2022 Annual Report

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

OR

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

Commission File Number 001-39864

BETTER THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**85-3472546**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
548 Market Street #49404	
San Francisco, California	**94104**
(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, par value $0.0001 per share	BTTX	Nasdaq Stock Market, LLC

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the Registrant's common stock on The Nasdaq Capital Market on June 30, 2022 was $15,314,200

The number of shares of the Registrant's Common Stock outstanding as of March 24, 2023 was 23,852,272.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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PART I

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K or (this "Annual 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 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Annual 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.

The forward-looking statements are based on the current expectations of the Company and its management and are inherently subject to uncertainties and changes in circumstances and their potential effects and speak only as of the date of such statement. There can be no assurance that future developments will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties 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:

- our limited operating history and significant financial losses since inception;
- our ability to obtain funding for our operations and our ability to continue as a going concern;
- our ability to successfully launch, commercialize, market and achieve and maintain market acceptance for BT-001 and our other product candidates, if authorized for marketing, 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 clinical trials;
- the rate and degree of market acceptance of BT-001 and our other product candidates, if authorized for marketing, by physicians, patients, third-party payors and others in the medical community;
- the willingness of the U.S. Food and Drug Administration ("FDA") to authorize prescription digital therapeutics ("PDTs") for marketing and for insurance companies to reimburse their use at favorable rates;
- our expectations related to the potential benefits of BT-001 and our product candidates, and of cognitive behavioral therapy ("CBT") and its potential treatment applications;
- our ability to build our own sales and marketing capabilities to commercialize our product candidates, if authorized for marketing, 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;
- developments and expectations relating to our competitors and our industry, including any regulatory developments;
- the pricing, reimbursement and cost-effectiveness of our product candidates, if authorized for marketing;
- 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 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;
- the effect of global economic and political developments, including the conflict in Ukraine, and the COVID-19 pandemic on the foregoing; and
- other risks and uncertainties detailed under the section entitled "Risk Factors."

The forward-looking statements contained in this Annual 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 I, Item 1A, "Risk Factors in this Annual 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 global economic and political developments and the 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 in this Annual 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 1. Business.

Overview

We are a prescription digital therapeutics company developing a clinically validated, software-based novel form of CBT to address the root causes of cardiometabolic diseases ("CMDx"). Our mission is to advance human health through the power of behavior change. We are developing a proprietary platform of FDA regulated software-based PDTs for the treatment of cardiometabolic diseases by addressing the underlying causes of the diseases. Our initial development efforts are focused on type 2 diabetes ("T2D"), hypertension, hyperlipidemia, non-alcoholic fatty liver disease ("NAFLD"), non-alcoholic steatohepatitis ("NASH") and chronic kidney disease ("CKD"). Founded in 2015, we are led by executives that have track records of building multi-billion dollar businesses and extensive industry experience in developing and commercializing therapeutics.

We selected cardiometabolic diseases as our initial target markets because they 1) share lifestyle behavior as a common root cause, potentially enabling rapid expansion of our platform across multiple related diseases, 2) rank amongst the most prevalent and costly chronic diseases that are largely reversible and preventable, offering opportunities for transformative impact and 3) represent areas of significant unmet need because currently available drugs predominantly treat symptoms, rather than addressing the root causes, often resulting in disease progression and more costly healthcare interventions over time.

Our clinically validated PDTs are intended to be prescribed by physicians and reimbursed by payers like traditional medicines. The mode of action embedded in our PDTs is a novel form of CBT, targeting the specific behaviors that cause the diseases we seek to treat. The CBT delivered by our PDTs is designed to enable changes in neural pathways of the brain so that lasting changes in behavior become possible.

Our lead PDT product candidate, BT-001, completed a first-in-class open label, randomized, controlled, parallel group clinical trial for the treatment of patients with T2D in July 2022 and successfully met its primary and secondary endpoints as well as a host of exploratory endpoints. We submitted a *de novo* classification request to the FDA in September 2022, seeking marketing authorization of BT-001 for the treatment of adult patients with T2D and in October 2022, the FDA notified us that our *de novo* classification request was accepted for substantive review. A portion of our data was published in the peer reviewed journal Diabetes Care in October 2022. As part of the typical *de novo* review process as expected by us, in February 2023, we received a Request for Additional Information from the FDA notifying us that, after review of our submission, the FDA determined that additional information is required. The letter outlined the FDA's view that our submission has a number of deficiencies, classified into major and minor deficiencies. We requested a meeting with the FDA to clarify several of the major deficiencies noted as well as to seek guidance on our options to address them. That meeting also took place in February. During the meeting the FDA provided helpful context, clarifications and guidance, and we are now compiling our response to address the FDA's comments. We believe we can address the FDA's questions, and our previously provided guidance that we anticipate FDA's decision by the middle of 2023 remains unchanged. If we are unable to resolve the deficiencies, we may need to amend the indications for use for which we are seeking authorization and/or conduct another clinical trial, and the authorization and commercial launch of BT-001 could be significantly delayed or the authorization could be denied.

We also achieved positive top-line results in our LivVita study, a first-ever clinical study evaluating the feasibility of our digitally delivered CBT to reduce liver fat and improve liver disease biomarkers as a potential treatment for NAFLD and NASH. Currently, there is no FDA approved treatment for these conditions, which affect one in four Americans and cause approximately $100 billion in direct medical costs annually. Because of the significant unmet medical need, we intend to apply for breakthrough device designation from the FDA for our investigational CBT-based treatment platform for these indications in the first half of 2023. We plan to use data from this study and the exploratory endpoints from the BT-001 pivotal trial to inform the potential initiation of additional pivotal trials in support of seeking FDA authorization in CMDx indications beyond T2D.

We believe we are differentiated from other companies in the PDT space in several important ways, which we believe has the potential to result in better commercial launch performance and peak revenue than those observed for previously approved PDTs: 1) with our focus on cardiometabolic diseases, and T2D as our lead indication, we are targeting very large patient populations with significant unmet medical needs; 2) our investigational PDTs are designed to deliver a treatment intervention that fits into the existing treatment paradigm, e.g., current clinical guidelines for the treatment of diabetes highlight behavior change as the foundation of treatment; 3) our proposed therapy has the potential to generate substantial health economic benefits and the utilization of our PDTs has the potential to improve profitability for payers; and 4) we have a team with extensive industry experience in developing and commercializing therapeutics. Furthermore, we believe our internally developed novel form of CBT is differentiated from other approaches in the digital therapeutics space that are incorporating CBT principles.

The clinical trial for BT-001 was the largest randomized controlled study of a PDT conducted to date and included a diverse, nationally representative population of 668 patients with a body mass index ("BMI") $\geq$ 25 mg/m^2, advanced and difficult to treat 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 ("SOC") with or without BT-001 and 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. Two important study design features, based on guidance received in our interactions with FDA, included a) the ability for physicians to adjust diabetes medication for all participants throughout the duration of the trial and b) that participants randomly assigned to use BT-001 were not mandated or incentivized to use the CBT features contained in BT-001. We believe these features established a very high bar for evaluating efficacy.

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 in A1c from baseline after 90 days of treatment. BT-001 met the primary endpoint, showing a highly statistically significant improvement in A1c relative to the control group (-0.4%, n=610, p <0.001). BT-001 showed a sustained and statistically significant change relative to the control group on the secondary efficacy endpoint, which was the mean change in A1c from baseline at 180 days (-0.3%, n=517, p =0.01). Importantly, BT-001 met the 180 day endpoint even though 1.5 times more SOC patients increased blood sugar lowering medications relative to those in the BT-001 arm prior to the 180 day A1c draw. After the day 180 A1c draw, 1.7 times more SOC control patients increased their medications compared to BT-001 patients. BT-001 demonstrated sustained and numerically improved A1c levels, with A1c reduction from baseline improving from 0.3% at 90 days to 0.4% at 180 days across the intent-to-treat population, suggesting a durable treatment effect. Half of the BT-001 patients achieved a meaningful reduction in A1c (defined as 0.4% reduction), with a mean A1c reduction of 1.3% within this subset. The clinical trial also provided evidence that beyond reductions in A1c: (1) there was a clear dose-response between greater engagement in CBT and greater reductions in A1c, supporting CBT as a mechanism of action, (2) measures of patient engagement, adherence, persistence, and satisfaction were all positive, (3) BT-001 resulted in reassuring safety data, with significantly fewer adverse (p<0.001) and serious adverse events (p=0.01) as compared to the SOC control group, and (4) exploratory endpoint data revealed additional cardiometabolic improvements as well as the potential to reduce the need for medications and lower healthcare utilization compared to the control group, supporting the potential, if authorized, for BT-001 to improve overall health of patients with T2D and potentially reduce cost of care associated with the progression of the disease.

The LivVita study, our clinical study evaluating the feasibility of our digitally delivered CBT to reduce fatty liver and improve liver disease biomarkers as a potential treatment for NAFLD and NASH was conducted in collaboration with Arizona Liver Health, a leading liver clinical research center. This single arm interventional cohort study enrolled 22 patients who were given access to a 90-day CBT-based treatment platform. This clinical study met its primary endpoint, showing a statistically significant positive signal with an average relative reduction in Magnetic Resonance Imaging-Proton Density Fat Fraction ("MRI-PDFF") of 16% (p=0.01) in the intent-to-treat population (n=19). Additionally, the clinical study showed (i) a statistically significant mean reduction in alanine transaminase (ALT) of -17 IU/L (p=0.002), (ii) a statistically significant mean change in FAST Score of 20% (p=0.01), (iii) no serious adverse events or device related adverse events, and (iv) high engagement and patient satisfaction with treatment, with a Net Promoter Score of +75 and 94% of subjects still using the app after 90 days. NAFLD and NASH affects over 80 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 NAFLD or NASH.

We also initiated real world evidence studies to evaluate the long-term effectiveness and healthcare utilization changes associated with the use of BT-001 for the treatment of T2D. The randomized, controlled, multi-site studies are expected to enroll 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 the fourth quarter of 2023, once a sufficient number of patients have completed an incremental 180 days of treatment. The study seeks to provide payers and providers with long-term data related to usage and outcomes in a real-world setting.

We have conducted primary market research into the potential for reimbursement coverage of our lead product candidate by representative payer groups and believe widespread reimbursement coverage can be established over time, subject to FDA marketing authorization. These findings have been further supported by larger, independent research studies, such as the one conducted by Xcenda, L.L.C ("Xcenda") and presented at the AMCP Nexus meeting ("AMCP") in October 2022.

Essential elements of our value proposition to our stakeholders include:

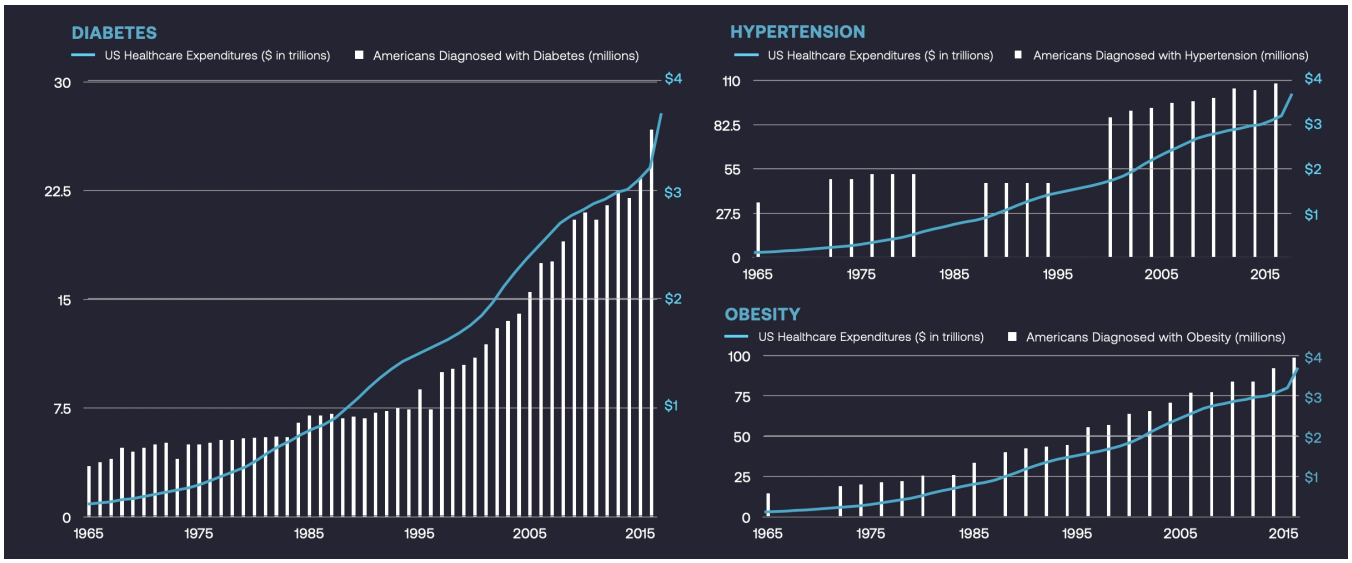
- *The ability to treat the root causes of CMDx* - We believe we can reframe the dynamic of T2D care away from the expectation that the patient's health will inevitably decline to an expectation that disease progression will be halted and, for many patients, the disease may be reversed altogether. We believe our investigational therapeutics may also have utility in the prevention of disease.
- *The potential to generate substantial health economic benefits* - The data generated in our pivotal study indicate the potential to significantly reduce cost of care associated with the progression of T2D, which we understand to be an important criterion in the coverage decision by payers. We believe this benefit will equally apply to other cardiometabolic diseases we are targeting.

- *Regulatory and platform leverage* - We estimate that 20 or more CMDx share essentially the same behavioral root causes our platform is designed to address. The regulatory pathway for PDTs is faster than for traditional therapeutics and requires substantially less investment. Every patient we treat with our product candidates generates data that we can use to improve our platform, including our CBT treatment algorithms. The exponential rate at which our patient data is expected to increase, especially if we are able to obtain FDA marketing authorization and commercialize BT-001, will enhance our ability to continuously improve our platform and future products, making it increasingly challenging, we believe, for potential competitors to offer products comparable in quality to ours.
- *First-mover advantage* - We estimate we have a two-to-three-year lead over potential competitors in bringing to market, if authorized, an FDA-regulated PDT for the treatment of T2D.

Inadequacies of the Current Treatment Paradigm

The U.S. has arrived at a massive, worsening, and unsustainable healthcare crisis. The prevalence of CMDx and U.S. healthcare spending have trended upwards over half a century. A crisis this large is not the result of only one factor such as genetics. The advent of digital entertainment, changes in the food we eat, and other social determinants have all played a role.

U.S. Healthcare Spending and Prevalence of CMDx



The use of prescription drugs to treat CMDx can provide symptomatic relief and, in some cases, control the progression of disease. However, medications generally do not address root causes, which are predominantly behavioral. There is clear consensus in the scientific and medical community that poor diet, lack of exercise and other lifestyle factors drive the onset, co-morbidity and mortality associated with CMDx. Just three CMDx, T2D, hypertension, and hyperlipidemia, account for more than $100 billion in annual prescription drug spending in the United States, none of which addresses root causes.

An estimated 37 million people in the United States have T2D. Another estimated 96 million people in the United States have prediabetes, 70% of which are expected to develop into T2D during their lifetimes. The annual direct medical costs in the United States for treating T2D exceeded $237 billion in 2017, representing an increase of $61 billion since 2012. These costs are forecasted to increase to $472 billion by 2030.

Despite advances in pharmacological treatment, about half of U.S. patients with T2D are not achieving glycemic control (i.e., an A1c <7%). Even when adequate glycemic control is achieved via pharmacotherapy, a substantially elevated risk due to all-cause mortality still exists. According to the American Diabetes Association ("ADA"), the behavioral determinants of T2D are a significant contributor to both poor glycemic control and mortality risk.

The role of behaviors, including dietary pattern and exercise, in the development and progression of T2D and other cardiometabolic conditions is well established. These behavioral determinants are resistant to change because they are created and reinforced by strong social norms and culturally reinforced ideas. The use of CBT to directly target these behaviors is a critically important means of achieving high-quality CMDx care. Unfortunately for patients, the U.S. health system is not organized to provide comprehensive CBT at the scale needed. While clinical guidelines consistently recommend that healthcare providers facilitate behavioral changes, they often do not have the ability to provide or prescribe effective behavioral therapy to their patients.

Accordingly, significant unmet needs remain in the therapeutic treatment of CMDx and in the control of associated healthcare spending. We believe that to address this problem, we must focus on its root causes and address the near-complete absence to date of behavior-modifying therapeutics for CMDx.

Our Solution

We have combined medical, behavioral and data sciences to develop a clinically proven software-based therapeutics platform targeting behavior change at scale. Our platform allows for the creation of multiple PDTs that are designed to treat patients with CBT, delivered digitally via an app, to address the underlying causes of CMDx. Once authorized by the FDA, our PDTs are intended to be prescribed by physicians and reimbursed by health insurance providers.

CBT is a treatment paradigm originally developed for the management of psychiatric conditions such as anxiety and obsessive-compulsive disorder. Traditional CBT aims to correct behavioral responses to a situation that are either non-productive or have adverse effects (maladaptive behaviors) by identifying and changing the core beliefs that produced them. It has since been successfully applied to a wide range of chronic conditions, including CMDx, and has been observed to be generally well-tolerated and to have the potential to provide durable treatment effects, either alone or in combination with other therapies. In current practice, CBT represents a family of therapies that have evolved over several decades and include modalities such as acceptance and commitment therapy, dialectical behavior therapy, and mindfulness-based cognitive therapy.

Our solution to the crisis described above is a novel form of behavioral therapy developed by us for patients with T2D and other CMDx designed specifically to address the cognitive patterns and mental structures that drive dietary patterns and associated lifestyle behaviors.

CBT systematically targets the cognitive structures, behavioral routines, emotional patterns and coping skills that underlie culturally specific eating behaviors. The content and delivery mechanisms of our novel CBT were developed internally from first principles, leveraging experience from clinician- and health coach-patient interactions to distill common maladaptive thinking and beliefs pertaining to diet and lifestyle. It is designed as a digitally delivered therapy so that it can be widely disseminated to large patient populations yet personalized to the individual patient using artificial intelligence (AI)-driven feedback loops.

Our PDTs enable the delivery of CBT at scale to fill this critical gap in care. To be widely adopted, we believe an effective PDT needs to be prescribed by healthcare providers and reimbursed by payers like a traditional prescription medication. This allows a digital therapeutic to leverage and bolster the trust established in a patient-provider relationship and to provide actionable data back to both provider and patient that can help advance care.

Our PDTs are intended to be used by patients under the guidance of their primary care provider and may fill an important gap in existing clinical guidelines. Our first PDT candidate, BT-001, if authorized by FDA, is intended to improve glycemic control in adult patients with T2D by targeting the behaviors that are root causes, with the potential for patients' physicians to ultimately reduce or eliminate over time the ongoing need for prescription medications to manage these chronic diseases. With a goal of pursuing commercialization first in T2D, we see a compelling opportunity to quickly and efficiently leverage our therapeutics platform to create additional PDTs targeting a broad range of CMDx, and for us to play a significant role in helping reduce the human and monetary costs of CMDx that are currently unsustainable and increasing.

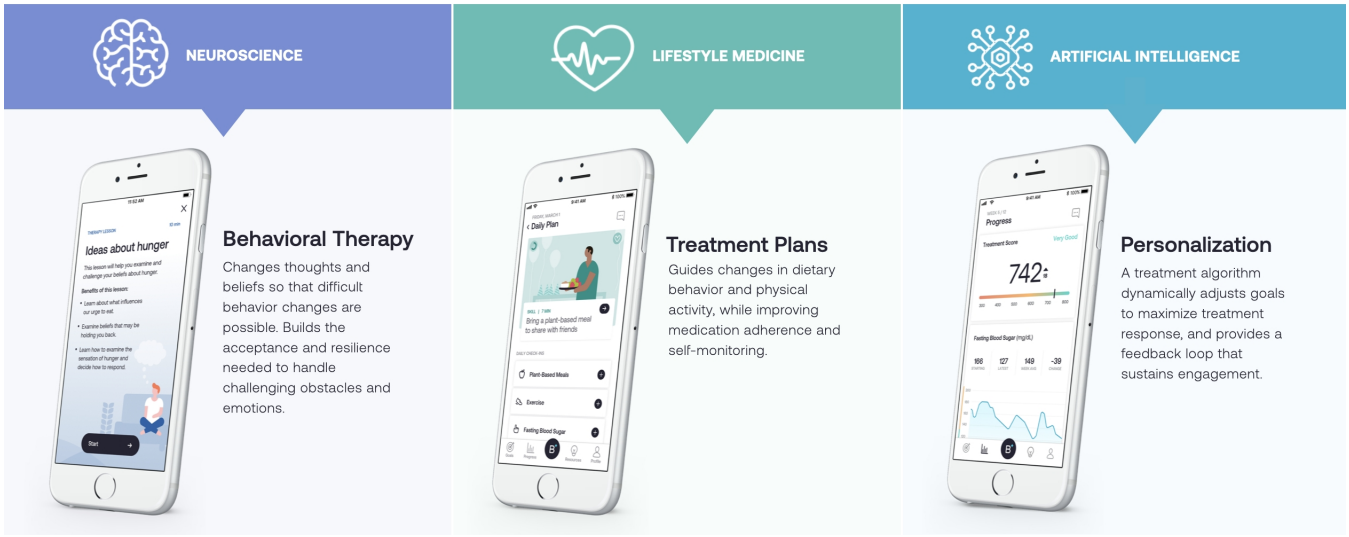
Our Platform

We believe that our platform, if successful in producing an FDA-authorized and marketed product, can support the discovery and development of additional PDTs that can be advanced in clinical development to treat CMDx using CBT. The platform consists of three integrated components.

