditions through a novel form of cognitive behavioral therapy. The FDA may lack experience in evaluating the safety and effectiveness of product candidates based on cognitive behavioral therapy, which could result in a longer than expected regulatory review process, increase expected development costs and delay or prevent potential commercialization of product candidates.

Risks Related to Government Regulation

Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.

We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use; clinical trials; product safety; premarket clearance and approval; establishment registration and device listing; marketing, sales and distribution; complaint handling; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through periodic unannounced inspections. We do not know whether we will pass any future FDA inspections or those conducted by foreign regulatory agencies. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or marketing authorizations; withdrawals or suspensions of any current marketing authorizations, resulting in prohibitions on the sale and distribution of any of our marketed products; and in the most serious cases, criminal penalties.

We may not receive the necessary de novo classification grant for our BT-001 digital therapeutic or clearances for future expanded indications of our BT-001 digital therapeutic product candidate, and failure to timely obtain these regulatory authorizations would adversely affect our ability to grow our business.

Our strategy is dependent on the initial de novo classification by FDA of our BT-001 digital therapeutic granting its ability for marketing in the United States. In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing products, we must first receive either clearance under Section 510(k) of the FD&C Act, or authorization under the de novo classification process added under the FDAMA, or premarket approval ("PMA") from the FDA, unless an exemption applies.

The de novo classification process, which is the development pathway required based on discussions with the FDA for our BT-001 digital therapeutic for our current planned use in treatment of T2D, provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. A de novo classification is a risk-based classification process where devices that are classified into Class I or Class II through a de novo classification request may be marketed and used as predicates for future premarket notification 510(k) submissions.

In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the United States market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence demonstrations. We plan to pursue the 510(k) clearance process for the addition of expanded indications for our BT-001 digital therapeutic.

Where the de novo classification or 510(k) clearance pathways are not available for medical devices, and where no policy of enforcement discretion exists enabling a manufacturer to market a medical device without obtaining premarket authorization, the process of obtaining PMA approval may apply, which is the most rigorous product development pathway for seeking marketing approval for a medical device. In review of a PMA application, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to pre-clinical, clinical trial, technical, manufacturing and labeling data beyond that which is required to support a de novo classification request or 510(k) clearance submission. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) or the de novo classification process may require a new 510(k) clearance or a new de novo classification request. Both the PMA approval, de novo classification, and the 510(k) clearance processes can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer, while the de novo classification request process is usually longer and requires a clinical trial. The process of obtaining a PMA is much more costly and uncertain than the de novo or 510(k) clearance processes and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved, granted marketing authorization or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business. Furthermore, even if we are granted regulatory authorizations, clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

In the United States, we are currently developing our BT-001 digital therapeutic through the de novo classification pathway. Any modification to our BT-001 digital therapeutic that has not been previously authorized may require us to submit a 510(k) premarket clearance application or a subsequent de novo classification request prior to implementing the change for marketing. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

The FDA can delay, limit or deny de novo classification, clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials or the interpretation of data from pre-clinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our pre-clinical or pilot studies and clinical trials may be insufficient to support de novo classification, clearance or approval where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks; and

- the potential for medical device policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for de novo classification, clearance or approval.

In addition, the FDA may change its policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay de novo classification, clearance or approval of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new authorizations, increase the costs of compliance or restrict our ability to maintain any authorizations we may successfully obtain.

We may market digital products for uses under current FDA enforcement discretion or outside of the current definition of a "medical device" in the United States.

Currently, the FDA's regulatory framework permits the marketing of certain digital applications and products outside of the FDA's active regulation under its device authorities or, in other cases, completely outside FDA regulation if the product uses do not meet the definition of a "medical device." From time to time, we may develop and commercialize products that we determine fall within the current areas of FDA enforcement discretion or outside the definition of a medical device, but the FDA may not agree with our determination. If the FDA disagrees with any such determinations that we make, we may be required to cease further marketing or distribution of those products until such time as we obtain any required premarket authorization, clearance or approval for those products and we may be subject to receiving an FDA untitled letter or warning letter for such product marketing and distribution activities, amongst other potential enforcement mechanisms available to the FDA.

Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a products from the market.

After de novo classification, if granted, for our BT-001 digital therapeutic product candidate, we will be subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, labeling, sale, promotion, advertising, medical device reporting, registration, distribution, and listing of devices. For example, we must submit reports to the FDA, for certain adverse events. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of these medical device adverse event reports, the FDA might ask for additional information or initiate further investigation.