Behavioral Therapy. The behavioral therapy components of the platform consist of lessons, skill- building modules, and a mechanism for goal setting. These components deliver CBT to patients at a pace and sequence that is designed to maximize treatment outcomes on an individual basis. They target the ideas, beliefs, and expectations that drive the behaviors known to be root causes for CMDx to help change neural pathways of the brain, reducing or removing obstacles to making sustained behavioral changes. Our investigational PDT, BT-001, if authorized by the FDA, is intended to treat T2D and consists of 26 therapy lessons, intended to be completed at a rate of about one per week. Each therapy lesson takes 5 to 20 minutes to complete. Associated with each lesson are skill-building modules, enabling practical application of the therapy lesson content in daily life. There are 96 skill-building modules in BT-001, and patients engage in them on a self-directed basis.

Treatment Plans. A daily treatment plan is the primary engagement interface for patients. It guides changes in diet and exercise consistent with daily and weekly goals, encourages adherence to prescribed medications, and enables self-monitoring of disease biometrics. Brief, daily self-reported measures of both behaviors and biometrics serve as inputs to our treatment algorithms.

Personalization. We use artificial intelligence, or AI, pre-programmed into our algorithm to adjust goals and personalize treatment plans to each individual patient based on their engagement and inputs. Remotely monitored app-engagement data, self-reported measures, and patient specific health data serve as the primary inputs into our proprietary treatment algorithms. We also use gamification and various feedback mechanisms to reward progress, encourage ongoing use, and visualize the impact of behavior changes made on the primary measures of disease status.



Inception, Development and Validation of Our Platform

We began development of our platform in 2015, starting with a small number of features thought to be essential for supporting effective and sustained behavior changes based on clinical evidence. Through a cycle of iteration and usability testing, we advanced the platform to a minimal state of readiness, paired the software with board-certified, physician-supervised health coaches, and studied it in various patient populations with CMDx. Those early feasibility studies demonstrated clinical potential comparable to commonly prescribed medications for the treatment of diabetes and hypertension. The data from those earlier studies were peer-reviewed and published in medical journals (see Problem, Solution and Market Opportunity by Product Candidate—BT-001— Diabetes; Hypertension), and informed further development of a software-only configuration. The first software-only product candidate, BT-001, to emerge from this platform was tested in a pilot study among patients with uncontrolled T2D, which demonstrated that use of BT-001 resulted in a clinically meaningful improvement in glycemic control. The data from the pilot study was presented at Endocrine 2020. Thereafter, BT-001 was tested in the largest randomized, controlled clinical trial conducted of PDT to date (see Problem, Solution and Market Opportunity by Product Candidate—BT-001 — Diabetes—Pivotal Trial of BT-001). We included these data in our *de novo* classification request to the FDA.

In order to establish a comprehensive framework for ongoing product development, we adhere to rigorous product development procedures and processes documented in a commercially scalable Quality Management System ("QMS"). We believe this allows us to employ an agile software development process that results in the highest levels of product innovation while helping ensure consistent product quality and patient safety.

The foundational elements of our QMS are Design Controls and Risk Management Procedures which:

- Ensure our product development processes and documentation comply with regulatory requirements (FDA 21 CFR Part 820 and ISO 14971).
- Establish a repeatable framework for how we design, validate and deploy product candidates and product features.
- Define standard operating procedures, including a series of checks and balances and stakeholder signoffs to help ensure oversight of patient safety at each phase of development.

Platform Leverage

Because CMDx share common root causes which our platform is designed to address, we believe we can create products to treat additional CMDx with relatively small changes to our lead PDT candidate, BT-001. This will greatly reduce product development time and cost. We further believe that learnings and improvements on any PDT can be leveraged across the platform. Additionally, because so many CMDx have comorbidities with other CMDx (e.g., patients diagnosed with diabetes are often also diagnosed with heart disease), we can gather data on effectiveness across many diseases with a single study. In October 2022, BT-001 was accepted for substantive review for marketing authorization by the FDA. This is our first product candidate submitted to the FDA through the *de novo* classification process. We expect to apply for and to commercialize subsequent products through the 510(k) process if we obtain BT-001 marketing authorization through the *de novo* classification process. The 510(k) process typically requires a shorter pre-market review period.

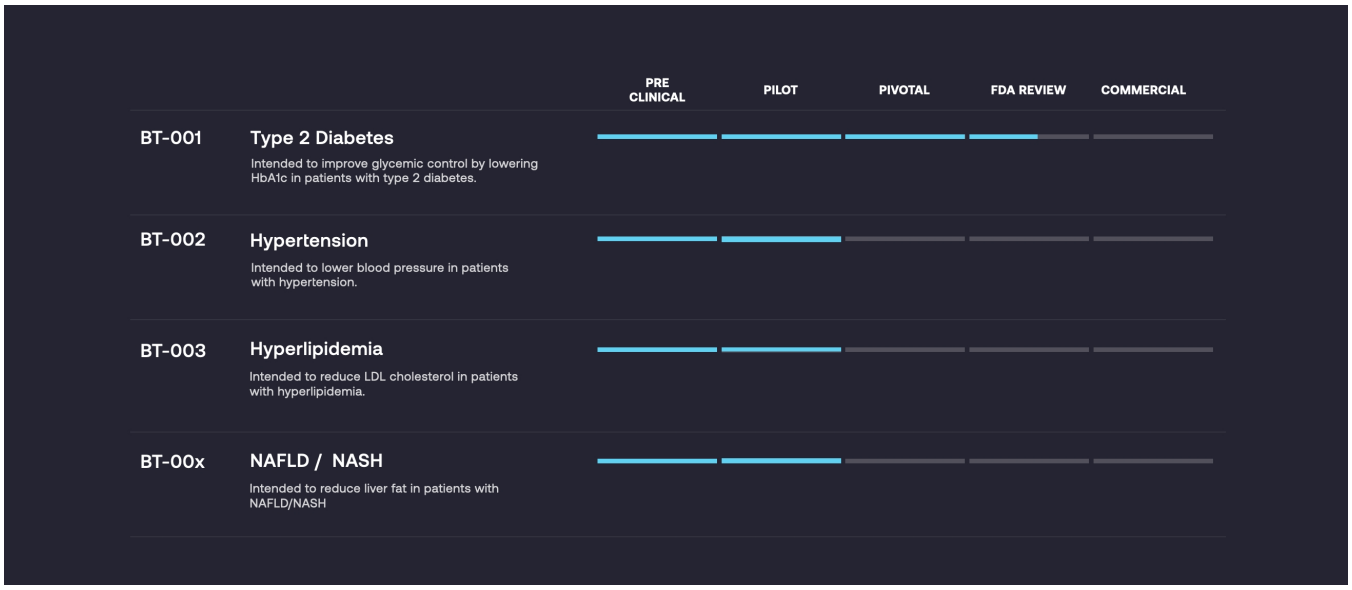
As a result of these efficiencies, we believe we have the potential to develop a portfolio of PDTs for some of the most prevalent diseases in the U.S. at a fraction of the time and cost of traditional therapeutics.

Market Opportunity

In 2016, the direct annual medical costs due to CMDx potentially addressed by the company's platform were approximately $490 billion. Overall, approximately 30% of direct medical costs are associated with medications; in T2D however, the portion associated with medications is approximately 43%. According to the Milken Institute, total direct medical costs by indication in the United States in 2016 were approximately as follows:

- T2D: $190 billion (or $237 billion in 2017 according to the ADA)
- NAFLD and NASH: $100 billion
- Dyslipidemia: $75 billion
- Coronary heart disease: $72 billion
- Hypertension: $66 billion
- Stroke: $52 billion
- Congestive heart failure: $30 billion
- End-stage renal disease: $5 billion

Our Pipeline



We expect to rapidly develop and, if authorized by the FDA, commercialize multiple product candidates. Our clinical development and regulatory strategy prospectively offer a tempo of related, high-value product launches that, if authorized by the FDA, will be differentiated from a traditional molecular therapeutics company. Unlike traditional therapeutics that require discrete and sequential Phase I, II, and III trials, followed by a lengthy regulatory review process, we expect that our PDTs will require a single potentially pivotal trial to generate the data required for submission to the FDA. We believe these potentially pivotal trials can be conducted at a fraction of the cost and time of a traditional new drug trial, and be subject to what we believe to be, a potentially shorter regulatory review process.

Software Instead of Drugs: Unique Benefits of Digital Therapeutics

Digital therapeutics are an emerging new class of therapies, aimed at addressing the root cause of certain diseases. Many of the most common chronic diseases are caused by diet, exercise and other lifestyle factors. These behaviors could be influenced or changed by digitally delivered behavioral therapies that have demonstrated activity against the same clinical endpoints used in traditional drug development. While traditional pharmaceutical drugs tend to mitigate specific symptoms, behavioral therapies addressing the root cause of a disease have the potential to prevent and/or reverse disease progression. In addition, digital therapeutics may offer several unique benefits over traditional pharmaceutical drugs including:

- Broad access to care across sociodemographic groups, and the ability to deploy them to almost any patient, in any location, including those that have traditionally not had ready access to certain therapies.
- Ability to obtain real time insights about their use and responsiveness. Unlike traditional drugs, which do not change once approved, digital therapies are subject to continuous improvement based on the data their use generates. Like periodic software updates in other industries, for most digital therapies, version 5.0 is expected to be an improvement from prior versions, which potentially translates into better patient engagement, with the potential for improved activity and tolerability.
- Substantially broader, patient specific insights for physicians and health systems about the use and efficacy of digital therapies to improve the ability to provide better care. These data also offer the opportunity for novel, efficient and accurate value-based pricing models which may be a win-win for both patients and payers.
- Ability to fundamentally change the course of a disease by addressing the root cause. Behavior change tends to improve not just a single symptom but a broad range of health measures. Consequently, digital behavioral therapies carry the potential to drive significantly better overall long-term health outcomes and substantially reduce the overall cost of care.
- The time and investment required to develop digital therapies is substantially less than for traditional pharmaceutical drugs, potentially enabling faster and more cost-efficient expansion into other indications or therapeutic areas.

Problem, Solution and Market Opportunity by Product Candidate

BT-001 — Diabetes

T2D is a chronic health condition that results in high levels of blood sugar. It occurs when the body is unable to use insulin properly. Insulin allows blood sugar, which comes mainly from the food we eat, to enter cells to be used for energy. It is highly likely that patients with T2D will also develop one or more other medical conditions such as high blood pressure, high cholesterol, heart disease, and/or chronic kidney disease.

T2D is the most common type of diabetes. It was estimated that 37 million adults in the U.S. had T2D in 2019. 27 million adults are receiving medical care for T2D, but only about 13 million of these patients have well controlled blood sugars. In addition, approximately 96 million U.S. adults have prediabetes, up to 70% of which are expected to develop T2D during their lifetime.

The ADA and American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for the management of T2D recommend a) changing behaviors to lower blood sugar, blood pressure, and cholesterol, b) regular monitoring of blood sugar, kidney, heart, blood vessels, eye and nerve function, and c) chronic use of antihyperglycemic medications. Widespread failure to change behavior and the inability of current medications to address root causes of T2D has resulted in a massive, growing and unsustainable crisis in the treatment of this disease.

Solution

Under the guidance of a physician, BT-001 is an investigational PDT that, if authorized for marketing by FDA, will be intended to help patients with T2D improve glycemic control. The BT-001 software delivers behavioral therapy to patients via a mobile application that targets behaviors related to improving glycemic control and is intended to reduce A1c. The physician ensures the patient is an appropriate candidate for behavioral therapy, monitors the patient for treatment effects and adjusts concurrent medications as needed.

Market Opportunity

According to the ADA, patients diagnosed with diabetes have annual medical costs that are 2.3 times higher than patients without diabetes. The ADA estimated that patients diagnosed with T2D incurred average medical costs of $16,750 in 2017, of which about $9,600 was attributed directly to diabetes. Additionally, the ADA estimates total annual drug cost for treating diabetes in 2017 to be approximately $102 billion, which is a four-fold increase since 2007. This includes nearly $15 billion for insulin, $16 billion for other antihyperglycemic agents, and $71 billion for other prescription drugs that can be attributed to higher disease prevalence associated with diabetes.

Clinical Development

Early feasibility study

In 2017, we conducted a 12-week feasibility study in 118 patients with T2D. The intervention was delivered by an early version of BT-001 paired with a health coach providing remote support to patients approximately every two weeks by phone. Study participants all had baseline A1c > 6.5% (mean = 8.1%), were mostly female (81%), resided in 38 U.S. states, and had a mean age of 51 years.

After 12-weeks, mean change in A1c was -.8% ($p<.001$) (this result is considered to be statistically significant), and among those participants with baseline A1c >7.0%, mean change was -1.1% ($p<.001$) (this result is considered to be statistically significant). Greater glycemic control was observed in those that used BT-001 more often ($p=.03$) (this result is considered to be statistically significant). The average engagement rate was 4.3 times per day and retention was 86% in this broadly distributed sample.

Data from the study were peer-reviewed and published in the Journal of Medical Internet Research Diabetes in 2018.

Key findings of the pilot study

In early 2020, we completed a single-arm, uncontrolled, unblinded pilot study of BT-001, presented the data at Endocrine 2020, and published results in the Journal of the Endocrine Society. In our single-arm pilot study, the addition of the BT-001 treatment regimen to subjects who were, on average, already taking 2.2 oral diabetes medications and continued those medications during the study resulted in an average of 1.0% estimated reduction in A1c of participants after 84 days. While the pilot study was not designed as a head-to-head comparison of BT-001 to oral medications, these data compare favorably to historical data published in the Journal of Diabetes Care in August 2010 which suggest an average 0.5% — 1.25% range of A1c reduction from untreated baseline with oral medications alone. The key finding was that the clinical outcomes measured were just as strong using a software-only product as for the earlier software-plus-coaching configuration. In the early feasibility study, the outcomes were attributed to the combination of the early BT-001 software and the remote human intervention delivered by health coaches and behavioral specialists. In contrast, the outcomes found in the pilot could be attributed directly to the use of BT-001 software.

The pilot study involved 80 adults with T2D residing in 32 U.S. states, including those with increasing prevalence of diabetes (e.g., Florida, Indiana and North Carolina), who used BT-001 for up to 12 weeks. At baseline, these patients all had poorly controlled diabetes despite taking on average multiple antihyperglycemic medications. Participants had a 3-day average fasting blood glucose value of 152 mg/dL or greater, corresponding to a baseline A1c of 7% or greater. On average, participants were 55.7 years old, had a BMI in the obese range, were taking 2.2 antihyperglycemic medications and were diagnosed with T2D 10.4 years prior to the start of the study.

Use of BT-001 resulted in clinically meaningful improvement in glycemic control. The mean decrease in fasting blood glucose (or FBG) of -22.9 mg/dL ($p<.001$) corresponds to approximately a 1.0% reduction in A1c. An A1c reduction of 1.0% has been associated with a 21% decrease in diabetes related mortality and a 40% reduction in microvascular complications in the UK Prospective Diabetes Study, a multi-site randomized intervention trial involving 5,102 patients with 20-years of follow up. These results suggested use of BT-001 may be associated with meaningful improvements in glycemic control in a widely distributed treatment population and offers potential as a standalone treatment or when used alongside medications.

We observed a significant dose response ($p=.04$) (this result is considered to be statistically significant) between the degree of engagement in CBT content and improvements in glycemic control among adults with T2D. This was encouraging because it indicated that digitally delivered behavioral therapy using only software has the potential to treat disease at scale. Reductions in blood glucose were more significant and occurred faster than we had expected. BT-001 allows patients to make behavioral changes at a self-determined pace, which means that for some individuals it might take longer to see blood glucose reductions. In this context, blood sugar control was achieved more rapidly than expected, with 42% of participants achieving a fasting blood glucose less than 152 mg/dL (corresponding to an A1c < 7%, which is commonly regarded as the goal for A1c for most patients with T2D) and 16% achieving a fasting blood glucose less than 130 mg/dL (corresponding, on average to an A1c < 6.5%, a much more aggressive goal for A1c) after an average of 65 days. Bi-weekly fasting blood sugar values for participants are displayed in the table below, which suggests a rapid and progressive improvement in blood glucose. We hypothesized that longer duration of use may result in even greater improvements.

Improvements in blood glucose occurred in participants from across the country and with longstanding diabetes. No serious adverse events were observed in the study period. While it is commonly assumed that only newly diagnosed patients will benefit from behavioral therapy, based on the generally accepted view that the lowering of HbA1c of 0.4 is significant, we were encouraged to see a clinical activity from the usage of BT-001 in patients who were on average diagnosed with diabetes more than 10 years ago.

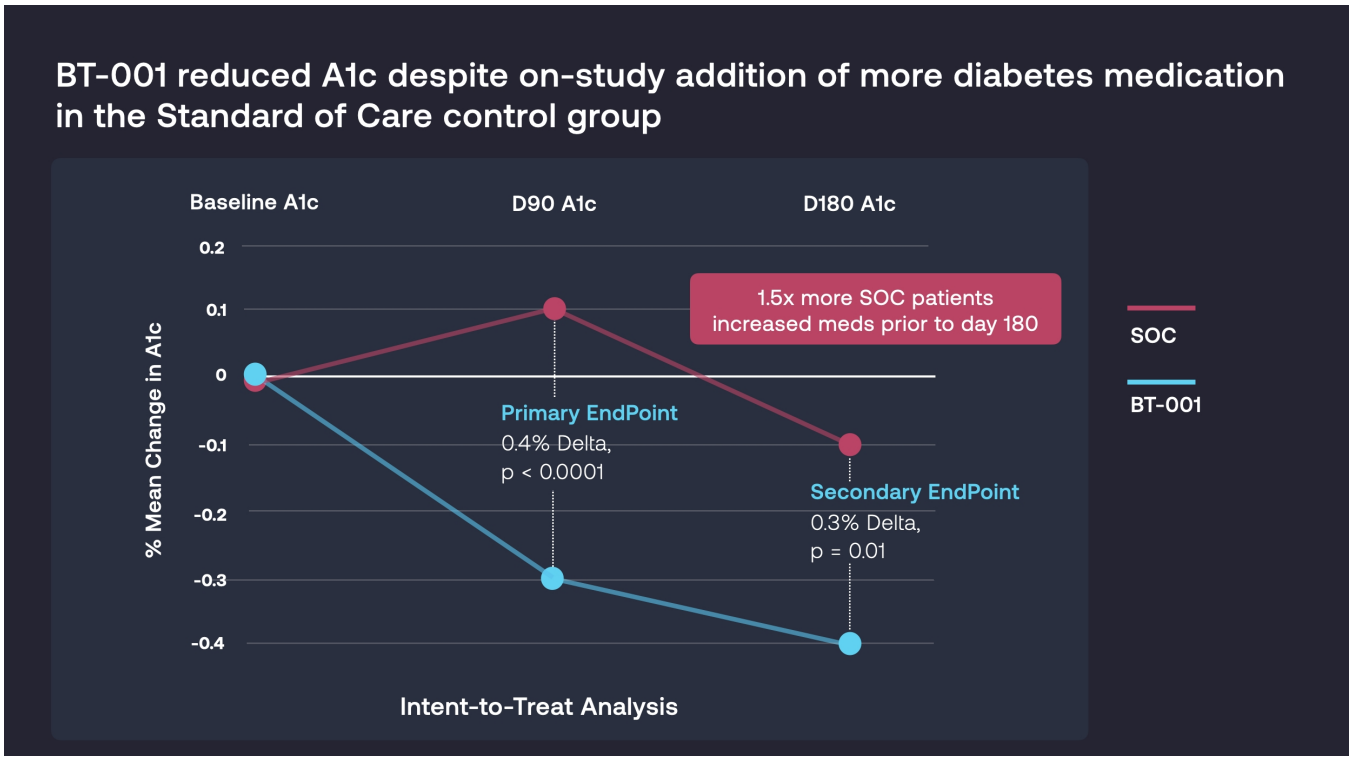
Pivotal Trial of BT-001

We screened the first patient in our pivotal unblinded study of BT-001 in February 2021 and completed full enrollment in the fourth quarter of 2021, enrolling a total of 668 patients.

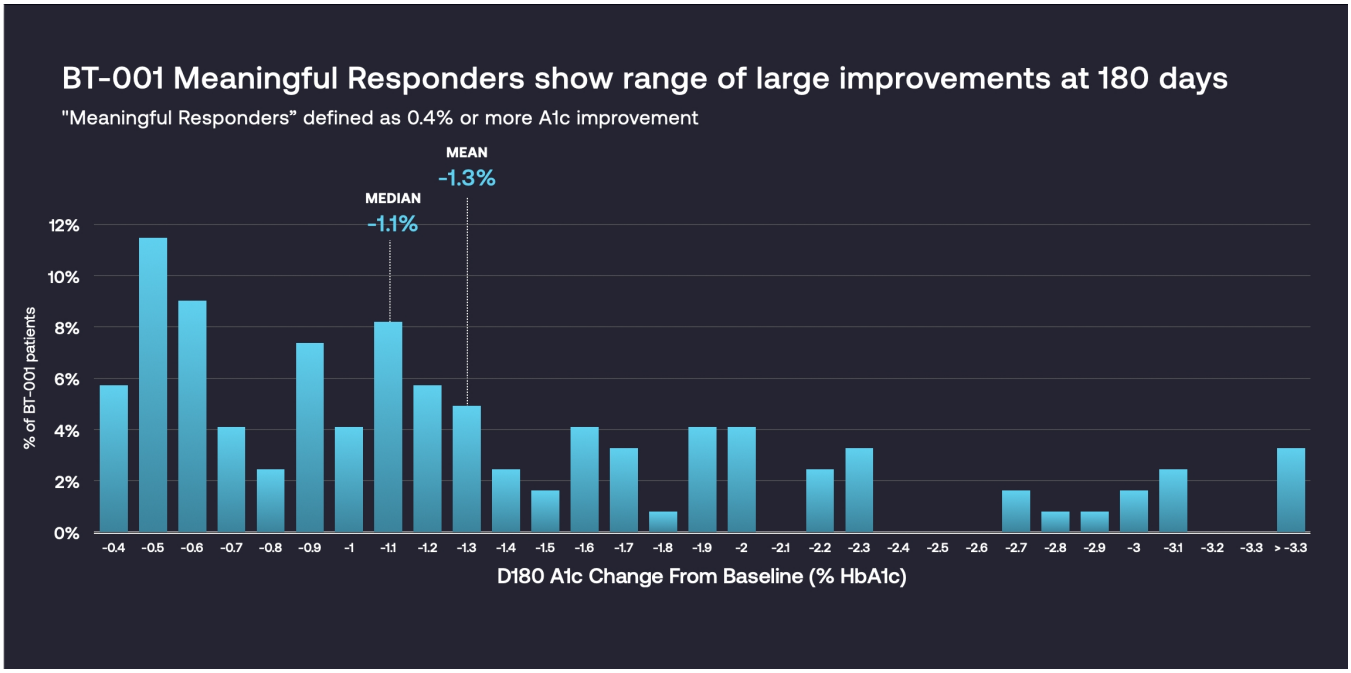
Patients interested in participating in the BT-001 pivotal trial were included if they were between 18 and 75 years old, had a BMI of 25 kg/m2 or greater, had no recent changes in antihyperglycemic medications. Potential participants were excluded if they used prandial insulin, tobacco or other addictive substances or were taking medications that would interfere with study measures, such as chemotherapy or steroids. Participants with unstable or life-threatening medical illnesses, such as COVID-19 or active suicidality and patients with heart failure, kidney failure or history of angina within the previous six months were also excluded. The aim of recruitment was to generate a nationally representative sample of adults with T2D located in 5 geographically distinct regions.

Those who passed the screening period were randomized in a 1-to-1 manner to either an SOC group or an SOC plus BT-001 group. Both groups had blood tests and biometrics collected at 90 days and 180 days and were followed closely for adverse events during the entire study period. In addition to A1c levels, study staff collected laboratory measures of cholesterol, inflammatory markers, and cardiovascular risk, along with blood pressure and weight at baseline, day 90 and day 180. Participants were also asked to complete standardized surveys to assess changes in depression, quality of life and patient satisfaction at day 90 and day 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 in A1c from baseline after 90 days of treatment. BT-001 met the primary endpoint, showing a highly statistically significant improvement in A1c relative to the control group (-0.4%, n=610, p <0.001). BT-001 showed a sustained and statistically significant change relative to the control group on the secondary efficacy endpoint, which was the mean change in A1c from baseline at 180 days (-0.3%, n=517, p =0.01). Importantly, BT-001 met the 180 day endpoint even though 1.5 times more SOC patients increased blood sugar lowering medications relative to those in the BT-001 arm prior to the 180 day A1c draw.



After the day 180 A1c draw, 1.7 times more SOC control patients increased their medications compared to BT-001 patients. BT-001 demonstrated sustained and numerically improved A1c levels, with A1c reduction from baseline improving from 0.3% at 90 days to 0.4% at 180 days across the intent-to-treat population, suggesting a durable treatment effect. Half of the BT-001 patients achieved a meaningful reduction in A1c (defined as 0.4% reduction), with a mean A1c reduction of 1.3% within this subset.



The clinical trial also provided evidence that beyond reductions in A1c: (1) there was a clear dose-response between greater engagement in CBT and greater reductions in A1c, supporting CBT as a mechanism of action, (2) measures of patient engagement, adherence, persistence, and satisfaction were all positive, (3) BT-001 resulted in reassuring safety data, with significantly fewer adverse ($p<0.001$) and serious adverse events ($p=0.01$) as compared to the SOC control group, and (4) exploratory endpoint data revealed additional cardiometabolic improvements as well as the potential to reduce the need for medications and lower healthcare utilization compared to the control group, supporting the potential for BT-001 to improve overall health of patients with T2D and potentially reduce cost of care associated with the progression of the disease. Based on positive primary and secondary endpoint data from the BT-001 pivotal clinical trial, we submitted a *de novo* classification request with the FDA in September 2022, seeking marketing authorization of BT-001 for the treatment of adult patients with T2D. We plan to use the data from this study to inform the potential initiation of additional pivotal trials to expand our PDT pipeline.

In October 2022, the FDA notified us that our *de novo* classification request was accepted for substantive review. As part of the typical *de novo* review process as expected by us, in February 2023, we received a Request for Additional Information from the FDA notifying us that, after review of our submission, the FDA determined that additional information is required and placed the review on hold. The letter outlined the FDA's view that our submission has a number of deficiencies, classified into major and minor deficiencies. We requested a meeting with the FDA to clarify several of the major deficiencies noted as well as to seek guidance on our options to address them. That meeting also took place in February. During the meeting the FDA provided helpful context, clarifications and guidance, and we are now compiling our response to address the FDA's comments. We believe we can address the FDA's concerns, and our previously provided guidance that we anticipate FDA's decision by the middle of 2023 remains unchanged. If we are unable to resolve the deficiencies, we may need to amend the indications for use for which we are seeking authorization and/or conduct another clinical trial, and the authorization and commercial launch of BT-001 could be significantly delayed or the authorization could be denied.

We have also initiated real world evidence studies to evaluate the long-term effectiveness and healthcare utilization changes associated with the use of BT-001 for the treatment of T2D with Mass General Brigham, Colorado Prevention Center Clinical Research, University of Colorado and Durham Veterans Administration Medical Center. The randomized, controlled, multi-site studies are expected to enroll 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 the fourth quarter of 2023, once a sufficient number of patients has completed an incremental 180 days of treatment. The study seeks to provide payers and providers with longer-term data related to usage and outcomes in a real-world setting.

Hypertension

Hypertension is a chronic health condition that results in high blood pressure. It occurs when the body is unable to properly regulate the pressure of blood moving through blood vessels. With chronic hypertension, the body's organs are put under constant stress and are more likely to break down. It is common for patients with longstanding hypertension to develop heart disease, stroke, chronic kidney disease and/or dementia.

Hypertension is one of the most common chronic diseases. In 2017, it was estimated that 108 million U.S. adults have hypertension. Of these patients who are already taking blood pressure lowering medications, approximately 35% still have uncontrolled blood pressure.

Guidelines for the management of hypertension recommend a) changing behaviors to lower blood pressure, b) regular monitoring of blood pressure, kidney, and heart function, c) chronic use of anti-hypertensive medications. Widespread failure to change behavior and the inability of current medications to address root causes of hypertension has resulted in a massive, growing and unsustainable crisis in the treatment of this disease.

Solution

We may expand our platform to include a PDT to help patients with hypertension improve their blood pressure, under the guidance of a physician. The software is designed to deliver behavioral therapy to patients via a mobile application that targets behaviors related to achieving blood pressure control and is intended to reduce systolic and diastolic blood pressure.

Market Opportunity

Patients with hypertension are estimated to have nearly triple the prescription drug costs as patients without hypertension. A 2016 study published in the Journal of the American Heart Association concludes the annual prescription drug cost was $2,400 for individuals with hypertension versus only $815 for those without hypertension. For all adults in the United States with hypertension, this represents an estimated annual incremental drug cost for patients with hypertension of $42 billion in 2016.

Clinical Development

We plan to refine a detailed plan for a potentially pivotal trial using blood pressure data obtained from the BT-001 randomized, controlled trial. In the BT-001 trial, approximately two thirds of participants reported hypertension as a comorbidity, with approximately 18% of all participants having poorly controlled hypertension at baseline. Because the BT-001 trial included measurement of blood pressure along with A1c at every time point, we have 90 and 180 day randomized, controlled data on blood pressure for approximately 400 participants, which we believe may be sufficient pilot data to allow for planning the potentially pivotal trial in hypertension.

It is anticipated that a pivotal trial would evaluate the safety and effectiveness in a nationally representative sample of approximately 500 U.S. adults with hypertension located in 5 geographically distinct regions. Adults, aged 18-75, would be included if their resting blood pressure is poorly controlled (i.e., over 140/90 mmHg). These participants would be randomized in a one-to-one fashion to a control or intervention group. The control group would be provided standard of care treatment. The intervention group would be provided standard of care along with the hypertension product candidate. The primary outcome measure would be resting systolic blood pressure, measured at 90 days. The secondary outcome measure would be resting systolic blood pressure, measured at 180 days.

Hyperlipidemia

Hyperlipidemia is a chronic health condition that results in high levels of blood cholesterol. It occurs when the body is unable to get rid of harmful types of cholesterol circulating in the blood. Low-density-lipoprotein ("LDL") cholesterol is the most common form of harmful cholesterol. A dietary pattern high in unhealthy fats, cholesterol, and refined carbohydrates along with insufficient exercise, are the most common causes of high blood cholesterol. Over time, the presence of too much harmful cholesterol leads to cholesterol build up in the body's arteries, limiting blood flow. It is very common for patients with longstanding hyperlipidemia to develop one or more other medical conditions caused by cholesterol build-up such as heart disease, stroke, and/or peripheral artery disease.

Hyperlipidemia is one of the most common chronic diseases. It was estimated that 65 million adults in the U.S. had hyperlipidemia in 2016. In 2016, it was estimated that 28 million adults had poorly controlled cholesterol levels.

Guidelines for the management of hyperlipidemia recommend a) changing behaviors to lower harmful cholesterol and raise healthy cholesterol levels, b) regular monitoring of blood cholesterol, blood sugar, and blood pressure, and c) chronic use of cholesterol-lowering medications. Widespread failure to change behavior and the inability of current medications to address root causes of hyperlipidemia has resulted in a massive, growing and unsustainable crisis in the treatment of this disease.

Solution

We may expand our platform to include a PDT to help patients with hyperlipidemia improve cholesterol levels, under the guidance of a physician. The software is designed to deliver behavioral therapy to patients via a mobile application that targets behaviors related to the control of cholesterol levels and is intended to reduce LDL cholesterol.

Market Opportunity

According to the American Heart Association, the annual incremental drug cost for patients with hyperlipidemia was estimated to be $12 billion in 2016. Also, due to updated clinical guidelines which make more aggressive treatment recommendations, an additional 12.3 million more Americans would be treated with cholesterol-lowering medications by 2025, increasing treatment costs by $13.3 billion per year.

Clinical Development

We expect to refine a detailed plan for a potentially pivotal trial using blood cholesterol data obtained from the BT-001 randomized, controlled trial. In the BT-001 trial, approximately 45% of participants reported comorbid hyperlipidemia, with approximately one third of all participants having poorly controlled LDL cholesterol at baseline. Because the BT-001 trial included measurement of fasting blood cholesterol along with A1c at every time point, we have 90 and 180 day randomized, controlled data on cholesterol for approximately 380 participants, which we believe may be sufficient pilot data to allow for planning the potentially pivotal trial in hyperlipidemia.

It is anticipated that a pivotal trial would evaluate the safety and effectiveness in a nationally representative sample of approximately 500 U.S. adults with hyperlipidemia located in 5 geographically distinct regions. Adults, aged 18-75, would be included if their fasting LDL cholesterol is poorly controlled (i.e., above their risk-adjusted target). These participants would be randomized in a one-to-one fashion to a control or intervention group. The control group would be provided standard of care treatment. The intervention group would be provided standard of care along with the hyperlipidemia product candidate. The primary outcome measure would be fasting LDL cholesterol, measured at 90 days. The secondary outcome measure would be fasting LDL cholesterol, measured at 180 days.

NAFLD and NASH

NAFLD is a condition that results in a buildup of fat in the liver and NASH is the progression of the disease and includes liver inflammation and damage.

NAFLD is a common chronic disease and a growing threat to public health. The condition currently affects an estimated 20-30% of all U.S. adults and approximately 70% of those with T2D. NASH affects approximately 5% of American adults and has recently become the leading indication for liver transplant.

Despite the magnitude of these conditions, no FDA-approved treatments currently exist. Guidelines for the management of NAFLD and NASH recommend behavioral modification including weight loss, improving dietary quality and increasing physical activity. These interventions have been proven to have favorable effects on slowing and even reversing the progression of liver steatosis and fibrosis. Widespread failure to change behavior and lack of approved FDA pharmacotherapy has resulted in a massive, growing, and unsustainable crisis in the treatment of these conditions.

Solution

We may expand our platform to include a PDT to help patients with NAFLD and NASH to improve liver fat, under the guidance of a physician. The software is designed to deliver behavioral therapy to patients via a mobile application that targets behaviors related to the control of liver fat levels and is intended to reduce liver fat.

Market Opportunity

The direct medical costs associated with NAFLD and NASH were estimated to be $103 billion in 2016.

Clinical Development

We completed a feasibility pilot study of CBT to examine its potential to reduce liver fat and improve liver disease biomarkers as a potential treatment for NAFLD and NASH. The study was conducted in collaboration with Arizona Liver Health, a leading liver clinical research center. This single arm interventional cohort study enrolled 22 patients who were given access to a 90-day CBT-based treatment period. This clinical study met its primary endpoint, showing a statistically significant positive signal with an average relative reduction in MRI-PDFF of 16% (p=0.01) in the intent-to-treat population (n=19). Additionally, the clinical study showed (i) a statistically significant mean reduction in alanine transaminase (ALT) of -17 IU/L (p=0.002), (ii) a statistically significant mean change in FAST Score of 20% (p=0.01), (iii) no serious adverse events or device related adverse events, and (iv) high engagement and patient satisfaction with treatment, with a Net Promoter Score of +75 and 94% of subjects still using the app after 90 days. A detailed plan for the potentially pivotal trial will be refined using MRI-PDFF data obtained from the NAFLD and NASH pilot studies. Because of the significant unmet medical need, we intend to apply for breakthrough device designation with the FDA for our investigational CBT based treatment platform for these indications in the first half of 2023.

Competitive Advantages

To establish competitive advantage in our target markets, we are building on our early recognition of the potential of PDTs in CMDx, our focus on treating root causes, and our ability to leverage our platform to accelerate regulatory clearances of subsequent product launches. We believe we have the following advantages over existing and/or potential competitors:

- *Regulatory Lead Time*. To achieve marketing authorization as a PDT, the FDA requires safety and efficacy data from a randomized controlled clinical trial, an extensive submission package for review, and a wait time for that decision, during which time FDA may make inquiries or requests of the applicant. Given that we are unaware of any competitors focused on PDTs in CMDx, we believe this current absence in the pipelines of competitors affords us a lead time for our products, if authorized.
- *First Mover Market Advantage*. In combination with other increasing advantages, we believe the branding and marketing benefits of launching our products as the first of a novel class of CBT digital therapeutics will enable us to achieve and maintain a meaningful share of CMDx markets held by PDTs, despite potential launches by followers.
- *Intellectual Property*. We have filed four patent families covering methods of treatment, methods of managing medications, and the systems and software that comprise our platform. The expiration of any U.S. or foreign patents issuing from the first two families is between 2038 and 2039. The expiration of any U.S. or foreign patents issuing from the third family is 2039. The expiration of any U.S. or foreign patents issuing from the fourth family is 2042.
- *Network Effects*. Every patient we treat generates data that we can use to improve our algorithms. The rate at which our patient data are increasing and our ability to continuously improve our products based on these data will make it increasingly challenging, we believe, for followers to offer products comparable in quality to ours.
- *The potential to reverse disease*. At the time of diagnosis with T2D the primary unknowns are the rates at which the patient is going to get sicker and require additional medications. We recognize a significant opportunity to intervene at certain points in the progression of this disease. To halt disease progression and for many patients reverse the disease altogether, we believe we can help reframe the dynamic of intervention around T2D care away from the expectation of inevitable decline.

- *Rapid and low-cost development compared to traditional therapeutics*. Unlike developing new traditional therapeutics, we believe we can generate the data needed to support regulatory authorization or clearance on the basis of a single pivotal randomized controlled trial. We expect many of these trials can be conducted at a fraction of the time and cost of a traditional drug trial, followed by, on average, a potentially shorter regulatory review process.
- *Continuously improving therapeutics and more informed clinical decisions*. With certain restrictions, we can use data generated through patient use of our PDTs to make continuous improvements in our existing and future products to incrementally increase efficacy and generalizability. We could also potentially use data to improve clinical decisions when it can be provided back to the prescribing physician, and future products could possibly help guide the appropriate de-prescription of medications in those patients that are successful in changing behaviors and improving their condition.

Company Strategy

We aspire to change the way CMDx are treated to improve patient health and reduce healthcare spending. We believe our platform technology, first-to-market advantage, intellectual property portfolio, and groundbreaking research will facilitate the achievement of this goal. Our immediate focus is on:

- **Advancing our lead product candidate, BT-001, through regulatory authorization**. Approximately 27 million patients in the United States are receiving treatment for T2D, of which approximately 13 million are uncontrolled (A1c 7% or above). In our single-arm pilot study, the addition of the BT-001 treatment regimen to subjects who were, on average, already taking 2.2 oral diabetes medications and continued those medications during the study resulted in an average 1.0% estimated reduction in A1c in participants after 84 days. While the pilot study was not designed as a head-to-head comparison of BT-001 to oral medications, these data compare favorably to historical data published in the Journal of Diabetes Care in August 2010 which suggest an average 0.5% — 1.25% range of A1c reduction from untreated baseline with oral medications alone. In July 2022, we completed a randomized controlled pivotal trial of BT-001 in patients with uncontrolled T2D. The trial met both its primary and secondary endpoints with clinically and statistically significant results. Half of patients using BT-001 achieved a clinically meaningful response, defined as an A1c reduction of 0.4% or more, with a mean decline in A1c from baseline of 1.3% in this subgroup at 180 days. Results further indicated that patients who did not use BT-001 were more likely to be placed on additional medications to improve A1c control. A clear dose-response between greater engagement in CBT and greater reductions in A1c was found, supporting CBT as a mechanism of action. In addition, exploratory data revealed cardiometabolic improvements as well as lower medication utilization compared to the control group, supporting the potential for BT-001 to improve the overall health of patients with T2D and potentially reduce the usage of increasingly costly T2D medications associated with the progression of the disease. In October 2022, the FDA notified us that our *de novo* classification request for marketing authorization of BT-001 was accepted for substantive review. As part of the typical *de novo* review process as expected by us, in February 2023, we received a Request for Additional Information from the FDA notifying us that, after review of our submission, the FDA determined that additional information is required. The letter outlined the FDA's view that our submission has a number of deficiencies, classified into major and minor deficiencies. We requested a meeting with the FDA to clarify several of the major deficiencies noted as well as to seek guidance on our options to address them. That meeting also took place in February. During the meeting the FDA provided helpful context, clarifications and guidance, and we are now compiling our response to address the FDA's comments. We believe we can address the FDA's questions, and our previously provided guidance that we anticipate FDA's decision by the middle of 2023 remains unchanged. If we are unable to resolve the deficiencies, we may need to amend the indications for use for which we are seeking authorization and/or conduct another clinical trial, and the authorization and commercial launch of BT-001 could be significantly delayed or the authorization could be denied.