In addition, our digital therapeutics may become subject to post-market study requirements. Any failure to conduct the required studies in accordance with an IRB, and informed consent requirements, or adverse findings in these studies, could also be grounds for modification or withdrawal of marketing authorization for any product we may commercialize.

The FDA and the FTC, also regulate the advertising and promotion of our products and services to ensure that the claims we make are consistent with our regulatory authorizations, that there is adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory authorization to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our products;
- patient notifications for repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future marketing authorizations of new products, new intended uses, or modifications to any marketed products we may commercialize;

- withdrawals or suspensions of our regulatory authorizations, resulting in prohibitions on sales and distribution of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations.

If treatment guidelines for diabetes patient management change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for one or more of our product candidates.

If treatment guidelines for diabetes patient management change or the standard of care for this or any other conditions in which we seek to develop digital therapeutics evolves, we may need to redesign the applicable product or product candidates we market or seek to develop and may need to seek and obtain new de novo classifications, clearances or approvals from the FDA and the equivalent from foreign regulatory authorities. If treatment guidelines or the standards of care change so that different treatments become desirable, the clinical utility of one or more of our products could be diminished and our business could be adversely affected.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Although our products, if authorized for marketing, are marketed for the specific therapeutic uses for which the devices were designed and our personnel will be trained to not promote our products for uses outside of the FDA-approved indications for use, known as "off-label uses," we cannot, however, prevent a physician from using our products in ways, when in the physician's independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if primary care physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those authorized, cleared or approved by the FDA or authorized by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among primary care physicians and patients.

If following authorization of our BT-001 digital therapeutic or any other product candidates we may commercialize the FDA or any foreign regulatory body determines that our promotional materials or training include promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter or warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authorities, such as false claims laws for any products for which we obtain government reimbursement, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, physicians may misuse our products with their patients if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused, we may become subject to costly litigation by our patients or their patients. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations for any devices we may market, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device authorization, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new authorizations, clearance or approvals for the device before we may market or distribute the corrected device. Seeking such authorizations, clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with patients, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

In the event we seek to market our products in international markets, if we do not obtain and maintain international regulatory registrations or marketing authorizations for our products, we will be unable to market and sell our products outside of the United States.

Sales of our products outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we obtain the marketing authorization of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or marketing authorizations, can be expensive and time-consuming, and we may not receive regulatory authorizations, clearances or approvals in each country in which we may plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations or marketing authorizations, if required by other countries, may be longer than that required for FDA de novo classification, clearance or approval, and requirements for such registrations and marketing authorizations may significantly differ from FDA requirements. If we modify our products, we may need to apply for additional regulatory authorizations before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Regulatory de novo classification, clearance or approval by the FDA does not ensure registration or marketing authorization by regulatory authorities in other countries, and registration or marketing authorization by one or more foreign regulatory authorities does not ensure registration or marketing authorization by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining registration or marketing authorization in one country may have a negative effect on the regulatory process in others.

Risks Related to Healthcare Laws and Regulation

The insurance coverage and reimbursement status of newly-authorized products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for any of our product candidates, if authorized for marketing, could limit our ability to market those products and decrease our ability to generate revenue.

In the United States and markets in other countries, patients generally rely on third-party payers to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payers, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new products are typically made by CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. The availability of coverage and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford treatments. Sales of product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly authorized, cleared, or approved products and coverage may be more limited than the purposes for which the medicine is authorized for marketing by the FDA or comparable foreign regulatory authorities.

Factors payers consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Each payer determines whether or not it will provide coverage for a treatment, what amount it will pay the manufacturer for the treatment and on what tier of its formulary it will be placed. The position on a payer's list of covered drugs, biological products, and medical devices, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payers to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. There may be significant delays in obtaining such coverage and reimbursement for newly marketed products, and coverage may be more limited than the purposes for which the product is authorized for marketing by the FDA.

Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers, by any future laws limiting product prices.

Third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing authorization. If coverage and adequate reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our product candidates.

In addition, in some foreign countries, the proposed pricing for a prescription device must be approved before it may be lawfully marketed. The requirements governing product pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product to currently available therapies. A Member State may approve a specific price for the products or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws health information privacy and security laws, and other health care laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

We are subject to applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute and the FCA, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute our products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry (e.g., healthcare providers, physicians and third-party payers), are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. We also may be subject to patient information and privacy and security regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA or federal civil money penalties.
- the federal civil and criminal false claims laws and civil monetary penalty laws, such as the FCA, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. A person can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- The U.S. federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payer. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and the FCA, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payers, including private insurers. Several states also impose other marketing restrictions or require medical device manufacturers to make marketing or price disclosures to the state. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge and may not comply under one or more of such laws, regulations, and guidance. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other healthcare providers are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), and imprisonment, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results.

We are subject to data privacy and security laws and regulations governing our collection, use, disclosure, or storage of personally identifiable information, including protected health information and payment card data, which may impose restrictions on us and our operations and subject us to penalties if we are unable to fully comply with such laws.

Numerous federal and state laws and regulations govern the collection, use, disclosure, storage and transmission of personally identifiable information, including protected health information. These laws and regulations, including their interpretation by governmental agencies, are subject to frequent change and could have a negative impact on our business. In addition, in the future, industry requirements or guidance, contractual obligations, and/or legislation at both the federal and the state level may limit, forbid or regulate the use or transmission of health information outside of the United States. These varying interpretations can create complex compliance issues for us and our partners and potentially expose us to additional expense, adverse publicity and liability, any of which could adversely affect our business.

Federal and state consumer protection laws are increasingly being applied by the FTC, and states' attorneys general to regulate the collection, use, storage and disclosure of personal or personally identifiable information, through websites or otherwise, and to regulate the presentation of website content.

The security measures that we and our third-party vendors and subcontractors have in place to ensure compliance with privacy and data protection laws may not protect our facilities and systems from security breaches, acts of vandalism or theft, computer viruses, misplaced or lost data, programming and human errors or other similar events. Even though we provide for appropriate protections through our agreements with our third party vendors, we still have limited control over their actions and practices. A breach of privacy or security of personally identifiable health information may result in an enforcement action, including criminal and civil liability, against us. We are not able to predict the extent of the impact such incidents may have on our business. Enforcement actions against us could be costly and could interrupt regular operations, which may adversely affect our business. While we have not received any notices of violation of the applicable privacy and data protection laws and believe we are in compliance with such laws, there can be no assurance that we will not receive such notices in the future.

There is ongoing concern from privacy advocates, regulators and others regarding data privacy and security issues, and the number of jurisdictions with data privacy and security laws has been increasing. Also, there are ongoing public policy discussions regarding whether the standards for de-identification, anonymization or pseudonymization of health information are sufficient, and the risk of re-identification sufficiently small, to adequately protect patient privacy. We expect that there will continue to be new proposed and amended laws, regulations and industry standards concerning privacy, data protection and information security in the United States, such as the CCPA. Further, the CPRA was passed by California voters on November 3, 2020. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). Other U.S. states also are considering omnibus privacy legislation and industry organizations regularly adopt and advocate for new standards in these areas. While the CCPA and CPRA contains an exceptions for certain activities involving PHI under HIPAA, we cannot yet determine the impact the CCPA, CPRA or other such future laws, regulations and standards may have on our business.

Future laws, regulations, standards, obligations amendments, and changes in the interpretation of existing laws, regulations, standards and obligations could impair our or our clients' ability to collect, use or disclose information relating to patients or consumers, including information derived therefrom, which could decrease demand for our Platform, increase our costs and impair our ability to maintain and grow our client base and increase our revenue. Accordingly, we may find it necessary or desirable to fundamentally change our business activities and practices or to expend significant resources to modify our software or platform and otherwise adapt to these changes.

Further, our patients may expect us to comply with more stringent privacy and data security requirements than those imposed by laws, regulations or self-regulatory requirements, and we may be obligated contractually to comply with additional or different standards relating to our handling or protection of data.

Any failure or perceived failure by us to comply with federal or state laws or regulations, industry standards or other legal obligations, or any actual or suspected privacy or security incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of personally identifiable information or other data, may result in governmental enforcement actions and prosecutions, private litigation, fines and penalties or adverse publicity and could cause our clients to lose trust in us, which could have an adverse effect on our reputation and business. We may be unable to make such changes and modifications in a commercially reasonable manner or at all, and our ability to develop new products could be limited. Any of these developments could harm our business, financial condition and results of operations. Privacy and data security concerns, whether valid or not valid, may inhibit retention of our Platform by existing clients or adoption of our Platform by new clients.