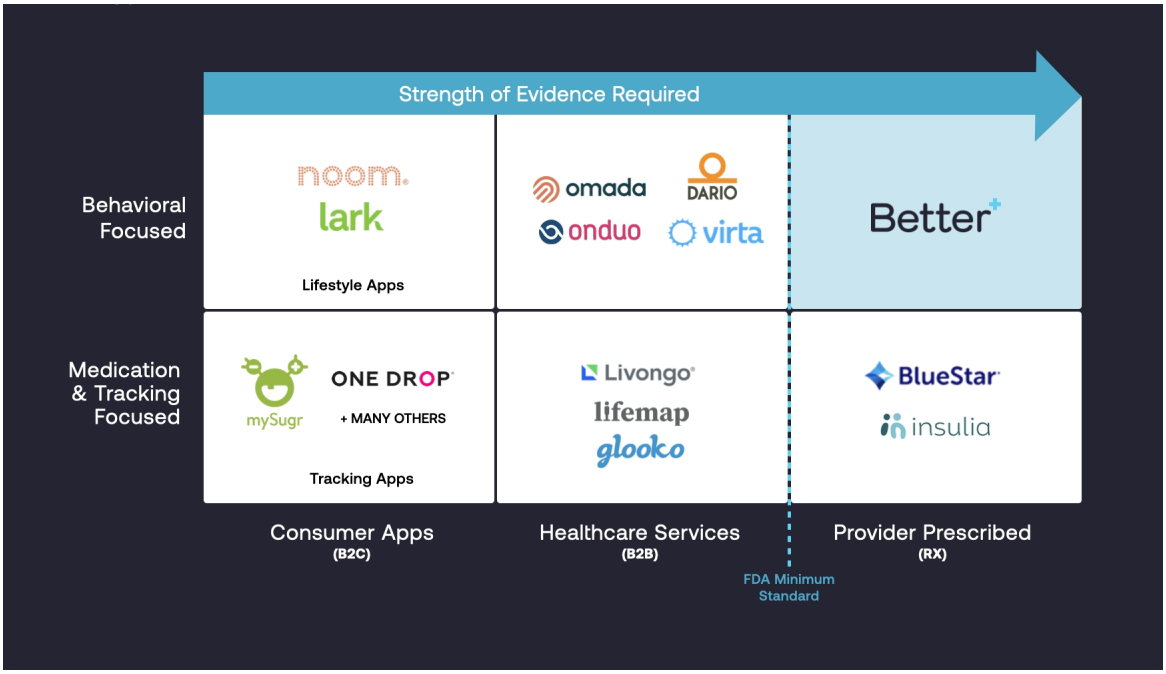
- **Securing broad coverage and reimbursement for our PDTs**. We believe a PDT that targets root causes of CMDx, addresses common comorbidities, potentially reduces or eliminates the ongoing need for medications and has the potential to substantially reduce other health care costs by halting or reversing disease progression would offer significant value to payers. In May 2022, we conducted initial pricing research with 15 payers that included national plans, regional plans and pharmacy benefit managers ("PBMs"). In December 2022, we conducted a single blinded study to test a draft value story for BT-001 with payers. Participants (n=10) were either current or recent payer pharmacy-and-therapeutics ("P&T") formulary or medical policy decision-makers. The draft value story reviewed included disease burden, unmet need, treatment landscape, and a draft of BT-001's product and clinical information. Feedback from this research study has been used to refine our value story presentation for payers. We plan to use this presentation in connection with preauthorization information exchange conversations with payers beginning in March 2023. In February 2023, we conducted a separate double blinded study with participants (n=7) who are current payer decision makers to understand the role Value Based Arrangements ("VBAs") might play in negotiations with payers. We tested several variables upon which agreements could be structured including patient engagement metrics, clinical outcomes, and financial targets. Overall payers reacted positively to BT-001's target product profile and the pivotal trial results. Results also suggest we should expect VBAs to be part of the negotiations. Finally, Health Economic Outcomes Research ("HEOR") models have been completed and are undergoing optimization. Messages emerging from the outcomes of these models will be tested in March with additional pricing and payer research scheduled for the first half of 2023 to further inform our decisions on price.
- **Building a focused sales force to introduce our products to primary care providers and endocrinologists**. To inform our targeted approach to the market at launch, we used claims analysis to identify the providers, the health systems, and the payers with the highest concentration of uncontrolled T2D patients. The insights from this work have pointed us to 50 integrated delivery networks/health systems which overlap with approximately 25 regionally dominant payers. The insights from the claims analysis allow us to focus our initial launch execution plans in those geographies where this overlap exists, and then expand over time as we gain coverage and access with both regional and national plans. Additional characterization of the identified health systems and payers will further prioritize our targets. We believe we can execute on this strategy at launch with no more than 50 field-facing representatives, made up of a combination of payer leads, account managers and Medical Science Liaisons. We expect that due to the unique, innovative nature of our products and our first mover advantage in large CMDx markets, we will be able to attract dedicated and talented sales professionals. We plan to increase the size of our sales force as reimbursement coverage increases to expand our reach in T2D and to support follow on products.
- **Integrating our products into the standard of care**. Clinical guidelines for T2D and other CMDx recommend that healthcare providers facilitate behavioral changes as the first line of therapy and throughout the disease progression. Recent updates to the 2022 Standards of Medical Care in Diabetes recommend all people with diabetes participate in diabetes self-management education and receive the support needed to facilitate the knowledge, decision-making, and skills mastery for diabetes self-care, and notes that digital coaching and digital self-management interventions can be effective methods to deliver diabetes self-management education and support. However, physicians often do not have the ability to provide or any tools to prescribe effective behavioral therapy to their patients. This is the gap in treatment we seek to fill. Through publications, presentations and medical education, we will help providers understand the potential of BT-001 and future products to fully enact treatment guidelines. We conduct rigorous clinical research and will continue to publish the results of our research in peer-reviewed journals. To date, we have published seven studies, of which six are peer-reviewed journal articles, and our research has been highlighted at several conferences including the American College of Lifestyle Medicine, IPSOR 2019, Endocrine 2020, the Society of Vascular Medicine 2022, the Harvard School of Public Health Teaching Kitchen Research Conference 2022, and the American Heart Association 2022.
- **Using our platform capabilities to accelerate development across CMDx**. We estimate that 20 or more CMDx indications share essentially the same root causes. Many CMDx have comorbidities with other CMDx, so we have the ability to gather efficacy data on multiple diseases with each clinical trial we conduct. This allows us to continually improve our platform for the benefit of all CMDx and accelerate the development and regulatory authorization or clearance of products targeting new indications.

Competition

The pharmaceutical, biotechnology and digital health industries are characterized by rapidly advancing technologies, intense competition and an emphasis on proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including large pharmaceutical and biotechnology companies, digital health companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of cardiometabolic therapies. Any products that we successfully develop and commercialize will compete with new therapies that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop therapeutics as treatments for CMDx. There are many other companies that have commercialized and/or are developing such treatments for CMDx including large pharmaceutical and biotechnology companies such as Novo Nordisk, Eli Lilly, Merck, Sanofi, AstraZeneca, and Novartis.

The competitive landscape shown below, while not comprehensive, illustrates our competitors in the market space commonly described as "diabetes tech", the digital health space focused on addressing problems associated with T2D. We believe the competitive landscape is best understood by comparing the primary mechanism of action (behavioral support/intervention or improving medication adherence and tracking); to the business model for patient acquisition (apps marketed direct-to-consumer; tech-enabled healthcare services offered to members of health plans, most often those of self-insured employers; or regulated products prescribed by providers).



While some solutions have evolved to include elements of various mechanisms such as behavioral support, reminders for medication adherence, or remote monitoring and transmission of biometric data, in our view, each has a primary mechanism for affecting disease and a clearly defined model for acquiring patients or consumers.

To our knowledge, upon regulatory authorization, BT-001 will be the only regulated PDT with a direct treatment claim for T2D that can be prescribed by providers and reimbursed by insurance, much like prescription drugs or other FDA authorized medical devices. Exploiting this opportunity requires us to generate significant evidence of safety, efficacy and impact on the total cost of care. While many early market entrants (in fact, nearly 360,000 health and wellness apps are now available in Apple's App Store) are making marketing claims related to the ability to improve T2D care and are acquiring patients through their employers or direct-to-consumer advertising, we believe the landscape will change dramatically when new solutions, backed by clinical evidence from well-designed clinical trials, that can be prescribed by providers and covered by insurance become broadly available. There are a number of companies in the prescription digital therapeutics space but none of these companies have commercialized a prescription digital therapeutic to target a cardiometabolic disease at this time.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory marketing authorizations and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and digital health industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer or more effective, are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory authorization for their products more rapidly than we may obtain authorization for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our products, if authorized for marketing, are likely to be their efficacy, safety, convenience, price, and the availability of reimbursement from government and commercial payers.

Intellectual Property

Our success depends in part upon our ability to protect our core technology and intellectual property. To protect our intellectual property rights, we rely on patents, trademarks, copyrights and trade secret laws, confidentiality procedures, and employee disclosure and invention assignment agreements. Our intellectual property is critical to our business and we strive to protect it through a variety of approaches, including by obtaining and maintaining patent protection in the United States and internationally for our digital therapeutic platform, novel treatment algorithms and uses thereof, and other inventions that are important to our business. For our digital therapeutic platform, we generally intend to pursue patent protection covering the machine learning aspects and key features of our products, along with the methods of use in treating a wide variety of cardiometabolic disorders and assisting patients and their caregivers in the management of disease. As we continue the development of our product candidates, we intend to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through claims covering additional methods of use as well as subsequent iterations and improvements to our products and use of predictive analytics.

As of December 31, 2022, there are two patent families with one granted U.S. Patent issued on June 7, 2022 (No. 11,355,228) and a total of ten pending U.S. and foreign applications in Europe and Canada, with claims directed to systems encompassing our digital therapeutic platform, and related methods of use in treating cardiometabolic disorders. The statutory expiration for any U.S. and foreign patents issuing from these two patent families will be between 2038 and 2039, subject to any patent term adjustment and/or extension. There is also a third patent family with national stage applications pending in the U.S., Europe and Canada, with claims directed to methods for predicting health outcomes and managing chronic medications. The statutory expiration for any U.S. and foreign patents issuing in this patent family will be 2039, subject to any patent term adjustment and/or extension. In addition, there is a fourth patent family represented by a pending international PCT application with claims directed to various implementations of nutritional CBT in our digital therapeutic platform. The statutory expiration for any U.S. and foreign patents issuing in this patent family will be 2042, subject to any patent term adjustment and/or extension.

Government Regulation

Insurance and Coverage

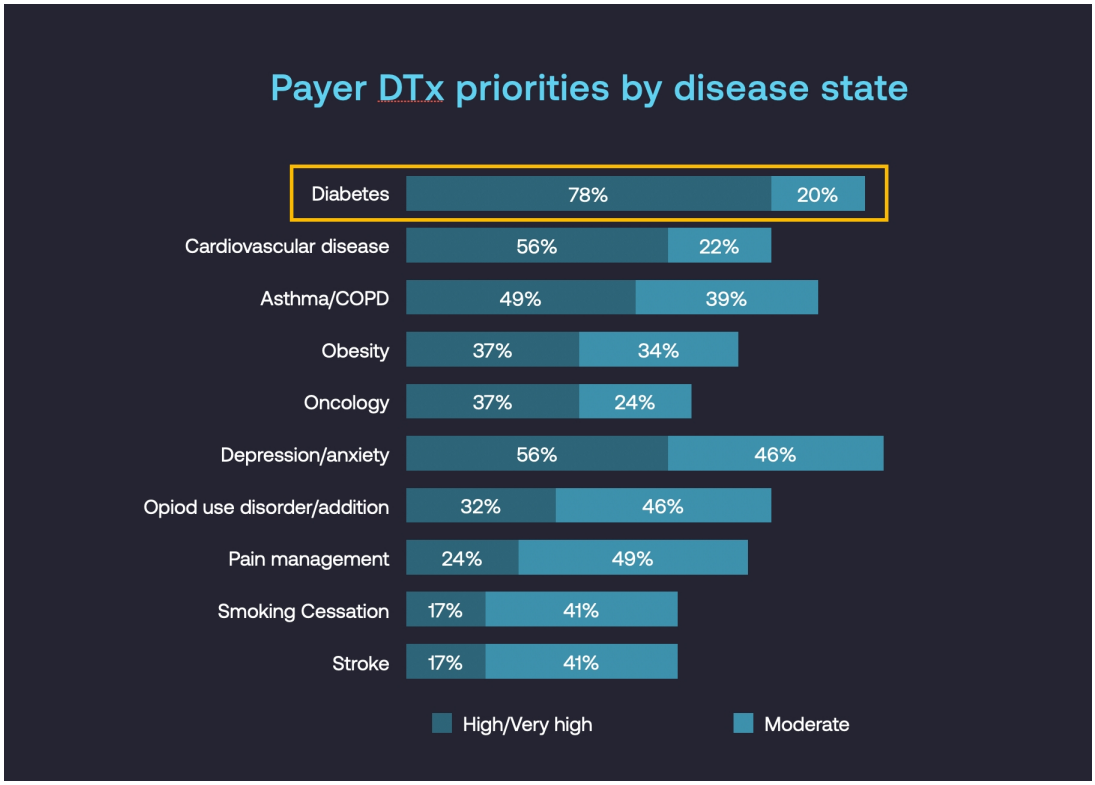
In the United States and markets in other countries, patients generally rely on third-party payers to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers is critical to new product acceptance. Our ability to successfully commercialize our products, if authorized for marketing, 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 treatments they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new treatments are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"). CMS decides whether and to what extent a new treatment will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Commercial payers can cover products that are not covered by Medicare. Currently, there is no Medicare category for PDTs, so it may be that coverage is established with commercial payers before Medicare. 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 products that we may develop will depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar health care management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers.

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

Payers consider the following factors 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, under what benefit (pharmacy, medical, other), what amount it will pay the manufacturer for the treatment and on what tier of its pharmacy formulary or under what medical coverage policy 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 health care costs. Based on our own market research conducted with payers, as well as third party research recently published by Xcenda and presented at the AMCP in October 2022, we believe we will be able to obtain broad coverage over time. For example, in the research published by Xcenda and presented at AMCP, payers perceived diabetes as the highest priority area for managing PDT products.



Patients are unlikely to use our product 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 authorized products, and coverage may be more limited than the purposes for which the product is authorized by the FDA.

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 device 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 medicinal 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 product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal 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 products. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Health Care Laws and Regulations

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 U.S. federal False Claims Act ("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,
- the federal Health Insurance Portability and Accountability Act of 1996 ("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 the Health Information Technology for Economic and Clinical Health Act of 2009 ("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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act ("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 the CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members.
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs, and

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

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.

Data Privacy and Security 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. 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.

Federal and state consumer protection laws are increasingly being applied by the United States Federal Trade Commission ("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.

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 California Consumer Privacy Act ("CCPA"), which went into effect on January 1, 2020 and has been amended several times. Further, a new California privacy law, the California Privacy Rights Act ("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). Additionally, a new Virginia privacy law, the Comprehensive Data Protection Act ("VCDPA"), was signed into law on March 2, 2021 and is also scheduled to take effect on January 1, 2023. The VCDPA will impose many similar obligations regarding the processing and storing of personal information as the CCPA and the CPRA. 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, CPRA, and VCDPA contain exceptions for certain activities involving Protected Health Information ("PHI") already regulated under HIPAA, we cannot yet determine the impact the CCPA, CPRA, VCDPA or other such future laws, regulations and standards may have on our business.

Health Care Legislative Reform

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. Effective January 1, 2025, certain provisions of the Inflation Reduction Act of 2022 will reduce Medicare Part D beneficiaries' annual out-of-pocket maximum from $7,050 to $2,000, thereby effectively eliminating the coverage gap.

Since its enactment, there have been numerous judicial, administrative, executive and legislative 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 ACA was enacted:

- In August 2011, the Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress, including a reduction of Medicare payments to providers up to 2% per fiscal year, and due to subsequent legislative amendments, this will remain in effect through 2031 unless additional Congressional action is taken.
- The U.S. American Taxpayer Relief Act of 2012 was signed into law in 2013, which among other things, further reduced Medicare payments to several types of providers.
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- The Further Consolidated Appropriations Act, signed into law in 2019, repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instituted in the future.

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 therapies 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 received for any approved device, which could have an adverse effect on customers 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 product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop products. 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 approval that may have been obtained and we may not achieve or sustain profitability.

FDA Regulation

United States

We are developing medical devices that are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and its implementing regulations, as well as other federal and state regulatory bodies in the United States and comparable authorities in other countries under other statutes and regulations. The laws and regulations govern, among other things, product design and development, preclinical and clinical testing, manufacturing, packaging, labeling, storage, recordkeeping and reporting, clearance, *de novo* classification or approval, marketing, distribution, promotion, import and export and post-market surveillance. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as issuance of warning letters, import detentions, civil monetary penalties and/or judicial sanctions, such as product seizures, injunctions and criminal prosecution.

FDA's Pre-market Clearance, Grant and Approval Requirements

Each digital therapeutic we seek to commercially distribute in the United States will require either a prior *de novo* classification grant, 510(k) clearance, unless it is exempt, or an approved pre-market approval application ("PMA") from the FDA under its medical device authorities. Generally, if a new device has a predicate that is already on the market under a 510(k) clearance, the FDA will allow that new device to be marketed under a 510(k) clearance; or if there is no legally marketed predicate device and general controls alone or with special controls provide reasonable assurance of safety and efficacy, the FDA will allow the new device to be marketed under a *de novo* classification grant; otherwise, a PMA is required. Medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurance of safety and efficacy. Class I devices are deemed to be low risk and are subject to the general controls of the FD&C Act, such as provisions that relate to: adulteration; misbranding; registration and listing; notification, including repair, replacement, or refund; records and reports; and good manufacturing practices. Most Class I devices are classified as exempt from pre-market notification under section 510(k) of the FD&C Act, and therefore may be commercially distributed without obtaining 510(k) clearance from the FDA. Class II devices are subject to both general controls and special controls to provide reasonable assurance of safety and effectiveness. Special controls include performance standards, post market surveillance, patient registries and guidance documents. A manufacturer may be required to submit to the FDA a pre-market notification requesting permission to commercially distribute some Class II devices. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III. A Class III device cannot be marketed in the United States unless the FDA approves the device after submission of a PMA. However, there are some Class III devices for which FDA has not yet called for a PMA. For these devices, the manufacturer must submit a pre-market notification and obtain 510(k) clearance in order to commercially distribute these devices. The FDA can also impose sales, marketing or other restrictions on devices in order to assure that they are used in a safe and effective manner.

510(k) Clearance Pathway

When a 510(k) clearance is required, we must submit a pre-market notification to the FDA demonstrating that our proposed device is substantially equivalent to a predicate device, which is a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976. By regulation, a 510(k) pre-market notification must be submitted to the FDA at least 90 days before we intend to distribute a device. As a practical matter, clearance often takes significantly longer. To demonstrate substantial equivalence, the manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or different technological characteristics and the information in the 510(k) pre-market notification demonstrates that the device is equally safe and effective and does not raise different questions of safety and efficacy. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously cleared device or use, the FDA will place the device into Class III.

There are three types of 510(k)s: traditional; special; and abbreviated. Special 510(k)s are for devices that are modified and the modification needs a new 510(k), and the methods used to evaluate the changes are well established, and the results can be sufficiently reviewed in a summary or risk analysis format. Abbreviated 510(k)s are for devices that conform to a recognized standard. The special and abbreviated 510(k)s are intended to streamline review, and the FDA intends to process special 510(k)s within 30 days of receipt.

***De novo* Classification**

When it is determined there is no legally marketed predicate device, the *de novo* process provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and efficacy for the intended use. Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 ("FDAMA") established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. If the manufacturer seeks classification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and efficacy of the medical device. Prior to the enactment of the FDA Safety and Innovation Act of 2012 ("FDASIA"), a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) pre-market notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the *de novo* application. Under the Medical Device User Fee Amendments of 2022 ("MDUFA V"), the FDA has stated that it intends to reach a decision on 70% of *de novo* requests within 150 days. However, the timeline for review can be much longer.

Once a *de novo* request is accepted for review, the FDA will conduct its substantive review. During the substantive review, the FDA may require additional information regarding the device that is necessary for the FDA to complete the review of the *de novo* request. The FDA may attempt to resolve any outstanding deficiencies interactively in real-time (i.e., interactive review). If the FDA believes that additional information needed from the requester is not suitable for interactive review and/or cannot be provided within a reasonable timeframe, the FDA will issue a Request for Additional Information, which places the *de novo* request on hold. The requester has 180 calendar days from the date of the Request for Additional Information to submit a complete response to each item identified by the FDA. If the FDA does not receive a complete response to all deficiencies in the Request for Additional Information within 180 days, the *de novo* request will be considered withdrawn and deleted from the FDA’s review system. If the *de novo* request is deleted, the *de novo* requester will need to submit a new request to pursue the FDA’s marketing authorization for that device.

The FDA may reject the *de novo* classification request if, among other reasons, it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed or if the applicant has not adequately addressed deficiencies related to its clinical trial and identified by FDA in a Request for Additional Information. 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 pre-market notification 510(k) submissions.

Pre-market Approval Pathway

A PMA must be submitted to the FDA for Class III devices for which the FDA has required a PMA. The PMA process is much more demanding than the 510(k) pre-market notification process. A PMA must be supported by extensive data, including but not limited to technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction reasonable evidence of safety and efficacy of the device.

After a PMA is submitted, the FDA has 45 days to determine whether the application is sufficiently complete to permit a substantive review and thus whether the FDA will file the application for review. The FDA has 180 days to review a filed PMA, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. Although the FDA is not bound by the advisory panel decision, the panel's recommendations are important to the FDA's overall decision-making process. In addition, the FDA may conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the Quality System Regulation ("QSR"). The agency also may inspect one or more clinical sites to assure compliance with FDA's regulations.

FDA allows applicants to submit discrete sections (modules) of the PMA to FDA for review soon after completing the testing and analysis. FDA intends the modular review approach to provide a mechanism by which applicants may submit preclinical data and manufacturing information for review while still collecting, compiling, and analyzing the clinical data. Therefore, a modular PMA is a compilation of sections or "modules" submitted at different times that together become a complete application. Additionally, the modular approach allows the applicant to potentially resolve any deficiencies noted by FDA earlier in the review process than would occur with a traditional PMA application.

Upon completion of the PMA review, the FDA may: (i) approve the PMA which authorizes commercial marketing with specific prescribing information for one or more indications, which can be more limited than those originally sought; (ii) issue an approvable letter which indicates the FDA's belief that the PMA is approvable and states what additional information the FDA requires, or the post-approval commitments that must be agreed to prior to approval; (iii) issue a not approvable letter which outlines steps required for approval, but which are typically more onerous than those in an approvable letter, and may require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years; or (iv) deny the application. If the FDA issues an approvable or not approvable letter, the applicant has 180 days to respond, after which the FDA's review clock is reset.

Clinical Trials

Clinical trials are almost always required to support pre-market approval, are often required for a *de novo* classification grant, and are sometimes required for 510(k) clearance. In the United States, for significant risk devices, these trials require submission of an application for an investigational device exemption ("IDE") to the FDA prior to initiating clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific number of patients at specified study sites. During the trial, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting and recordkeeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices and comply with all reporting and recordkeeping requirements. Clinical trials for significant risk devices may not begin until the IDE application is approved by the FDA and the appropriate institutional review boards ("IRBs") at the clinical trial sites. An IRB is an appropriately constituted group that has been formally designated to review and monitor medical research involving subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety and welfare of human research subjects. A nonsignificant risk device does not require FDA approval of an IDE; however, the clinical trial must still be conducted in compliance with various requirements of FDA's IDE regulations and be approved by an IRB at the clinical trials sites. The FDA or the IRB at each site at which a clinical trial is being performed may withdraw approval of a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits or a failure to comply with FDA or IRB requirements. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and efficacy of the device, may be equivocal or may otherwise not be sufficient to obtain approval or clearance of the product.

Sponsors of clinical trials of devices are required to register with *www.clinicaltrials.gov*, a public database of clinical trial information. Information related to the device, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration.

Ongoing Regulation by the FDA

Even after a device receives clearance, *de novo* classification or approval and is placed on the market, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and the FDA prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses and other requirements related to promotional activities;
- medical device reporting regulations, which require that manufactures report to the FDA if their device may have caused or contributed to a death or serious injury, or if their device malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;
- corrections and removal reporting regulations, which require that manufactures report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FD&C Act that may present a risk to health; and
- post market surveillance regulations, which apply to certain Class II or III devices when necessary to protect the public health or to provide additional safety and efficacy data for the device.

After a device receives 510(k) clearance or a *de novo* classification grant, any modification that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, will require a new clearance or possibly a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a determination not to seek a new 510(k) clearance, the FDA may retroactively require a manufacturer to seek 510(k) clearance or possibly a pre-market approval. The FDA could also require a manufacturer to cease marketing and distribution and/or recall the modified device until 510(k) clearance or pre-market approval is obtained. Also, in these circumstances, manufacturers may be subject to significant regulatory fines and penalties.

Some changes to an approved PMA device, including changes in indications, labeling or manufacturing processes or facilities, require submission and FDA approval of a new PMA or PMA supplement, as appropriate, before the change can be implemented. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the device covered by the original PMA. The FDA uses the same procedures and actions in reviewing PMA supplements as it does in reviewing original PMAs.

FDA regulations require manufacturers to register with the FDA and to list the devices they market. Additionally, the California Department of Health Services ("CDHS") requires manufacturers to register within the state. Following these registrations, the FDA and the CDHS inspect manufacturers on a routine basis for compliance with the QSR and applicable state regulations. These regulations require that we manufacture our products and maintain related documentation in a prescribed manner with respect to manufacturing, testing and control activities. We are also subject to other federal, state and local laws and regulations relating to safe working conditions, laboratory and manufacturing practices. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

- warning or untitled letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, voluntary or mandatory recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- delay in processing submissions or applications for new products or modifications to existing products;
- withdrawing approvals that have already been granted; and
- criminal prosecution.

The Medical Device Reporting laws and regulations require manufacturers to provide information to the FDA when they receive or otherwise become aware of information that reasonably suggests their devices may have caused or contributed to a death or serious injury as well as a device malfunction that likely would cause or contribute to death or serious injury if the malfunction were to recur. In addition, the FDA prohibits marketed devices from being marketed for off-label uses and regulates the advertising of certain devices as well. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution, including FCA liability for products covered under the federal health care programs.

Finally, newly discovered or developed safety or efficacy data may require changes to a marketed product’s labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA’s policies may change, which could delay or prevent regulatory clearance or approval of our products under development.

Based on published guidance and four interactions with the FDA, the regulatory pathway for BT-001 will be via a *de novo* classification request submission. In October 2022, the FDA notified us that our *de novo* classification request for BT-001 was accepted for substantive review. After receiving marketing authorization for BT-001, we expect our following product candidates will most likely pursue 510(k) clearances.

Coverage and Reimbursement

Despite widespread coverage of medications and digital disease management programs, commercial insurers, Medicare, and Medicaid (collectively "payers") in the U.S. continue to be challenged with achieving cost effective care for their T2D patient populations. It is estimated that T2D adds an incremental $10,000 per patient per year or more in direct medical costs of which prescription drugs make up $4,500 per patient per year. Despite these high per patient costs and the considerable resources payers invest in the management of the disease, approximately half of T2D patients are not able to achieve glycemic control.

We believe a PDT that targets root causes of CMDx, addresses common comorbidities, potentially reduces or eliminates the ongoing need for medications and has the potential to substantially reduce other health care costs by halting or reversing disease progression would offer significant value to payers. In May 2022, we conducted initial pricing research with 15 payers that included national plans, regional plans and PBMs. In December 2022, we conducted a single blinded study to test a draft value story for BT-001 with payers. Participants (n=10) were either current or recent payer P&T formulary or medical policy decision-makers. The draft value proposition reviewed included disease burden, unmet need, treatment landscape, and a draft of BT-001's product and clinical information. Feedback from this research study has been used to refine our value proposition presentation for payers. We plan to use this presentation in pre-authorization health economics information exchange conversations with payers beginning in March 2023. In February 2023, we conducted a separate double blinded study with participants (n=7) who are current payer decision makers to understand how we might optimize contract structures with payers. We tested several variables upon which agreements could be structured including patient engagement metrics, clinical outcomes, and financial targets. Overall payers reacted positively to BT-001's target product profile and the pivotal trial results. Finally, HEOR models have been completed and are undergoing optimization. Additional pricing and payer research is planned for the first half of 2023. Collectively, the outcomes of these research and modeling efforts will inform our decisions on pricing and contract structure.

To optimize payer reimbursement coverage following a potential commercial launch, we are generating evidence to substantiate the value of BT-001 with longer-term data related to usage and outcomes in a real world setting. This is additive to the evidence generated from our six-month randomized controlled pivotal trial. We are conducting such real world evidence studies in partnerships with Mass General Brigham, Colorado Prevention Center Clinical Research, University of Colorado and Durham Veterans Administration Medical Center.

We also expect to supplement this evidence with an assessment of the total cost of care in our intended patient population using multi-payer claims datasets. To estimate BT-001's effect on total cost of care, we plan to leverage the totality of evidence related to BT-001 use to create robust cost-effectiveness and budget impact models. We expect to publish these results with reputable organizations and utilize this evidence in the development of our AMCP value dossier for submission to formulary review committees. We have been engaging with payers to gain insights related to clinical evidence expectations to be considered for coverage. Upon evidence availability, we intend to engage in pre-authorization health economics information exchange conversations with payers to begin reimbursement coverage discussions beginning in March 2023.

We cannot predict whether we will be successful in obtaining broad payer coverage or sufficient reimbursement for BT-001 over time; however, the following factors support positive coverage and reimbursement decisions from payers: (1) BT-001 addresses an enormous problem (T2D) on which commercial payers and Medicare (which insure approximately 86% of diabetes patients) spend approximately $200 billion each year; (2) BT-001 has the potential to save payers money by reducing medication usage and overall healthcare costs; and (3) BT-001 fills a gap in existing clinical guidelines and integrates with existing provider workflows.

Sales and Marketing

The intended use at launch for BT-001 would be to improve glycemic control in patients with uncontrolled T2D, under the supervision of their physician. This represents a target patient population of about 13 million in the U.S. and $40 billion a year spent on prescription drugs. It is estimated that 86% of T2D patients receive regular care from their primary care provider to treat their condition.

Go-to-market strategy

While there are approximately 13 million uncontrolled adult T2D patients in the US, we expect to have a focused approach. To inform our approach, we have identified providers, health systems and payers with the highest concentration of uncontrolled T2D patients. Analysis has pointed us to 50 integrated delivery networks or health systems which overlap with approximately 25 regionally dominant payers, covering about 40 million lives, or 45% of total lives covered by regional payers. These targets will serve to support a strong initial launch with a comparatively nimble team deployed in those geographies where this overlap exists.

A patient claims analysis identified a patient cohort with the greatest potential benefit for BT-001 and we have matched these patients to health care providers on which we will focus. These same providers also treat other patients with T2D beyond the uncontrolled specific population used in our claims analysis, who may also be appropriate candidates for a prescription, thereby expanding the universe of patients who may be introduced to BT-001 in the first few months of commercialization. We expect to execute on this strategy at launch with no more than 50-field facing representatives made up of a combination of payer leads, account managers and medical science liaisons. Over time, as we gain coverage and access with both regional and national plans, we can expand our field facing team.

Current work is underway to prepare for commercial launch, if BT-001 is authorized for marketing, and includes gaining presence among clinical stakeholders within their scientific meetings. We are leveraging evidence generated from our pivotal trial and real-world use studies to publish clinical and health outcomes data to showcase BT-001's benefits. Abstracts are in development for submissions to meetings later this year to coincide with the early launch period of BT-001. With the evidence generated, we also expect to begin the process of advocating for the incorporation of BT-001 into future consensus guidelines to further integrate its use as a first line PDT for treating T2D. We are building a medical affairs organization to steer these efforts and whose primary responsibilities will include engaging thought leaders in scientific discourse, establishing an advisory board of key opinion leaders, creating a speaker's panel and building advocates to support inclusion of BT-001 as part of future T2D consensus guidelines. Our medical affairs team will also play a critical, ongoing role in generating and publishing evidence that demonstrates the impact BT-001 and future platform products can have on clinical outcomes, durability of effect and total cost of care.

We are also engaging key opinion leader advisors to inform our educational programming and marketing materials for launch. We plan to continue our investment in targeting analytics, as well as digital and non-personal promotion. As payer reimbursement coverage increases, we expect to implement targeted, direct to consumer advertising to drive awareness among patients on the benefits of BT-001 in T2D.

Integration with the Standard of Care

T2D is a devastating disease that progressively worsens over time and often leads to the development of complex comorbidities, such as hypertension, high cholesterol, heart failure and chronic kidney disease. Lacking the tools to address the maladaptive behaviors that cause disease progression, providers utilize the only treatment options currently available — medications. As a patient's diabetes worsens, providers typically add multiple medications in an attempt to achieve glycemic control for their patients. By age 65, T2D patients are taking an average of five medications for treating diabetes and common comorbidities, while many are failing to achieve glycemic control.

Clinical treatment guidelines from the ADA recommend use of behavioral therapy as a first line treatment throughout the disease progression on a standalone basis or alongside medications. Recent updates to the 2022 Standards of Medical Care in Diabetes recommend all people with diabetes participate in diabetes self-management education and receive the support needed to facilitate the knowledge, decision-making, and skills mastery for diabetes self-care, and notes that digital coaching and digital self-management interventions can be effective methods to deliver diabetes self-management education and support. Despite widespread alignment with these consensus guidelines, there are currently no FDA-regulated treatments available to address this unmet need or practical way for the healthcare system to deliver them. BT-001 represents a unique opportunity for providers to prescribe to their patients FDA-regulated behavioral therapy. Because BT-001 is specifically intended to address the behaviors that are the root causes of their condition, our first-to-market PDT treatment of T2D holds out the hope for many of these patients to achieve better glycemic control, reduce or eliminate the need for medications, and avoid insulin therapy altogether.

Initial target patients will include those patients 18 and older who are not at A1c target despite receiving one new non-insulin treatment. These patients are progressing to an escalation in therapy and would be motivated to seek alternative solutions. Our claims data analysis pointed us to the highest concentration of T2D patients who would benefit the most from BT-001 meeting this definition. Findings suggest we can reach close to half a million patients with a modestly sized sales team of less than 50 representatives by calling on a targeted group of physicians who treat the majority of these uncontrolled T2D patients. BT-001 is intended to fit easily within existing provider workflows to enable adoption at scale. BT-001 will be prescription-based and follow the same standard of care for the management of T2D. BT-001 is intended to work in conjunction with drug therapy with the opportunity to stabilize a patient's disease and drive improvement of A1C. The provider remains as the central caregiver with BT-001 offering a way to enhance the doctor-patient relationship with a treatment that aids a patient with key behavioral change regimens in between doctor visits with the opportunity to make lasting lifestyle changes.

Partnering

We are engaging in business development efforts to maximize the value of BT-001 and our platform in non-dilutive ways. We are exploring opportunities to partner with pharmaceutical medical technology and technology companies that are marketing traditional drug therapies for CMDx and have a strategic interest in digital health or have the organizational infrastructure to support the successful development and commercialization of our platform. Opportunities may also exist to co-develop novel combination products with a pharmaceutical company operating in the cardiometabolic space.

We intend to commercialize our products in the United States. We will also pursue opportunities to partner with pharmaceutical companies to commercialize our products outside of the United States.

Employees and Human Capital Resources

As of December 31, 2022, we had 54 employees, all of which were full-time employees, including 40 in research and development, 3 in sales and marketing, and 11 in general and administrative. None of our employees are represented by a labor union and we believe that our relationships with our employees are good.

We believe that our future success depends upon our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off. As part of our promotion and retention efforts, we also invest in ongoing development.

Our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels and continue to focus on extending our diversity and inclusion initiatives across our entire workforce, from working with managers to developing strategies for building diverse teams to promoting the advancement of leaders from different backgrounds.

Legal Proceedings

We are not currently a party to any material legal proceedings. In the ordinary course of business, we may be subject to legal proceedings, claims and litigation.

Corporate Information

We were formed as a Delaware limited liability company on April 1, 2015 under the name Nutrition Development Group LLC ("LLC"). The LLC's name was changed to Farewell LLC on August 18, 2016 and to Better Therapeutics LLC on January 4, 2018. The LLC merged into its wholly owned subsidiary Better Therapeutics, Inc., a Delaware corporation, ("Legacy BTX") on August 14, 2020, with Legacy BTX surviving the merger. On October 28, 2021, Legacy BTX merged with and into MCAD Merger Sub, Inc., a wholly-owned subsidiary of Mountain Crest Acquisition Corp. II, ("MCAD") (such merger, the "business combination"), and MCAD was renamed Better Therapeutics, Inc.

We are a remote, "fully distributed" company and do not have offices. Our business mailing address is 548 Market Street, #49404 San Francisco, CA 94104, and our telephone number is (415) 887-2311. Our website address is http://www.bettertx.com. The information contained in or accessible from our website is not incorporated into this Annual Report, and you should not consider it part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

Available Information

We file annual reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements and other information with the SEC. Our filings with the SEC are available on the SEC's website at www.sec.gov. We also maintain a website at http://www.bettertx.com. We make available, free of charge, in the Investor Relations section of our website, documents we file with or furnish to the SEC, including our annual reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any exhibits and amendments to those reports. We make this information available as soon as reasonably practicable after we electronically file such materials with, or furnish such information to, the SEC. The other information found on our website is not part of this or any other report we file with, or furnish to, the SEC.

Item 1A. Risk Factors.

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Annual Report and in other documents that we file with the SEC, in evaluating the Company and our business. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks that we face. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations.

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.
  - There is substantial doubt about our ability to continue as a going concern.
  - 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, successfully complete our real world evidence programs, or if we experience delays in doing so, our business will be materially harmed.
  - If physicians are not willing to change current practices to adopt BT-001 or if our products otherwise fail to achieve and maintain market acceptance, if authorized for marketing, our business, financial condition and results of operation would 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 any product candidate authorized for marketing.
  - Any failure to offer high-quality patient support or support to HCPs prescribing our product 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.
  - 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.
- **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 BT-001, or other product candidates, or if such classification or clearance is delayed, or if the FDA limits our intended use or limits the clinical data included in our labeling, 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.
- 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 or clearance.

- **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.
  - Failure to establish, protect or enforce our intellectual property rights could harm our business and results of operations.
- **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 may not receive the necessary *de novo* classification grant for BT-001 or clearances for future expanded indications of BT-001, 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.
- **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.
  - Federal, state and local employment-related laws and regulations could increase our cost of doing business and subject us to fines and lawsuits.
- **Risks Related to Our Common Stock**
  - The price of our common stock may be volatile.
  - Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

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 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, if BT-001 is authorized by the FDA. 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 $39.8 million and $40.3 million for the twelve months ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $111.5 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 marketing 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 commercialization, if authorized by the FDA;
- 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 regulatory, clinical, quality control, medical, scientific and other technical personnel to support our clinical operations;
- expand our operational, financial and management systems and increase 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 any 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.

There is substantial doubt about our ability to continue as a going concern.

We have incurred significant financial losses since our inception. Our net loss was $39.8 million and $40.3 million for the twelve months ended December 31, 2022 and 2021, respectively, and we had an accumulated deficit of $111.5 million as of December 31, 2022. Moreover, we anticipate that we will continue to incur significant financial losses for the foreseeable future. Our existing cash and cash equivalents of $15.7 million as of December 31, 2022 is expected to fund our operations through the first quarter of 2023. Accordingly, there is substantial doubt about our ability to continue as a going concern. Our financial statements included elsewhere in this Annual Report do not include any adjustments that might result from the outcome of this uncertainty. Additionally, our independent registered public accounting firm's report for the year ended December 31, 2022 contains an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern.

We plan to seek additional funding through various financing sources, including the sale of equity and/or debt securities, and we are exploring other non-dilutive financing options. There can be no assurance that any future financing efforts will be successful. If we are unable to obtain additional funding, or 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 could also be required to limit or terminate our operations, make reductions in our workforce, discontinue our development programs, liquidate all or a portion of our assets or pursue other strategic alternatives, in which case investors may not receive any return on their investment and may lose their entire investment.

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 favorable 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, 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 and any future clinical trials. 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 authorization 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 translation of product(s) in non-English markets;
- the costs of regulatory filings in foreign countries;
- 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 through 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 product candidate for which a *de novo* classification request is pending with the FDA 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 pre-commercialization efforts for our more advanced 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 and current limited runway for funding, 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 ourselves.

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 marketing 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, successfully complete our real world evidence programs, or if we experience delays in doing so, our business will be materially harmed.

To date, we as an organization have not obtained marketing authorization for any product candidates. Our future success and ability to generate revenue from our product candidates is dependent on our ability to obtain regulatory marketing authorization for and commercialize BT-001. We completed our pivotal clinical trial for BT-001 in July 2022 and our *de novo* classification request was accepted for substantive review by the FDA in October 2022. If BT-001 encounters 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 our *de novo* classification request pending with the FDA for 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 of the data 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;
- greater than anticipated clinical trial or manufacturing costs;
- delays in the review of our *de novo* classification request by the FDA, delays in submitting 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, or comparable foreign regulatory authorities regarding the scope or design of our clinical trials; or
- 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 product candidates in particular.

If physicians are not willing to change current practices to adopt BT-001 or if our products otherwise fail to achieve and maintain market acceptance, if authorized for marketing, our business, financial condition and results of operation would 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.

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. 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. However, 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, 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 or new workflow processes 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.

Additionally, 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. If our products fail to achieve market acceptance for any reason, our business, financial condition and results of operation would 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.

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 authorized for marketing.

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 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 authorization 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 approvals and marketing authorizations 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, if authorized by the FDA, 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;
- pricing; and
- reimbursement.

Any failure to offer high-quality patient support or support to HCPs prescribing our product 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 we rely.

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 we rely, 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 ongoing 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 mobile and 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, Inc. ("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 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 and in May 2022, we drew down an additional $5 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. We did not initiate a second pivotal trial prior to September 15, 2022 that was required under the Loan Agreement, and hence, as a result the associated borrowing is no longer available to the Company.

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.

Additionally, the Loan Agreement contains subjective acceleration clauses that would allow Hercules Capital to accelerate the scheduled maturities and obligations under the Loan Agreement if they determine that there has been a Material Adverse Change (as defined in the Loan Agreement) in our business, financial condition or the prospect of repayment of any obligations under the Loan Agreement, among other things. In the event a subjective acceleration clause is invoked, the outstanding principal, interest, end of term charge and prepayment penalty under the Loan Agreement would become payable on demand by Hercules Capital. There is no assurance that Hercules Capital will not invoke an acceleration clause in the future, which would have an adverse effect on our business and financial condition.

Hercules Capital's 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.

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.

Our ability to use net operating loss carryforwards ("NOLs") and credits to offset future taxable income may be subject to certain limitations.

Our NOLs could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. NOLs generated in taxable years beginning before January 1, 2018 are permitted to be carried forward for 20 taxable years under applicable U.S. federal income tax law. Under current U.S. federal income tax law, NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, NOLs generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely. As of December 31, 2022, we had NOLs for U.S. federal and state income tax purposes of approximately $59.8 million. NOLs generated between January 1, 2020 and December 31, 2022 for U.S. federal tax reporting purposes of approximately $56.7 million have an indefinite life. NOLs generated between January 1, 2020 and December 31, 2022 for state tax reporting purposes of approximately $3.0 million will begin to expire in 2035.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" (defined under Section 382 of the Code and applicable Treasury Regulations as a greater than 50 percentage point change (by value) in a corporation's equity ownership by certain stockholders over a rolling three-year period) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We have not determined whether the NOLs from our operations are limited under Section 382 of the Code; however, based on a preliminary review of information available, other than the NOL attributes that were carried forward from the Business Combination, the Company does not believe its NOLs are currently limited by Section 382. We may have experienced ownership changes in the past and may experience ownership changes in the future, including as a result of our business combination or subsequent shifts in our stock ownership (some of which are outside our control). Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. NOL attributes that were carried forward from our business combination are expected to be subject to the limitations under Section 382. The NOLs subject to that limitation are $77 thousand as of December 31, 2022 and 2021. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition.