Healthcare legislative reform measures and constraints on national budget social security systems may have a material adverse effect on our business and results of operations.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the ACA, was enacted, which, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been judicial, Congressional and executive challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions were suspended from May 1, 2020 through March 31, 2022 due to the ongoing COVID-19 pandemic. Following the temporary suspension, a 1% payment reduction began April 1, 2022 and lasted through June 30, 2022, the 2% payment reduction resumed on July 1, 2022.

There has been increasing legislative and enforcement interest in the United States with respect to product pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to product pricing, reduce the cost of products under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. It is unclear what effect such legislative and enforcement interest may have on prescription devices.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any marketed device, which could have an adverse effect on patients for our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from products that we may successfully develop and for which we may obtain regulatory marketing authorization and may affect our overall financial condition and ability to develop product candidates. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates we may develop may lose any regulatory marketing authorization that may have been obtained and we may not achieve or sustain profitability.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, vendors and other agents may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, vendors and other agents may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates applicable regulations, including those laws requiring the reporting of true, complete and accurate information to regulatory agencies, manufacturing standards and U.S. federal and state healthcare laws and regulations. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. We could face liability under the U.S. federal Anti-Kickback Statute and similar U.S. state laws. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, referrals, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in significant regulatory sanctions and serious harm to our reputation. Further, should violations include promotion of unapproved (off-label) uses one or more of our products, we could face significant regulatory sanctions for unlawful promotion, as well as substantial penalties under the FCA, and similar state laws. Similar concerns could exist in jurisdictions outside of the United States as well. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. The precautions we take to detect and prevent misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations.

Risks Related to Our Legal and Regulatory Environment

Failure to comply with anti-bribery, anti-corruption and anti-money laundering laws could subject us to penalties and other adverse consequences.

We are subject to the U.S. Foreign Corrupt Practices Act (the "FCPA") and other anti-corruption, anti-bribery, and anti-money laundering laws in the jurisdictions in which we do business, both domestic and abroad. These laws generally prohibit us and our employees from improperly influencing government officials or commercial parties in order to obtain or retain business, direct business to any person or gain any improper advantage. The FCPA and similar applicable anti-bribery and anti-corruption laws also prohibit our third-party business partners, representatives and agents from engaging in corruption and bribery. We and our third-party business partners, representatives and agents may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We may be held liable for the corrupt or other illegal activities of these third-party business partners and intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize such activities. These laws also require that we keep accurate books and records and maintain internal controls and compliance procedures designed to prevent any such actions. While we have policies and procedures to address compliance with such laws, we cannot assure you that our employees and agents will not take actions in violation of our policies or applicable law, for which we may be ultimately held responsible. Our exposure for violating these laws will increase as we expand internationally and as we commence sales and operations in foreign jurisdictions. Any violation of the FCPA or other applicable anti-bribery, anti-corruption laws and anti- money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, imposition of significant legal fees, loss of export privileges, severe criminal or civil sanctions or suspension or debarment from U.S. government contracts, substantial diversion of management's attention, drop in stock price or overall adverse consequences to our business, all of which may have an adverse effect on our reputation, business, financial condition, and results of operations.

Federal, state and local employment-related laws and regulations could increase our cost of doing business and subject us to fines and lawsuits.

Our operations are subject to a variety of federal, state and local employment-related laws and regulations, including, but not limited to, the U.S. Fair Labor Standards Act, which governs such matters as minimum wages, the Family Medical Leave Act, overtime pay, compensable time, recordkeeping and other working conditions, Title VII of the Civil Rights Act, the Employee Retirement Income Security Act, the Americans with Disabilities Act, the National Labor Relations Act, regulations of the Equal Employment Opportunity Commission, regulations of the Office of Civil Rights, regulations of the Department of Labor (DOL), regulations of state attorneys general, federal and state wage and hour laws, and a variety of similar laws enacted by the federal and state governments that govern these and other employment-related matters. As our employees are located in a number of states, compliance with these evolving federal, state and local laws and regulations could substantially increase our cost of doing business while failure to do so could subject us to fines and lawsuits. We are currently subject to employee-related legal proceedings in the ordinary course of business. While we believe that we have adequate reserves for those losses that we believe are probable and can be reasonably estimated, the ultimate results of legal proceedings and claims cannot be predicted with certainty.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the applicable listing standards of The Nasdaq Capital Market ("Nasdaq"). We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time-consuming and costly and place significant strain on our personnel, systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we will file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. We are also continuing to improve our internal control over financial reporting, which includes hiring additional accounting and financial personnel to implement such processes and controls. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs and significant management oversight. If any of these new or improved controls and systems do not perform as expected, we may experience material weaknesses in our controls.

Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our results of operations or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting also could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on Nasdaq. We are not currently required to comply with the SEC rules that implement Section 404 of the Sarbanes-Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. As a public company, we are required to provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report on Form 10-K.

Our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting until after we are no longer an "emerging growth company" as defined in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our internal control over financial reporting is documented, designed or operating. Any failure to maintain effective disclosure controls and internal control over financial reporting could have an adverse effect on our business and results of operations and could cause a decline in the price of our common stock.

If we fail to establish and maintain effective internal control over financial reporting, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. We identified a material weakness our internal control over financial reporting related to the inaccurate accounting for the value of shares to be issued to the underwriter at the closing of our IPO as well as inaccurate accounting for certain accrued expenses and prepaid expenses and the Company's restatement of its financial statements to reclassify all redeemable equity instruments to temporary equity from permanent equity. Up to and including the third fiscal quarter of 2021, our disclosure controls and procedures were not effective. We have implemented a remediation plan, described under Part I, Item 4, Evaluation of Disclosure Controls and Procedures of our Form 10-Q for the third quarter of 2021, to remediate the material weakness but can give no assurance that the measures we have taken will prevent any future material weaknesses or deficiencies in internal control over financial reporting. Even though we believe we have strengthened our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our financial statements.

Risks Related to Our Organizational Structure

Our executive chairman of the board of directors, David Perry has significant influence over the company.

As of June 20, 2022, Mr. Perry owns approximately 45.6% of the outstanding shares of our common stock. As long as Mr. Perry each owns or controls a significant percentage of outstanding voting power, he has the ability to strongly influence all corporate actions requiring stockholder approval, including the election and removal of directors and the size of our board of directors, any amendment of our certificate of incorporation or bylaws, or the approval of any merger or other significant corporate transaction, including a sale of substantially all of our assets. Some of these persons or entities may have interests different than yours.

Delaware law and our governing documents contain certain provisions, including anti-takeover provisions, that limit the ability of stockholders to take certain actions and could delay or discourage takeover attempts that stockholders may consider favorable.

Our governing documents and the Delaware General Corporation Law ("DGCL"), contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition deemed undesirable by the Board and therefore depress the trading price of our common stock. These provisions could also make it difficult for stockholders to take certain actions, including electing directors who are not nominated by the current members of the Board or taking other corporate actions, including effecting changes in our management. Among other things, our governing documents include provisions regarding:

- the ability of the Board to issue shares of preferred stock, including "blank check" preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the limitation of the liability, and indemnification of our directors and officers;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of stockholders after such date and could delay the ability of stockholders to force consideration of a stockholder proposal or to take action, including the removal of directors;
- the requirement that a special meeting of stockholders may be called only by a majority of our entire Board, which could delay the ability of stockholders to force consideration of a proposal or to take action, including the removal of directors;
- controlling the procedures for the conduct and scheduling of board of directors and stockholder meetings;
- the ability of the Board to amend the bylaws, which may allow the Board to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend the bylaws to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to the Board or to propose matters to be acted upon at a stockholders' meeting, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in the Board, and also may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in the Board or management.

Our amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders; (3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws (including the interpretation, validity or enforceability thereof); or (4) any action asserting a claim governed by the internal affairs doctrine. We refer to this provision in our bylaws as the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. We refer to this provision in our bylaws as the Federal Forum Provision. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Risks Related to Our Common Stock

Unstable market and economic conditions may have series adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in the rate of inflation, increases in unemployment rates and uncertainty about economic stability, including most recently in connection with the ongoing and evolving COVID-19 pandemic and economic and political developments, including the conflict in Ukraine, rising interest rates and high inflation. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. Our business could be also be impacted by volatility caused by geopolitical events, such as the conflict in Ukraine. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, scale back or discontinue the development and commercialization of one or more of our product candidates.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

If Nasdaq delists our shares of common stock from trading on its exchange for failure to meet Nasdaq's listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The price of our common stock may be volatile.