Changes in tax law may adversely affect us or our investors.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

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 BT-001 or other product candidates, or if such classification or clearance is delayed, or if the FDA limits our intended use or limits the clinical data included in our labeling, 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. In October 2022, the FDA notified us that our *de novo* classification request for BT-001 was accepted for substantive review. If we are not successful in obtaining timely marketing authorization of BT-001 from the FDA, or any of our other product candidates, we may never be able to pursue authorization by foreign regulatory authorities or to generate significant revenue and may be forced to cease operations. Specifically, we hope to pursue additional regulatory marketing clearances for BT-001 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. For example, as part of the typical *de novo* review process as expected by us, in February 2023, we received a Request for Additional Information from the FDA notifying us that, after review of our submission, the FDA determined that additional information is required. The letter outlined the FDA's view that our submission has a number of deficiencies, classified into major and minor deficiencies. We requested a meeting with the FDA to clarify several of the major deficiencies noted as well as to seek guidance on our options to address them. That meeting also took place in February. During the meeting the FDA provided helpful context, clarifications and guidance, and we are now compiling our response to address the FDA's comments. We believe we can address the FDA's questions, and our previously provided guidance that we anticipate FDA's decision by the middle of 2023 remains unchanged. If we are unable to resolve the deficiencies, we may need to amend the indications for use for which we are seeking authorization and/or conduct another clinical trial, and the authorization and commercial launch of BT-001 could be significantly delayed or the authorization could be denied.

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, BT-001 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 BT-001, as well as market acceptance in the United States of BT-001, and our failure to receive FDA de novo classification of BT-001 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 BT-001 application that we believe, if granted *de novo* classification, will serve as the basis for future marketing clearances for additional uses in other indications. While we have a *de novo* classification request for BT-001 pending with the FDA, we have not yet received *de novo* classification from the FDA to market and sell BT-001 in the United States for any use. 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 BT-001 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 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 pending *de novo* classification request for BT-001, we would need to seek *de novo* classification for the next digital therapeutic indication we seek to market. If *de novo* marketing authorization is granted for BT-001, it is uncertain whether, depending on their design and intended uses, future candidates may also be required by the FDA to obtain marketing authorization through the *de novo* classification process, which would lead to longer more expensive development. Unexpected or serious complications or other unforeseen negative effects related to the development or market acceptance of any 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 completed a pivotal clinical trial and our *de novo* classification request for BT-001 for the treatment of T2D was accepted for substantive review by the FDA in October 2022. 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 pivotal clinical trial of BT-001 in July 2022, but the FDA will ultimately determine whether these results 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) pre-market 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 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 and 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 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 differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain authorization for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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 BT-001 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 and in compliance with FDA regulations and expectations;
- 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 authorization or identify alternate regulatory pathways to market for such product candidates.

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 CBT for treating diabetes, heart disease, and other cardiometabolic conditions have been authorized to date. We are developing a platform of FDA-regulated, software-based, PDT candidates for treating such conditions through a novel form of CBT. The FDA may lack experience in evaluating the safety and effectiveness of product candidates based on CBT, 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 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 establish, 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 ("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 been 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 may 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 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; pre-market 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 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 BT-001 or clearances for future expanded indications of BT-001, 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 the FDA of BT-001 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 product, 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 pre-market approval, or 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 BT-001 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 pre-market 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 BT-001.

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 pre-market 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 preclinical, 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. 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 marketing authorizations 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 BT-001 through the *de novo* classification pathway. Some modifications to BT-001 that have not been previously authorized may require us to submit a 510(k) pre-market 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 preclinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our preclinical 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 pre-market 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 products from the market.

After *de novo* classification, if granted, for BT-001, 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 BT-001 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 device 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 time frame. 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.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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.

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 and whether we are successful in obtaining coverage from a broad spectrum of payers. 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 HHS. CMS decides whether and to what extent a new product 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. Further, if we are not successful in obtaining coverage from a broad spectrum of payers, our ability to successfully commercialize our product candidates may be impacted.

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 product 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 it will provide coverage for a treatment, under what benefit (pharmacy, medical, other), what amount it will pay the manufacturer for the treatment, and on what tier of its pharmacy formulary or under what medical coverage policy 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), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

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 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 ACA was enacted. The Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions that resulted in aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken.

In August 2022, the Inflation Reduction Act of 2022 (the "IRA") was signed into law. The IRA includes several provisions that may impact our business, depending on how various aspects of the IRA are implemented. Provisions that may impact our business include a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on all drugs in Medicare Part D, permitting the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delaying the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. The effect of IRA on our business and the healthcare industry in general is not yet known.

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 of 2002 (the "Sarbanes-Oxley Act") and the rules and regulations of the applicable listing standards of The Nasdaq Capital Market. 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 Jumpstart Our Business Startups Act of 2012 (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 ("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 our 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 implemented a remediation plan 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 December 31, 2022, Mr. Perry owns approximately 46% of the outstanding shares of our common stock. As long as Mr. Perry either 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 and 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 contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition deemed undesirable by our board of directors 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 our board of directors or taking other corporate actions, including effecting changes in our management. Among other things, our governing documents include provisions regarding:

- the ability of our board of directors 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 of directors, 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 our board of directors to amend the bylaws, which may allow our board of directors 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 our board of directors 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 our board of directors, 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 our board of directors 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

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 our operating performance and the performance of our competitors in general;
- material and adverse impact of the ongoing COVID-19 pandemic and economic and political developments, including the war in Ukraine, rising interest rates and high inflation, 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 our 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.

Unstable market and economic conditions may have serious 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 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 or delay our pursuit of potential in-licenses or acquisitions. In addition, there is a risk that one or more of our current service providers or other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

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.

A significant portion of our total outstanding shares may be sold into the market, which could cause the market price of our common stock to decline 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. As of December 31, 2022, we had outstanding 23,851,022 shares of common stock, which may be resold in the public market immediately without restriction, subject only to the restrictions of Rule 144 under the Securities Act. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our shares of common stock in the public market, the market price of our common stock could decline significantly.

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

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 innovation. 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 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 $1.235 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 our 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 our Annual Report on Form 10-K and take advantage of reduced disclosure obligations regarding executive compensation.

We will continue to 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 continue to 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 of directors 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.

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.

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.

Item 1B. Unresolved Staff Comments.

Not Applicable.

Item 2. Properties.

We do not own or lease any real property. We run a virtual office model and our business mailing address is 548 Market Street, #49404, San Francisco, CA 94104.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings, nor are we aware of any pending or threatened litigation. In the ordinary course of business, we may be subject to legal proceedings, claims and litigation.

Item 4. Mine Safety Disclosures.

Not Applicable

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information for Common Stock

Our common stock is listed for trading on The Nasdaq Capital Market under the symbol "BTTX".

Holders of Record

As of March 24, 2023 there were approximately 62 stockholders of record of our common stock.

Dividend Policy

We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We have never declared or paid any cash dividends on our capital stock. We do not intend to pay cash dividends to our stockholders in the foreseeable future. In addition, the terms of our loan agreement with Hercules Capital preclude us from paying dividends. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Persons

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes, included in Item 8 of this Annual Report. Unless otherwise specified all dollar amounts are in U.S. Dollars. Except for per share amounts, all amounts are in thousands, unless otherwise noted.

Overview

We are a prescription digital therapeutics company developing a clinically validated, software-based novel form of CBT to address the root causes of CMDx. Our mission is to advance human health through the power of behavior change. We are developing a proprietary platform of FDA regulated software-based PDTs for the treatment of cardiometabolic diseases by addressing the underlying causes of the diseases. Our initial development efforts are focused on T2D, hypertension, hyperlipidemia, NAFLD, NASH and CKD. Founded in 2015, we are led by executives that have track records of building multi-billion dollar businesses and extensive industry experience in developing and commercializing therapeutics.

We selected cardiometabolic diseases as our initial target markets because they 1) share lifestyle behavior as a common root cause, potentially enabling rapid expansion of our platform across multiple related diseases, 2) rank amongst the most prevalent and costly chronic diseases that are largely reversible and preventable, offering opportunities for transformative impact and 3) represent areas of significant unmet need because currently available drugs predominantly treat symptoms, rather than addressing the root causes, often resulting in disease progression and more costly healthcare interventions over time.

Our clinically validated PDTs are intended to be prescribed by physicians and reimbursed by payers like traditional medicines. The mode of action embedded in our PDTs is a novel form of CBT, targeting the specific behaviors that cause the diseases we seek to treat. The CBT delivered by our PDTs is designed to enable changes in neural pathways of the brain so that lasting changes in behavior become possible.

Our lead prescription digital therapeutic product candidate, BT-001, completed a first-in-class open label, randomized, controlled, parallel group clinical trial for the treatment of patients with T2D in July 2022 and successfully met its primary and secondary endpoints as well as a host of exploratory endpoints. We submitted a *de novo* classification request to the FDA in September 2022, seeking marketing authorization of BT-001 for the treatment of adult patients with T2D and in October 2022, the FDA notified us that our *de novo* classification request was accepted for substantive review. A portion of our data was published in the peer reviewed journal Diabetes Care in October 2022. As part of the typical *de novo* review process as expected by us, in February 2023, we received a Request for Additional Information from the FDA notifying us that, after review of our submission, the FDA determined that additional information is required and placed the review on hold. The letter outlined the FDA's view that our submission has a number of deficiencies, classified into major and minor deficiencies. We requested a meeting with the FDA to clarify several of the major deficiencies noted as well as to seek guidance on our options to address them. That meeting also took place in February. During the meeting the FDA provided helpful context, clarifications and guidance, and we are now compiling our response to address the FDA's comments. We believe we can address the FDA's questions, and our previously provided guidance that we anticipate FDA's decision by the middle of 2023 remains unchanged. If we are unable to resolve the deficiencies, we may need to amend the indications for use for which we are seeking authorization and/or conduct another clinical trial, and the authorization and commercial launch of BT-001 could be significantly delayed or the authorization could be denied.

We also achieved positive top-line results in our LivVita study, a first-ever clinical study evaluating the feasibility of our digitally delivered CBT to reduce liver fat and improve liver disease biomarkers as a potential treatment for NAFLD and NASH. Currently, there is no FDA approved treatment for these conditions, which affect one in four Americans and cause approximately $100 billion in direct medical costs annually. Because of the significant unmet medical need, we intend to apply for breakthrough device designation from the FDA for our investigational CBT-based treatment platform for these indications in the first half of 2023. We plan to use data from this study and the exploratory endpoints from the BT-001 pivotal trial to inform the potential initiation of additional pivotal trials in support of seeking FDA authorization in CMDx indications beyond T2D.

We believe we are differentiated from other companies in the PDT space in several important ways, which we believe has the potential to result in better commercial launch performance and peak revenue than those observed for previously approved PDTs: 1) with our focus on cardiometabolic diseases, and T2D as our lead indication, we are targeting very large patient populations with significant unmet medical needs; 2) our investigational PDTs are designed to deliver a treatment intervention that fits into the existing treatment paradigm, e.g., current clinical guidelines for the treatment of diabetes highlight behavior change as the foundation of treatment; 3) our proposed therapy has the potential to generate substantial health economic benefits and the utilization of our PDTs has the potential to improve profitability for payers; and 4) we have a team with extensive industry experience in developing and commercializing therapeutics. Furthermore, we believe our internally developed novel form of CBT is differentiated from other approaches in the digital therapeutics space that are incorporating CBT principles.

The clinical trial for BT-001 was the largest randomized controlled study of a PDT conducted to date and included a diverse, nationally representative population of 668 patients with a body mass index ("BMI ") $\geq$ 25 mg/m^2, advanced and difficult to treat 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-001 and 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. Two important study design features, based on guidance received in our interactions with FDA, included a) the ability for physicians to adjust diabetes medication for all participants throughout the duration of the trial and b) that participants randomly assigned to use BT-001 were not mandated or incentivized to use the CBT features contained in BT-001. We believe these features established a very high bar for evaluating efficacy.

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 in A1c from baseline after 90 days of treatment. BT-001 met the primary endpoint, showing a highly statistically significant improvement in A1c relative to the control group (-0.4%, n=610, $p <0.001$). BT-001 showed a sustained and statistically significant change relative to the control group on the secondary efficacy endpoint, which was the mean change in A1c from baseline at 180 days (-0.3%, n=517, $p =0.01$). Importantly, BT-001 met the 180 day endpoint even though 1.5 times more SOC patients increased blood sugar lowering medications relative to those in the BT-001 arm prior to the 180 day A1c draw. After the day 180 A1c draw, 1.7 times more SOC control patients increased their medications compared to BT-001 patients. BT-001 demonstrated sustained and numerically improved A1c levels, with A1c reduction from baseline improving from 0.3% at 90 days to 0.4% at 180 days across the intent-to-treat population, suggesting a durable treatment effect. Half of the BT-001 patients achieved a meaningful reduction in A1c (defined as 0.4% reduction), with a mean A1c reduction of 1.3% within this subset. The clinical trial also provided evidence that beyond reductions in A1c: (1) there was a clear dose-response between greater engagement in CBT and greater reductions in A1c, supporting CBT as a mechanism of action, (2) measures of patient engagement, adherence, persistence, and satisfaction were all positive, (3) BT-001 resulted in reassuring safety data, with significantly fewer adverse ($p<0.001$) and serious adverse events ($p=0.01$) as compared to the SOC control group, and (4) exploratory endpoint data revealed additional cardiometabolic improvements as well as the potential to reduce the need for medications and lower healthcare utilization compared to the control group, supporting the potential, if authorized, for BT-001 to improve overall health of patients with T2D and potentially reduce cost of care associated with the progression of the disease.

The LivVita study, our clinical study evaluating the feasibility of our digitally delivered CBT to reduce fatty liver and improve liver disease biomarkers as a potential treatment for NAFLD and NASH was conducted in collaboration with Arizona Liver Health, a leading liver clinical research center. This single arm interventional cohort study enrolled 22 patients who were given access to a 90-day CBT-based treatment platform. This clinical study met its primary endpoint, showing a statistically significant positive signal with an average relative reduction in MRI-PDFF of 16% ($p=0.01$) in the intent-to-treat population (n=19). Additionally, the clinical study showed (i) a statistically significant mean reduction in alanine transaminase (ALT) of -17 IU/L ($p=0.002$), (ii) a statistically significant mean change in FAST Score of 20% ($p=0.01$), (iii) no serious adverse events or device related adverse events, and (iv) high engagement and patient satisfaction with treatment, with a Net Promoter Score of +75 and 94% of subjects still using the app after 90 days. NAFLD and NASH affects over 80 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 NAFLD or NASH.

We also initiated real world evidence studies to evaluate the long-term effectiveness and healthcare utilization changes associated with the use of BT-001 for the treatment of T2D. The randomized, controlled, multi-site studies are expected to enroll 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 the fourth quarter of 2023, once a sufficient number of patients have completed an incremental 180 days of treatment. The study seeks to provide payers and providers with long-term data related to usage and outcomes in a real-world setting.

Financial Overview

Since our inception in 2015, we have focused substantially all of our resources on conducting research and development activities, including discovery and preclinical studies, establishing and maintaining our intellectual property, hiring personnel, raising capital and providing general and administrative support for these operations. We have recorded revenue from a pilot program with a private health insurance provider to provide a digital therapeutic program that includes a mobile app. We have funded our operations to date primarily from the issuance of convertible notes and simple agreements for future equity ("SAFEs"), the issuance and sale of our preferred units, borrowing on our Term Loan Facility and funding from the merger with MCAD.

We have incurred net losses in each year since inception. Our net losses were $39.8 million and $40.3 million for the twelve months ended December 31, 2022 and 2021, respectively. As of December 31, 2022 and December 31, 2021, we had an accumulated deficit of $111.5 million and $71.7 million, respectively. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses over at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities as we:

- advance our lead product candidate, BT-001, through commercialization, if authorized for marketing by the FDA;
- advance our pilot stage product candidates through clinical trials;
- pursue regulatory authorization or clearance of our products;
- operate as a public company;
- continue our preclinical programs and clinical development efforts; and
- continue research activities for the discovery of new products.

On April 6, 2021, we entered into a merger agreement with MCAD, a special purpose acquisition company (the "Merger Agreement"). 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 5,000,000 shares of its common stock for $10.00 per share (the "PIPE Shares"). On October 28, 2021, we completed the merger with MCAD. We raised $59 million in funding upon the completion of the business combination with MCAD. Under the Merger Agreement, MCAD acquired all of the outstanding shares of Legacy BTX in exchange for 15,174,729 shares of MCAD. In connection with the merger, MCAD was renamed Better Therapeutics, Inc.

Impact of COVID-19

In March 2020, the World Health Organization declared COVID-19 a global pandemic. The COVID-19 pandemic has not had a significant impact on our operations. The ultimate impact of the 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 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 for our treatments by commercial insurers, Medicare, Medicaid and the Veterans Administration, 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 pursue obtaining favorable rates and broad reimbursement coverage through demonstrating and generating a comprehensive portfolio 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 favorable rates and 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 multiple factors.

We are engaging in business development efforts to maximize the value of BT-001 and our platform in non-dilutive ways. We are exploring opportunities to partner with pharmaceutical, medical technology and technology companies who are marketing traditional drug therapies for CMDx, and have a strategic interest in digital health, or the organizational infrastructure to support the successful development and commercialization of our platform. Opportunities may also exist to co-develop novel combination products with a pharmaceutical company operating in the cardiometabolic space.

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 CROs and consultants engaged to manage and conduct clinical trials, other research and development expenses associated with software development and licenses, other external development services and expenses associated with analysis and publications of research findings. Additionally, our research and development expenses include internal personnel expenses, including expenses for salaries and benefits, 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 personnel-related costs, advertising and public relations costs and consulting services. We expect our sales and marketing expenses to increase for the foreseeable future as we prepare for the potential commercial launch of BT-001. Our sales and marketing efforts are expected to focus on targeting payers, patients and primary care physicians through general awareness and branded promotional activities. We initially plan to focus primarily on innovative healthcare systems and Integrated Delivery Networks to reach a sizable number of primary care physicians and endocrinologists with a modestly sized sales team.

General and Administrative

General and administrative expenses consist primarily of personnel-related costs and professional services including legal, audit and accounting services and business insurance. 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, investor relations activities and other administrative and professional services.

Interest Expense, Net

Interest expense, net primarily consists of interest expense related to the secured Term Loan Facility entered into in 2021, offset by interest earned on excess cash.

Results of Operations

Comparisons of the Years Ended December 31, 2022 and 2021

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

	Twelve Months Ended, December 31,			
	2022	2021	$ Change	% Change
Operating expenses:				
Research and development	16,440	19,436	(2,996)	-15%
Sales and marketing	6,979	2,336	4,643	199%
General and administrative	14,843	8,788	6,055	69%
Total operating expenses	$ 38,262	$ 30,560	$ 7,702	25%
Loss from operations	(38,262)	(30,560)	(7,702)	25%
Interest expense, net	(1,491)	(185)	(1,306)	706%
Gain on loan forgiveness	—	647	(647)	-100%
Change in fair value of SAFEs	—	(10,390)	10,390	-100%
Loss before provision for income taxes	(39,753)	(40,488)	735	-2%
Provision for (benefit from) income taxes	7	(153)	160	-105%
Net loss	$ (39,760)	$ (40,335)	$ 575	-1%

Research and Development Expenses

Research and development expenses were $16.4 million for the year ended December 31, 2022, compared to $19.4 million for the year ended December 31, 2021, representing a decrease of $3.0 million. The decrease was primarily due to a $6.4 million decrease in costs incurred for clinical trials in 2022 as we completed the BT-001 pivotal trial offset by a $2.5 million increase in personnel related costs related to expanding our software development capabilities and a $760 thousand increase in amortization of capitalized software costs.

Sales and Marketing Expenses

Sales and marketing expenses were $7.0 million for the year ended December 31, 2022, compared to $2.3 million for the year ended December 31, 2021, representing an increase of $4.6 million. The increase in sales and marketing expenses was primarily related to an increase of $1.2 million in personnel related costs and a $3.4 million increase in consulting and marketing expenses associated with commercial readiness activities to support the potential launch of BT-001.

General and Administrative Expenses

General and administrative expenses were $14.8 million for the year ended December 31, 2022, compared to $8.8 million for the year ended December 31, 2021, representing an increase of $6.1 million. The overall increase in general and administrative expenses was primarily related to the increased costs of being a public company, including $3.4 million in business insurance, $1.6 million in personnel related costs and $1.6 million in outside services, including consulting, audit and legal fees.

Interest Expense, Net

Interest expense, net was $1.5 million for the year ended December 31, 2022, compared to $0.2 million for the year ended December 31, 2021, representing an increase of $1.3 million. The increase in interest expense, net was the result of interest expenses incurred on the secured Term Loan Facility with Hercules Capital.

Change in Fair Value of SAFEs

The expense related to the change in fair value of our SAFEs was $0 for the year ended December 31, 2022, compared to a loss of $10.4 million for the year ended December 31, 2021. There was no change in the fair value of SAFEs in 2022 as a result of our business combination and the conversion of SAFEs to common stock.

Gain on Loan Forgiveness

On May 9, 2020, we received $640 thousand in aggregate loan proceeds from Celtic Bank Corporation pursuant to the Paycheck Protection Program (the "PPP Loan") established under the Coronavirus Aid, Relief, and Economic Security Act of 2020. In May 2021, we received approval of loan forgiveness and recorded a gain on loan forgiveness of $647 thousand representing the principal balance and accrued interest at the date of forgiveness.