The price of our common stock may fluctuate due to a variety of factors, including:

- changes in the industries in which we and our customers operate;
- variations in its operating performance and the performance of our competitors in general;
- material and adverse impacts of global economic and political developments, including the war in Ukraine, and the ongoing COVID-19 pandemic on the markets and the broader global economy;
- actual or anticipated fluctuations in our quarterly or annual operating results;

- publication of research reports by securities analysts about us or our competitors or its industry;
- the public's reaction to our press releases, our other public announcements and our filings with the SEC;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of our common stock available for public sale; and
- general economic and political conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war or terrorism.

These market and industry factors may materially reduce the market price of our common stock regardless of our operating performance.

Recent volatility in capital markets and lower market prices for our securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.

Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to develop and, if approved, commercialize our product candidates, support our business growth, retain or expand our current levels of personnel, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements;
- develop and, if approved, commercialize our product candidates and develop and maintain platform;
- pursue acquisitions or other strategic relationships; and
- respond to competitive pressures.

Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our business.

Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our common shares.

Securities research analysts may establish and publish their own periodic projections for us. These projections may vary widely and may not accurately predict the results we actually achieve. Our share price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our share price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our share price or trading volume could decline.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Although certain stockholders will be subject to certain restrictions regarding the transfer of our common stock, these shares may be sold after the expiration of the lock-up. As restrictions on resale end and the registration statements are available for use, the market price of our common stock could decline if the holders of currently restricted shares sell them or are perceived by the market as intending to sell them.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors, and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

Because we have no current plans to pay cash dividends on our common stock, you may not receive any return on investment unless you sell your common stock for a price greater than that which you paid for it.

We have no current plans to pay cash dividends on our common stock. The declaration, amount and payment of any future dividends will be at the sole discretion of our board of directors. Our board of directors may take into account general and economic conditions, our financial condition and operating results, our available cash, current and anticipated cash needs, capital requirements, contractual, legal, tax and regulatory restrictions, implications on the payment of dividends by us to our stockholders or by our subsidiary to us and such other factors as our board of directors may deem relevant. In addition, the terms of our loan agreement with Hercules Capital restrict our ability to pay cash dividends. Accordingly, we may not pay any dividends on our common stock in the foreseeable future.

Future offerings of debt or equity securities by us may adversely affect the market price of our common stock.

In the future, we may attempt to obtain financing or to further increase our capital resources by issuing additional shares of our common stock or offering debt or other equity securities, including commercial paper, medium-term notes, senior or subordinated notes, debt securities convertible into equity or shares of preferred stock. Future acquisitions could require substantial additional capital in excess of cash from operations. We would expect to obtain the capital required for acquisitions through a combination of additional issuances of equity, corporate indebtedness and/or cash from operations. Issuing additional shares of our common stock or other equity securities or securities convertible into equity may dilute the economic and voting rights of our existing stockholders or reduce the market price of our common stock or both. Upon liquidation, holders of such debt securities and preferred shares, if issued, and lenders with respect to other borrowings would receive a distribution of our available assets prior to the holders of our common stock. Debt securities convertible into equity could be subject to adjustments in the conversion ratio pursuant to which certain events may increase the number of equity securities issuable upon conversion. Preferred shares, if issued, could have a preference with respect to liquidating distributions or a preference with respect to dividend payments that could limit our ability to pay dividends to the holders of our common stock. Our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, which may adversely affect the amount, timing and nature of our future offerings.

General Risk Factors

If we fail to effectively manage our growth, we may be unable to execute our business plan, adequately address competitive challenges or maintain our corporate culture, and our business, financial condition and results of operations would be harmed.

The growth and expansion of our business creates significant challenges for our management, operational and financial resources. To effectively manage our growth, we must continue to improve our operational, financial and management processes and systems and to effectively expand, train and manage our employee base. As our organization continues to grow and we are required to implement more complex organizational management structures, we may find it increasingly difficult to maintain the benefits of our corporate culture. This could negatively affect our business performance.

We depend on our senior management team, and the loss of one or more of our executive officers or key employees or an inability to attract and retain highly skilled employees could adversely affect our business.