Liquidity and Capital Resources

We have primarily funded our operations through the sale of preferred stock, convertible notes, SAFEs and funding from our business combination with MCAD.

On April 6, 2021, we entered into the 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 our business combination, an aggregate of 5,000,000 PIPE Shares. On October 28, 2021, we completed the merger with MCAD. We raised $59 million in funding upon the completion of the business combination with MCAD. Under the Merger Agreement, MCAD acquired all of the outstanding shares of Legacy BTX in exchange for 15,174,729 shares of MCAD.

On August 18, 2021, we entered into a secured term loan agreement with Hercules Capital, Inc., providing for an up to $50 million senior secured term loan facility. The Term Loan Facility 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 Facility 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 Loan Agreement and subject to certain prepayment fees. We incurred $518 thousand of debt issuance costs related to borrowings under the Loan Agreement. Debt issuance costs are being amortized through the maturity date of the Term Loan Facility and are reported as a direct reduction of long-term debt on the balance sheets. In addition, we will be required to pay an end of term charge of the greater of (a) $893 and (b) 5.95% of the aggregate outstanding principal upon repayment of the Term Loan Facility. We are accruing this end of term charge over the term of the Loan Agreement and the accrued balance is reported as a direct addition to the long-term balance on the balance sheets. Amortization expense related to the debt issuance costs and accretion of the end of term charge, are both included in interest expense, net on the accompanying statements of operations and comprehensive loss and totaled $376 thousand and $23 thousand for the twelve months ended December 31, 2022 and 2021, respectively. We are permitted to borrow under the Term Loan Facility in four tranches based on the completion of certain milestones which include, as set forth more fully in the Loan Agreement: (i) $15.0 million upon the closing of our 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 authorization for the marketing of BT-001 for the improvement of glycemic control and have 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 Loan Agreement. In May 2022, we borrowed $5.0 million under the Loan Agreement. We did not initiate a second pivotal trial prior to September 15, 2022 that was required under the Loan Agreement and as a result the associated borrowing is no longer available to us. As December 31, 2022 and 2021, the outstanding debt balance, net of unamortized debt issuance costs and including the accrued end of term charge was $10.3 million and $9.5 million, respectively. The interest rate was 13.2% and 8.95% as of December 31, 2022 and 2021, and there was $168 thousand and $77 thousand of accrued interest included in other liabilities on the accompanying balance sheets as of December 31, 2022 and 2021, respectively.

The Loan Agreement contains customary representations, warranties, non-financial covenants, and events of default. The Loan Agreement also contains subjective acceleration clauses. In the event a subjective acceleration clause is invoked, the outstanding principal, interest, end of term charge and prepayment penalty would become payable on demand by the lender. The lender has not invoked any of the subjective acceleration clauses as of the date of issuance of these financial statements. As disclosed in Note 1 to the Company's financial statements, the Company's liquidity and capital resource issues could lead to the failure of a financial covenant in the year ending December 31, 2023 without additional funding.

As of December 31, 2022, we had $15.7 million in cash, and an accumulated deficit of $111.5 million. Our primary use of cash is to fund operating expenses, which predominantly consist of research and development expenses related to our lead product candidate, BT-001, preclinical programs, activities to prepare for a potential commercial launch, if BT-001 is authorized for marketing 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.

Under our current operating plan, we believe we have sufficient capital to fund our operations through the first quarter of 2023. Accordingly, there is substantial doubt regarding our ability to continue as a going concern. We plan to seek additional funding through various financing sources, including the sale of our equity and/or debt securities, and we are exploring other non-dilutive financing options. If we are unable to obtain additional funding, or 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 could also be required to limit or terminate our operations, make reductions in our workforce, discontinue our development programs, liquidate all or a portion of our assets or pursue other strategic alternatives.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for the periods presented below:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Cash used in operating activities	$ (28,930)	$ (30,818)
Cash used in investing activities	(1,180)	(1,071)
Cash provided by financing activities	5,284	72,332
Net increase (decrease) in cash and cash equivalents	$ (24,826)	$ 40,443

Cash Used in Operating Activities

During the twelve months ended December 31, 2022, cash used in operating activities was $28.9 million, which consisted of a net loss of $39.8 million offset by a decrease in our net operating assets and liabilities of $6.3 million and $4.6 million in non-cash charges. The net change in our operating assets and liabilities was primarily due to a decrease in prepaid expenses and other assets of $2.0 million and an increase in accounts payable and accrued expenses of $4.2 million. The non-cash charges of $4.6 million consisted primarily of share-based compensation expense and depreciation and amortization expense.

During the twelve months ended December 31, 2021, net cash used in operating activities was $30.8 million which consisted of a net loss of $40.3 million and an increase in our net operating assets and liabilities of $2.3 million, partially offset by $11.8 million in non-cash charges. The net change in our operating assets and liabilities was due to an increase in prepaid expenses and other assets of $4.6 million, partially offset by an increase in accounts payable and accrued expenses of $2.3 million. The non-cash charges of $11.9 million consisted of share-based compensation expense, deferred income taxes, depreciation and amortization expense, loss on the change in fair value of SAFEs and gain on PPP Loan forgiveness.

Cash Used in Investing Activities

During the twelve months ended December 31, 2022, cash used in investing activities was $1.2 million and was primarily related to capitalized internal-use software costs.

During the twelve months ended December 31, 2021, cash used in investing activities was $1.1 million and was primarily related to capitalized internal-use software costs.

Cash Provided by Financing Activities

During the twelve months ended December 31, 2022, cash provided by financing activities was $5.3 million and was related to proceeds received from the issuance of long-term debt, the issuance of shares under our 2021 Employee Stock Purchase Plan (the "2021 ESPP") and the exercise of common stock options.

During the twelve months ended December 31, 2021, cash provided by financing activities was $72.3 million consisting of $44.1 million in net proceeds from our Business Combination and PIPE investment, $18.7 million in net proceeds from the issuance of SAFEs and $9.5 million in net proceeds from the issuance of long-term debt.

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 December 31, 2022.

Off-Balance Sheet Arrangements

Since the date of our incorporation, we have not engaged in any off-balance sheet arrangements.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses, as well as the related disclosure of contingent assets and liabilities as of the date of the financial statements. Our estimates are based on our historical experience, management's evaluation of the relevant facts and circumstances and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources.

Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates.

While our significant accounting policies are described in the notes to our financial statements, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Fair Value Measurements

The carrying value of our financial instruments, including cash equivalents, accounts payable and accrued liabilities approximates fair value due to their short-term nature. Our Loan Agreement includes a variable interest rate and accordingly approximates fair value. Our investment portfolio consists of money market funds, which are carried at fair value. We have determined the carrying value to be equal to the fair value and have classified these investments as Level 1 financial instruments.

Property and Equipment, Net

Property and equipment, net, which includes computer, equipment and software is 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 our software based 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 undiscounted 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 twelve months ended December 31, 2022 that indicated the carrying amounts of any long-lived assets were not fully recoverable.

Equity-Based Compensation Expense

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.

The grant date fair value of options with performance-based market conditions is determined using a Monte-Carlo valuation simulation. For awards that vest based on service conditions and market conditions, we use the straight-line method to recognize compensation expense over the respective service period. For awards that contain performance conditions, we determine the appropriate amount to expense based on the anticipated achievement of performance targets, which requires judgment, including forecasting the achievement of future specified targets. At the date performance conditions are determined to be probable of achievement, we record a cumulative expense catch-up, with remaining expense amortized over the remaining service period. Throughout the performance period, we re-assess the estimated performance and update the number of performance-based awards that we believe will ultimately vest.

Discounted stock purchases under our 2021 ESPP are valued on the first date of the offering period using the Black-Scholes option-pricing model to compute the fair value of the lookback provision plus the purchase discount. Discounted stock purchases under our 2021 ESPP are recognized over the offering period.

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 calculations are presented in accordance with Financial Accounting Standards Board ("FASB") ASC Topic No. 260 Earnings per Share and are calculated on the basis of the weighted average number of common shares outstanding during the period. Diluted per share calculations includes the dilutive effect of common stock equivalents in years with net income. 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 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 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 $1.235 billion, or (c) in which we are deemed to be a "large accelerated filer" under 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.

Recently Adopted Accounting Pronouncements

See Note 2 to our annual financial statements for the year ended December 31, 2022.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our cash and cash equivalents as of December 31, 2022 and 2021 consisted of readily available checking funds and a money market account. We do not believe that our cash or cash equivalents have significant risk of default or illiquidity. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future any investment will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one financial institution that is in excess of federally insured limits.

As of December 31, 2022 our debt exposes us to risk of fluctuations in interest rates. As the prime interest rate increases, our interest rate will increase. A hypothetical 1% increase in the prime rate will result in a $150 thousand increase in interest expense.

Effects of Inflation

Although we cannot precisely determine the effects of inflation on our business, it is management's belief that the effects on operating results will not be significant. We do not believe that inflation has had a material impact on our results of operations for the periods presented, except with respect to payroll-related costs and interest expense.

Effects of Exchange Rate Fluctuations

We do not believe that exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

Item 8. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Shareholders and Board of Directors
Better Therapeutics, Inc.
San Francisco, California

Opinion on the Financial Statements
We have audited the accompanying balance sheets of Better Therapeutics, Inc. (the Company) as of December 31, 2022 and 2021, the related statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the years then ended, and the related notes to the financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern
The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a substantial accumulated deficit. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

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

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

/s/ Elliott Davis, LLC

We have served as the Company's auditor since 2021.

Greenville, South Carolina
March 30, 2023

BETTER THERAPEUTICS, INC.
BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,740	$ 40,566
Prepaid expenses	2,496	4,409
Other current assets	210	276
Total current assets	18,446	45,251
Capitalized software development costs, net	3,888	5,077
Property and equipment, net	121	82
Other long-term assets	488	548
Total Assets	$ 22,943	$ 50,958
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 3,035	$ 1,523
Accrued payroll	2,301	1,352
Other accrued expenses	3,626	1,858
Current portion of long-term debt	4,532	—
Total current liabilities	13,494	4,733
Long-term debt, net of current portion and debt issuance costs	10,348	9,505
Total liabilities	23,842	14,238
Commitments and contingencies (Note 14)		
Stockholders' equity (deficit)		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized as of December 31, 2022 and 2021, respectively and 23,851,022 and 23,602,718 shares issued and outstanding as of December 31, 2022 and 2021, respectively	2	2
Additional paid-in capital	110,602	108,461
Accumulated deficit	(111,503)	(71,743)
Total Stockholders' Equity (Deficit)	(899)	36,720
Total Liabilities and Stockholders' Equity (Deficit)	$ 22,943	$ 50,958

The accompanying notes are an integral part of these financial statements.

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

	Years Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	16,440	19,436
Sales and marketing	6,979	2,336
General and administrative	14,843	8,788
Total operating expenses	38,262	30,560
Loss from operations	(38,262)	(30,560)
Interest expense, net	(1,491)	(185)
Gain on Loan Forgiveness	—	647
Change in fair value of SAFEs	—	(10,390)
Loss before provision for (benefit from) income taxes	(39,753)	(40,488)
Provision for (benefit from) income taxes	7	(153)
Net loss	$ (39,760)	$ (40,335)
Net loss per share, basic and diluted	$ (1.69)	$ (3.11)
Weighted-average number of shares outstanding, basic and diluted	23,557,846	12,982,472

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Accumulated Stockholder Equity (Deficit)
	Shares	Amount			
Balance as of December 31, 2020, as adjusted	11,146,510	$ 1	$ 24,649	$ (31,408)	$ (6,758)
Net Loss	—	—	—	(40,335)	(40,335)
Forfeiture of restricted stock	(52,263)	—	—		—
Issuance of common stock in connection with business combination, net of issuance costs of $16,724	12,505,471	1	83,125	—	83,126
Issuance of common stock under equity incentive plans	3,000	—	1	—	1
Share based compensation	—	—	686	—	686
Balance as of December 31, 2021	23,602,718	$ 2	$ 108,461	$ (71,743)	$ 36,720
Net Loss	—	—	—	(39,760)	(39,760)
Issuance of common stock under equity incentive plans	248,304	—	284	—	284
Share based compensation	—	—	1,857	—	1,857
Balance as of December 31, 2022	23,851,022	$ 2	$ 110,602	$ (111,503)	$ (899)

The accompanying notes are an integral part of these financial statements.

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

	Years Ended December 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (39,760)	$ (40,335)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,729	1,619
Change in fair value of SAFEs	—	10,390
Loss on write-off of property and equipment	9	—
Share-based compensation expense	1,824	646
Deferred income taxes	—	(152)
Gain on loan forgiveness	—	(647)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	2,039	(4,613)
Accounts payable	1,512	1,009
Accrued expenses and other liabilities	2,717	1,265
Net cash used in operating activities	(28,930)	(30,818)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(106)	(55)
Capitalized internal-use software costs	(1,074)	(1,016)
Net cash used in investing activities	(1,180)	(1,071)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of SAFE notes	—	18,675
Proceeds from business combination and PIPE Investment	—	59,045
Payment of costs directly attributable to the issuance of common stock in connection with business combination and PIPE investment	—	(14,871)
Proceeds from issuance of long-term debt	5,000	10,000
Debt issuance costs	—	(518)
Proceeds from the issuance of shares under the employee stock purchase plan	257	—
Proceeds from exercise of stock options	27	1
Net cash provided by financing activities	5,284	72,332
Net change in cash and cash equivalents	(24,826)	40,443
Cash and cash equivalents, beginning of period	40,566	123
Cash and cash equivalents, end of period	$ 15,740	$ 40,566
Supplemental disclosures of cash flow information:		
Cash paid for Interest	$ 1,325	$ 85

The accompanying notes are an integral part of these financial statements.

BETTER THERAPEUTICS, INC.
NOTES TO FINANCIAL STATEMENTS

1. Organization and Description of Business

Better Therapeutics, Inc. (the "Company" or "Better"), a Delaware corporation, is a prescription digital therapeutics company developing a clinically validated, software-based novel form of cognitive behavioral therapy ("CBT") to address the root causes of cardiometabolic diseases ("CMDx"). The Company's mission is to advance human health through the power of behavior change. The Company is developing a proprietary platform of U.S. Food and Drug Administration ("FDA)" regulated, software-based prescription digital therapeutics ("PDTs") for the treatment of cardiometabolic diseases by addressing the underlying causes of the diseases. The Company's initial development efforts are focused on type 2 diabetes ("T2D"), hypertension, hyperlipidemia, non-alcoholic fatty liver disease ("NAFLD"), non-alcoholic steatohepatitis ("NASH") and chronic kidney disease ("CKD"). Founded in 2015, the Company is led by executives that have track records of building multi-billion dollar businesses and extensive industry experience in developing and commercializing therapeutics.

The Company's lead product candidate, BT-001, completed a first-in-class open label, randomized, controlled, parallel group clinical trial for the treatment of patients with T2D in July 2022 and successfully met its primary and secondary endpoints as well as a host of exploratory endpoints. The Company submitted a *de novo* classification request to the FDA in September 2022, seeking marketing authorization of BT-001 for the treatment of adult patients with T2D and in October 2022, the FDA notified the Company that its *de novo* classification request was accepted for substantive review. A portion of the Company's data was published in the peer reviewed journal Diabetes Care in October 2022. As part of the typical *de novo* review process as expected by the Company, in February 2023, the Company received a Request for Additional Information from the FDA notifying it that, after review of the Company's submission, the FDA determined that additional information is required and placed the review on hold. The letter outlined the FDA's view that the Company's submission has a number of deficiencies, classified into major and minor deficiencies. The Company requested a meeting with the FDA to clarify several of the major deficiencies noted as well as to seek guidance on its options to address them. That meeting also took place in February. During the meeting the FDA provided helpful context, clarifications and guidance, and the Company is now compiling its response to address the FDA's comments. The Company believes it can address the FDA's questions, and its previously provided guidance that it anticipates the FDA's decision by the middle of 2023 remains unchanged. If the Company is unable to resolve the deficiencies, it may need to amend the indications for use for which it is seeking authorization and/or conduct another clinical trial, and the authorization and commercial launch of BT-001 could be significantly delayed or the authorization could be denied.

The Company also achieved positive top-line results in its LivVita study, a first-ever clinical study evaluating the feasibility of its digitally delivered CBT to reduce liver fat and improve liver disease biomarkers as a potential treatment for NAFLD and NASH. Currently, there is no FDA approved treatment for these conditions, which affect one in four Americans and cause approximately $100 billion in direct medical costs annually. Because of the significant unmet medical need, the Company intends to apply for breakthrough device designation from the FDA for its investigational CBT-based treatment platform for these indications in the first half of 2023. The Company also plans to use data from this study and the exploratory endpoints from the BT-001 pivotal trial to inform the potential initiation of additional pivotal trials in support of seeking FDA authorization in CMDx indications beyond T2D.

The Company also initiated real world evidence studies to evaluate the long-term effectiveness and healthcare utilization changes associated with the use of BT-001 for the treatment of T2D. The randomized, controlled, multi-site studies are expected to enroll 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 the fourth quarter of 2023, once a sufficient number of patients have completed an incremental 180 days of treatment. The study seeks to provide payers and providers with long-term data related to usage and outcomes in a real-world setting.

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

Liquidity and Capital Resources

The Company is in the development stage and its activities have consisted principally of raising capital and performing research and development. Since inception the Company has incurred significant losses from operations. As of December 31, 2022, the Company had cash of $15.7 million and an accumulated deficit of $111.5 million. The Company incurred a net loss of $39.8 million and used $28.9 million of cash in operating activities during the year ended December 31, 2022. The Company incurred a net loss of $40.3 million and used $30.8 million of cash in operating activities during the year ended December 31, 2021. The Company's primary use of cash is to fund operating expenses, which consist predominantly of research and development expenses related to its lead product candidate, BT-001, real world evidence programs and general and administrative expenses. Cash used to fund operating expenses is impacted by the timing of when the Company pays these expenses, as reflected in the change in its outstanding accounts payable and accrued expenses.

The Company has incurred negative cash flows from operating activities and investing activities and significant losses from operations in the past. The Company expects to incur substantial expenses in the foreseeable future for the development and potential commercialization of its product candidates, ongoing internal research and development programs and general and administrative activities. At this time, the Company cannot reasonably estimate the nature, timing or aggregate amount of costs for its development, potential commercialization, internal research and development programs and general and administrative activities. However, in order to complete its planned product development, and to complete the process of obtaining regulatory authorization or clearance for its product candidates, as well as to build the sales, marketing and distribution infrastructure that it believes will be necessary to commercialize its product candidates, if approved, the Company will require substantial additional funding in the future. Under its current operating plan, the Company believes it has sufficient capital to fund its operations through the first quarter of 2023. These factors raise substantial doubt regarding the Company’s ability to continue as a going concern. The Company plans to seek additional funding through various financing sources, including the sale of our equity and/or debt securities, and it is exploring other non-dilutive options. If the Company is unable to obtain additional funding, or if it is unable to raise additional capital in sufficient amounts or on terms acceptable to it, the Company may have to significantly delay, reduce or terminate its product development programs or plans for commercialization. The Company could also be required to limit or terminate its operations, make reductions in its workforce, discontinue its development programs, liquidate all or portion of its assets or pursue other strategic alternatives.

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 COVID-19 pandemic and economic and political developments, including the conflict in Ukraine, rising interest and high inflation, and the impact of related responses. Any impact on the Company's 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 duration of the pandemic, business disruptions and the ultimate impact of COVID-19 and economic and political developments on financial markets and the global economy.

2. Summary of Significant Accounting Policies

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"). Amounts are presented in thousands except share and per share information.

Comprehensive Loss

For the years ended December 31, 2022 and 2021, there was no difference between comprehensive loss and net loss.

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, the Company's financial statements will be affected.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). The JOBS Act provides that an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has elected to avail itself of this extended transition period and, as a result, it does 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.

Concentration of Risk

Financial instruments that potentially subject the Company to credit risk consist principally of cash and cash equivalents. The Company maintains its cash primarily with domestic financial institutions of high credit quality, which may exceed federal deposit insurance corporation limits. The Company invest its cash equivalents in highly rated money market funds. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents and perform periodic evaluations of the credit standing of such institutions.

Fair Value Measurements

The carrying value of the Company's 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.

The Company measures 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. The Company defines 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

The Company reviews 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 undiscounted 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, the Company measures 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 twelve months ended December 31, 2022 and 2021 that indicated the carrying amounts of any long-lived assets were not fully recoverable.

Advertising Expense

The Company recognizes advertising expenses as they are incurred, and such costs are included in sales and marketing expense in the statements of operations. During the twelve months ended December 31, 2022 and 2021, advertising expense totaled $4 thousand and $2 thousand, respectively.

Equity-Based Compensation Expense

The Company accounts 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.

The Company accounts 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.

The fair value of each option award granted is estimated on the grant date. The grant date fair value of options with service based vesting conditions is determined 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 the Company's common stock, risk-free interest rates, and the dividend yield of the Company's common stock. The grant date fair value of options with performance-based market conditions is determined using a Monte-Carlo valuation simulation.

- Fair Value of Common Stock — The Company determines 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. The Company determines 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 the Company had no trading history for its common stock when we granted our option awards prior to the Business Combination (as defined below), 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 its limited trading history, the Company will continue to determine expected volatility using estimates 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.
- Expected dividend yield — The dividend yield assumption is zero as the Company has no history of or plans to make dividend payments.