Our success depends largely upon the continued services of our key executive officers. These executive officers are at-will employees and therefore they may terminate employment with us at any time with no advance notice. We rely on our leadership team in the areas of operations, clinical and software development, information security, marketing, compliance and general and administrative functions. From time to time, there may be changes in our executive management team resulting from the hiring or departure of executives, which could disrupt our business.

The loss of one or more of the members of our senior management team, or other key employees, could harm our business. The replacement of one or more of our executive officers or other key employees would likely involve significant time and costs and may significantly delay or prevent the achievement of our business objectives.

To continue to execute our growth strategy, we also must attract and retain highly skilled personnel. Competition is intense for qualified professionals. We may not be successful in continuing to attract and retain qualified personnel. We have from time to time in the past experienced, and we expect to continue to experience in the future, difficulty in hiring and retaining highly skilled personnel with appropriate qualifications. The pool of qualified personnel with experience working in the healthcare market is limited overall. In addition, many of the companies with which we compete for experienced personnel have greater resources than we have.

Additionally, our success is dependent on our ability to evolve our culture, align our talent with our business needs, engage our employees and inspire our employees to be open to change and innovate. Our business would be adversely affected if we fail to adequately plan for succession of our executives and senior management, or if we fail to effectively recruit, integrate, retain and develop key talent and/or align our talent with our business needs, in light of the current rapidly changing environment.

We will incur significant increased expenses and administrative burdens as a public company, which could have an adverse effect on our business, financial condition and results of operations.

As a public company, we will face increased legal, accounting, administrative and other costs and expenses as a public company that we did not incur as a private company. The Sarbanes-Oxley Act, including the requirements of Section 404, as well as rules and regulations subsequently implemented by the SEC, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations promulgated and to be promulgated thereunder, the ("PCAOB") and the securities exchanges, impose additional reporting and other obligations on public companies. Compliance with public company requirements will increase costs and make certain activities more time-consuming. A number of those requirements will require us to carry out activities we have not done previously. In addition, additional expenses associated with SEC reporting requirements will be incurred. Furthermore, if any issues in complying with those requirements are identified (for example, if the auditors identify a material weakness or significant deficiency in the internal control over financial reporting), we could incur additional costs rectifying those issues, and the existence of those issues could adversely affect our reputation or investor perceptions of it. It may also be more expensive to obtain director and officer liability insurance. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on our Board or as executive officers. The additional reporting and other obligations imposed by these rules and regulations will increase legal and financial compliance costs and the costs of related legal, accounting and administrative activities. These increased costs will require us to divert a significant amount of money that could otherwise be used to expand the business and achieve strategic objectives. Advocacy efforts by stockholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs.

We qualify as an "emerging growth company" and as a "smaller reporting company", and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies or smaller reporting companies, which could make our securities less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies.

We qualify as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the JOBS Act. As such, we are eligible for and intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act, (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which the market value of the shares of our common stock that are held by non-affiliates exceeds $700 million as of June 30 of that fiscal year, (ii) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more during such fiscal year, (iii) the date on which we have issued more than $1 billion in non-convertible debt in the prior three-year period or (iv) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stocks in our IPO. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7(a)(2)(B) of the Securities Act as long as we are an emerging growth company. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Investors may find our common stock less attractive because we will rely on these exemptions, which may result in a less active trading market for our common stock and its stock price may be more volatile.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700 million as of the prior June 30 and our annual revenue is less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million as of the prior June 30 or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of the prior June 30. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in this Annual Report and take advantage of reduced disclosure obligations regarding executive compensation.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL 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 (embedded within the Inline XBRL document)

* Filed herewith.

** This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

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

BETTER THERAPEUTICS, INC.
(Registrant)

Date: August 11, 2022

By: /s/ Frank Karbe
Frank Karbe
Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2022

By: /s/ Mark Heinen
Mark Heinen
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Frank Karbe, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Better Therapeutics, Inc. ("the registrant");

(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: August 11, 2022

By: /s/ Frank Karbe
Frank Karbe
Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark Heinen, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Better Therapeutics, Inc. ("the registrant");

(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: August 11, 2022

By: /s/ Mark Heinen
Mark Heinen
Head of Finance and Interim Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Better Therapeutics, Inc., (the "Company") on Form 10-Q for the period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Frank Karbe, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 11, 2022

By: /s/ Frank Karbe
Frank Karbe
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Better Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark Heinen, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 11, 2022

By: /s/ Mark Heinen
Mark Heinen
Head of Finance and Interim Chief Financial Officer