The grant date fair value of options with performance-based market conditions is determined using a Monte-Carlo valuation simulation. For awards that vest based on service conditions and market conditions, the Company uses the straight-line method to recognize compensation expense over the respective service period. For awards that contain performance conditions, the Company determines the appropriate amount to expense based on the anticipated achievement of performance targets, which requires judgment, including forecasting the achievement of future specified targets. At the date performance conditions are determined to be probable of achievement, the Company records a cumulative expense catch-up, with remaining expense amortized over the remaining service period. Throughout the performance period, the Company re-assesses the estimated performance and updates the number of performance-based awards that the Company believes will ultimately vest.

Discounted stock purchases under the Better Therapeutics, Inc. 2021 Employee Stock Purchase Plan (the "ESPP") are valued on the first date of the offering period using the Black-Scholes option-pricing model to compute the fair value of the lookback provision plus the purchase discount. Discounted stock purchases under the ESPP are recognized over the offering period.

The Company accounts 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

The Company accounts 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.

The Company assesses 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. The Company adopted Accounting Standards Update ("ASU") No. 2015-17, Income Taxes — Balance Sheet Classification of Deferred Taxes, and classified its deferred income taxes as non-current in the balance sheets.

The Company recognizes and measures 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. The Company evaluates its uncertain tax positions on a regular basis. The Company's 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 calculations are presented in accordance with Financial Accounting Standards Board ("FASB") ASC Topic No. 260 Earnings per Share and are calculated on the basis of the weighted average number of common shares outstanding during the period. Diluted per share calculations includes the dilutive effect of common stock equivalents in years with net income. As the Company has 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.

Revenue Recognition

On January 1, 2020, the Company adopted the requirements of Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASC 606"). ASC 606 establishes a principle for recognizing revenue upon the transfer of promised goods or services to customers, in an amount that reflects the expected consideration received in exchange for those goods or services. The adoption of ASC 606 also requires the adoption of ASC Subtopic 340-40, Other Assets and Deferred Costs-Contracts with Customers, which provides for the deferral of certain incremental costs of obtaining a contract with a customer. Collectively, references to ASC 606 used herein refer to both ASC 606 and Subtopic 340-40. The core principle of ASC 606 is to recognize revenue to depict the transfer of promised goods or services to clients in an amount that reflects the consideration the entity expects to be entitled in exchange for those goods or services. This principle is achieved through applying the following five-step approach:

- Identification of the contract, or contracts, with a client.
- Identification of the performance obligations in the contract.
- Determination of the transaction price.
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, the Company satisfies a performance obligation.

Segment Reporting

The Company operates as one operating segment as it only reports financial information on an aggregate basis to the Chief Executive Officer, its chief operating decision maker, who regularly reviews financial operating results for purposes of allocating resources and evaluating financial performance. There are no segment managers who are held accountable for operations, operating results, and plans for components or types of products or services below the unit level. As of December 31, 2022, all long-lived assets were in the United States.

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. The Company's adoption of this new standard on January 1, 2021 did not have a material impact on our financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes (Topic 740)*. This ASU simplifies the accounting for income taxes by, among other things, eliminating certain existing exceptions related to the general approach in ASC 740 relating to franchise taxes, reducing complexity in the interim-period accounting for year-to-date loss limitations and changes in tax laws, and clarifying the accounting for transactions outside of business combination that result in a step-up in the tax basis of goodwill. The transition requirements are primarily prospective, and the effective date is January 1, 2021. The Company's adoption of this new standard on January 1, 2021 did not have a material impact on our financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt — Debt with Conversion and Other Options (ASC 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (ASC 815-40)*. ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The ASU 2020-06 is part of the FASB's simplification initiative, which aims to reduce unnecessary complexity in GAAP. This ASU's amendments are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The Company is currently evaluating the impact ASU 2020-06 will have on its financial statements.

The Company has implemented all new accounting pronouncements that are in effect and that may impact its financial statements and does not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on its financial position or results of operations.

3. Business Combination

On April 6, 2021, the Company entered into a merger agreement (the "Merger Agreement") with Mountain Crest Acquisition Corp. II, ("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 (the "PIPE 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, MCAD merged with and into former Better Therapeutics, Inc, ("Legacy BTX"), with Legacy BTX surviving as a wholly owned subsidiary of MCAD with the new name Better Therapeutics, Inc. (the "Business Combination"). The Company 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.

The Company 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 had a majority of the voting power of the combined company, Legacy BTX would 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 would 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 BTX's 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 0.9475.

In connection with the Business Combination, the Company 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, The Company entered into subscription agreements 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 5,000,000 shares of MCAD's common stock for a purchase price of $10.00 per share, for aggregate gross proceeds of $50.0 million (the "PIPE Financing").

The Company received $9.5 million of MCAD cash and cash held in trust for net proceeds of $42.8 million. In addition, the Company also assumed $43 thousand of prepaid assets and $245 thousand of accrued liabilities upon the closing of the Business Combination.

4. Property and Equipment, net

Property and equipment consisted of the follow:

	December 31,	
	2022	2021
Computer, equipment and software	$ 178	$ 155
Furniture and fixtures	—	155
Property and equipment	178	310
Less: accumulated depreciation	(57)	(228)
Property and equipment, net	$ 121	$ 82

Depreciation expense for the twelve months ended December 31, 2022 and 2021 was $58 thousand and $62 thousand, respectively. All of the Company's long-lived assets are located in the United States.

5. Capitalized Internal Use Software

Capitalized internal use software and accumulated amortization were as follows:

	December 31,	
	2022	2021
Gross carrying amount	$ 7,718	$ 6,611
Accumulated amortization	(3,830)	(1,534)
Capitalized internal-use software, net	$ 3,888	$ 5,077

The Company has recorded amortization expense related to capitalized internal-use software of $ 2.3 million and $1.5 million for the twelve months ended December 31, 2022 and 2021, respectively.

6. Research and Development Payroll Tax Credits

As of December 31, 2022 and 2021, the Company had research and development payroll tax credit receivables of $45 thousand and $351 thousand, respectively reflected in other current assets.

7. Accrued Liabilities

	December 31,	
	2022	2021
Due to service providers	$ 1,335	$ 878
Due to professionals	506	542
Financed insurance	963	361
Accrued interest	168	77
Other	654	-
Other accrued liabilities	$ 3,626	$ 1,858

8. Debt

On May 9, 2020 (the "Origination Date"), the Company received $640 in aggregate loan proceeds (the "PPP Loan") from Celtic Bank Corporation (the "Lender") pursuant to the Paycheck Protection Program established under the Coronavirus Aid, Relief, and Economic Security Act of 2020 (the "CARES Act"). Payments of principal and interest were deferred for the first ten months following the Origination Date, and the PPP Loan would mature in two years after the Origination Date. 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 has 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. The gain recognized totaled $647, represented the principal balance and accrued interest at the date of forgiveness.

On August 18, 2021, the Company entered into a secured term loan agreement (the "Loan Agreement") with Hercules Capital, Inc. ("Hercules Capital") providing for an up to $50 million senior secured term loan facility (the "Term Loan Facility"). The Term Loan Facility has a maturity date of August 1, 2025, which can be extended to February 1, 2026, and is secured by substantially all of the Company's 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 Loan Agreement and subject to certain prepayment fees. The Company incurred $518 thousand of debt issuance costs related to the borrowings under the Loan Agreement. Debt issuance costs are being amortized through the maturity date of the Term Loan Facility and are reported as a direct reduction of long-term debt on the balance sheets. In addition, the Company will be required to pay an end of term charge of the greater of (a) $893 and (b) 5.95% of the aggregate outstanding principal upon repayment of the loan. The Company is accruing this end of term charge over the term of the Term Loan Facility and the accrued balance is reported as a direct addition to the long-term balance on the balance sheets. Amortization expense related to the debt issuance costs and accretion of the end of term charge, are both included in interest expense, net on the accompanying statements of operations and comprehensive loss and totaled $376 thousand and $23 thousand for the twelve months ended December 31, 2022 and 2021, respectively. The Company is permitted to borrow the loans in four tranches based on the completion of certain milestones which include, as set forth more fully in the Loan Agreement: (i) $15.0 million upon the closing of the Business Combination, (ii) $10.0 million when the Company achieves certain positive clinical trial results sufficient to submit a de-novo classification request with respect to BT-001 and has initiated a second pivotal trial prior to September 15, 2022, (iii) $10.0 million when the Company has received FDA approval for the marketing of BT-001 for the improvement of glycemic control and initiated a pivotal trial for a new indication in people with type 2 diabetes 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, the Company borrowed $10.0 million under the Loan Agreement. In May 2022, the Company borrowed $5.0 million under the Loan Agreement. The Company did not initiate a second pivotal trial prior to September 15, 2022 that was required under the Loan Agreement, and as a result the associated borrowing is no longer available to the Company. As of December 31, 2022 and 2021, the outstanding debt balance, net of unamortized debt issuance costs and including the accrued end of term charge was $10.3 million and $9.5 million, respectively. The interest rate was 13.2% and 8.95% as of December 31, 2022 and 2021, and there was $168 thousand and $77 thousand of accrued interest included in other liabilities on the accompanying balance sheets as of December 31, 2022 and 2021, respectively.

The Loan Agreement contains customary representations, warranties, financial and non-financial covenants, and events of default. The Loan Agreement also contains subjective acceleration clauses. In the event a subjective acceleration clause is invoked, the outstanding principal, interest, end of term charge and prepayment penalty would become payable on demand by the lender. The lender has not invoked any of the subjective acceleration clauses as of the date of issuance of these financial statements. As disclosed in Note 1, the Company's liquidity and capital resource issues could lead to the failure of a financial covenant in the year ending December 31, 2023 without additional funding.

Future payments on long-term debt as of December 31, 2022 are as follows:

Fiscal year ending December 31,	Amount
2023	4,532
2024	6,023
2025	4,445
Total debt	15,000
Less current portion long-term debt	(4,532)
Less unamortized debt issuance costs	(360)
Accrued end of term charge	240
Total long-term debt, net of current portion and debt issuance costs	$ 10,348

9. 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 fair value of the Company's SAFE agreements was based on significant inputs not observable in the market which caused the instruments to be classified as Level 3 measurement within the fair value hierarchy. During the year ended December 31, 2021, the SAFEs were marked to fair value resulting in a change in fair value reported as a loss of $10.4 million. On October 28, 2021, in connection with the Business Combination all SAFEs were converted to common stock.

10. Shareholders' Deficit

Common Stock

On October 28, 2021 in connection with the Business Combination all existing outstanding shares of common stock of Legacy BTX were exchanged for new shares of common stock of the Company at a conversion ratio of 0.9475% with a par value of $0.0001 per share. The Company accounted for the Business Combination as a reverse capitalization, and as a result the conversion of common shares was presented as of the earliest period presented with 11,146,510 shares of common stock issued and outstanding as of December 31, 2020. The number of shares of common stock issued and outstanding as of December 31, 2022 and 2021 was 23,851,022 and 23,602,718, respectively.

11. Net Loss Per Share Attributable to Common Stockholders

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

	Year Ended December 31,	
	2022	2021
Net Loss	$ (39,760)	$ (40,335)
Weighted-average number of shares of common stock outstanding	23,695,503	13,351,866
Less: weighted-average shares of common stock subject to vesting	(137,657)	(369,394)
Weighted-average shares of common stock outstanding used in the calculation of basic and diluted net loss per share attributable to shareholders	23,557,846	12,982,472
Net Loss per share, basic and diluted	$ (1.69)	$ (3.11)

As of December 31, 2022 and 2021 3,999,223 and 1,476,475 potentially dilutive stock options have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive.

12. Share-Based Compensation

In August 2020, the Company 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 the Company's common stock have been reserved for issuance pursuant to the plan. Upon the close of the Business Combination, no further shares will be issued out of the 2020 Plan.

In October 2021, the Company adopted the Better Therapeutics OpCo. 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 have been 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 2021 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 of the 2021 Plan (the "Annual Increase"). On January 1, 2023 the Company added 1.2 million shares to the plan for a total reserved for issuance of 3.0 million shares.

In October 2021, the Company adopted 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 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) 560,000 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 of the ESPP. On January 1, 2023 the Company added 238,510 shares to the plan for a total reserved for issuance of 566,753 shares.

In November 2022, the Company adopted the Better Therapeutics, Inc 2022 Inducement Plan (the "Inducement Plan") to grant equity awards to prospective officers and employees who are not currently employed by the Company. The equity-based incentives include non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards and dividend equivalent rights. A total of 600,000 shares of common stock have been initially reserved for issuance under the Inducement Plan.

Stock Options

Stock options are exercisable for periods not to exceed 10 years, and vest and contain such other terms and conditions as specified in the applicable award document. Stock options granted with service conditions 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. The Company has also issued options with performance-based and market-based vesting conditions. Stock option activity 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	$ 884
Granted	3,595,838	1.88		
Exercised	(60,520)	0.50		
Forfeited	(1,012,570)	4.66		
Balance as of December 31, 2022	3,999,223	$ 3.95	9.3	$ 64

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 twelve months ended December 31, 2022 and 2021 was $0.73 and $3.60 per share, respectively. As of December 31, 2022, total unrecognized compensation expense related to unvested stock options was $3.4 million, which is expected to be recognized over a weighted-average period of 2.92 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 the Company's 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 the Company's 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:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Expected Term (Years)	6.09	6.02
Expected Volatility	41.0%	42.0%
Risk-free interest rate	2.74%	1.22%
Dividend Yield	—	—

In July 2022, the Company granted options with performance-based vesting conditions to the Company's new Chief Executive Officer ("CEO"), which entitle the CEO with the right to purchase shares of common stock upon achievement of the Company's common stock reaching specified market prices for consecutive 90 day periods, the achievement of certain revenue and/or other targets as defined in the award agreements. The performance-based market awards consist of two separate specified award values that vest upon achievement of applicable performance goals, which can result in a vesting range of up to 1,850,000 shares in the aggregate. As of December 31, 2022, the performance-based conditions for the awards to the CEO have not been met. The related stock-based compensation expense is being recognized over a period of 8.0 years.

The total grant date fair value of performance-based market condition share awards granted during the twelve months ended December 31, 2022 was $31 thousand. The estimated fair values of these awards was determined using a Monte-Carlo valuation simulation, with the following most significant assumptions:

	Year Ended December 31, 2022
Valuation date stock price	1.68
Valuation date to end of performance period (Years)	10.00
Expected Volatility	38.8%
Risk-free interest rate	2.80%
Dividend Yield	—

Restricted Stock

During the twelve months ended December 31, 2022, 172 thousand shares of common stock vested and converted into unrestricted common stock. During the twelve months ended December 31, 2021 52,263 shares were forfeited and 235,634 shares vested and were converted into unrestricted common stock. As of December 31, 2022 there were 30 thousand shares of restricted stock outstanding.

Total stock-based compensation expense for time-based restricted stock of $13 thousand is expected to be recognized on a straight-line basis over approximately the next 0.5 years for the unvested restricted stock outstanding as of December 31, 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 twelve months ended December 31, 2022 the Company issued 187,784 shares and recorded $134 thousand of expense in connection with the ESPP.

Equity-Based Compensation Expense

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

	Year Ended December 31,	
	2022	2021
Research and development	$ 555	$ 250
Sales and marketing	(7)	6
General and administrative	1,276	390
Total equity-based compensation expense	$ 1,824	$ 646

For the twelve months ended December 31, 2022 and 2021, $33 thousand and $40 thousand of stock based compensation expense was included as part of capitalized internal-use software costs, respectively.

13. Income Taxes

The Company recorded an income tax provision of $7 thousand for the period ended December 31, 2022. The Company recorded an income tax benefit of $153 thousand for period ended December 31, 2021. The Company's provision for (benefit from) income taxes consisted of the following:

	December 31,	
	2022	2021
Current:		
Federal	$ —	$ —
State	7	(1)
Total current	7	(1)
Deferred:		
Federal	—	(152)
State	—	—
Total deferred	—	(152)
Total provision for (benefit from) income taxes	$ 7	$ (153)

The reconciliation of federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2022	2021
Expected income tax benefit at the federal statutory rate	$ (8,421)	$ (8,502)
State taxes, net of federal benefit	(80)	(42)
Research and development credit, net	—	—
Deferred tax true up	14	—
Non-deductible items	135	2,129
Change in valuation allowance	8,359	6,262
Total	$ 7	$ (153)

Significant components of the Company's deferred tax assets are summarized as follows:

	December 31, 2022	2021
Deferred tax assets:		
Federal and state new operating loss carryforwards	$ 12,025	$ 6,844
Research and development tax credits	207	207
Depreciation and amortization	12	25
Stock based compensation	277	55
Section 174 costs	2,613	—
Accruals and reserves	394	284
Gross deferred tax assets	$ 15,528	7,415
Less Valuation allowance	(14,706)	(6,347)
Net deferred tax assets	$ 822	$ 1,068
Deferred tax liabilities:		
Capitalized internal use software	(822)	(1,068)
Net deferred tax liabilities	(822)	(1,068)
Net deferred tax liability	$ —	$ —

As of December 31, 2022, the Company had $56.8 million of federal and $3.0 million of state net operating loss carryforwards available to offset future taxable income. Carryforwards for the current period and future years do not expire for federal purposes and begin to expire in 2035 for state purposes. As of December 31, 2022, the Company had federal and state research credit carryforwards of $122 thousand and $85 thousand, respectively, net of any reserve for uncertain tax positions under ASC 740-10. The federal research credits begin to expire in 2040 while the California research credits carry forward have an indefinite life.

Management regularly assesses the ability to realize deferred tax assets recorded based upon the weight of available evidence, including such factors as recent earnings history and expected future taxable income on a jurisdiction-by-jurisdiction basis. In the event that the Company changes its determination as to the amount of realizable deferred tax assets, the Company will adjust its valuation allowance with a corresponding impact to the provision for income taxes in the period in which such determination is made. The Company’s management believes that, based on a number of factors, it is more likely than not, that all or some portion of the deferred tax assets will not be realized; and accordingly, for the year ended December 31, 2022, the Company has provided a valuation allowance against the Company’s U.S. net deferred tax assets. The net change in the valuation allowance for the year ended December 31, 2022 was an increase of $8.4 million.

The Internal Revenue Code of 1986, as amended (the "Code"), imposes restrictions on the utilization of net operating losses in the event of an "ownership change" of a corporation. Accordingly, a company’s ability to use net operating losses may be limited as prescribed under Section 382 of the Code ("IRC Section 382"). Events which may cause limitations in the amount of the net operating losses that the Company may use in any one year include, but are not limited to, a cumulative ownership change of more than 50% over a three-year period. Utilization of the federal and state net operating losses may be subject to substantial annual limitation due to the ownership change limitations provided by the IRC Section 382 and similar state provisions. The Company has not completed a Section 382 analysis; however, based on a preliminary review of information available, other than the NOL attributes that were carried forward from the Business Combination, which are approximately $77 thousand at December 31, 2022, the Company does not believe it has experienced an ownership change and therefore none of its tax attributes are currently limited by IRC Section 382 or 383.

On March 27, 2020, the CARES Act was passed into law. The CARES Act includes several significant business tax provisions including modification to the taxable income limitation for utilization of net operating losses incurred in 2019 and 2020, an increase to the limitation on deductibility of certain business interest expense, bonus depreciation for purchases of qualified improvement property and special deductions on certain corporate charitable contributions. The Company analyzed the provisions of the CARES Act and determined there was no impact to its income tax provision for the year ended December 31, 2020.

Uncertain Tax Positions

The Company is required to inventory, evaluate, and measure all uncertain tax positions taken or to be taken on tax returns and to record liabilities for the amount of such positions that may not be sustained, or may only partially be sustained, upon examination by the relevant taxing authorities.

The following is a summary of the changes in the Company's gross unrecognized tax benefits:

Balance as of December 31, 2021	$	77
Increase related to tax position taken		—
Balance as of December 31, 2022	$	77

As of December 31, 2021, the total amount of gross unrecognized tax benefits was $77 thousand, which, if recognized, would not have an impact on the Company's effective tax rate, due to the valuation allowance. The Company estimates that there will be no material changes in its uncertain tax positions in the next 12 months. The Company's policy is to include interest and penalties related to unrecognized tax benefits as a component of income tax expense. There are no interest and penalties recognized in the statement of operations for the year ended December 31, 2022.

The Company files federal and state income tax returns in the U.S. For U.S. federal and state income tax purposes, the statute of limitations currently remains open for all years due to our NOL carryforwards. The Company is not currently under examination in any jurisdiction.

14. Commitments and Contingencies

From time to time, the Company becomes involved in claims, vendor disputes and other legal matters arising in the ordinary course of business. The Company investigates these claims as they arise. Although claims are inherently unpredictable, the Company is currently not aware of any matters that, if determined adversely to it, would individually or taken together have a material adverse effect on our business, results of operations, financial position or cash flows. The Company records liabilities for legal and other contingencies when losses are probable and estimable. During the twelve months ended December 31, 2022 the Company recorded an estimated accrued liability of $1.1 million related to a disputed change order with one of its vendors.

The Company enters 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.

15. Related Party Transactions

In March 2021, Andy Armanino, the former chief executive of 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 twelve months ended December 31, 2022 and 2021 the Company incurred zero and $36 thousand in fees related to these services, respectively.

16. Subsequent Events

On March 23, 2023 Company announced a reduction in workforce of approximately 35% of its employees and other cost saving initiatives as part of a cost reduction initiative to improve its cash runway and focus on the long-term success of the Company. The Company estimates that it will incur approximately $400 thousand in cash-based expenses related to severance and benefits in the second quarter of 2023.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's ("SEC") rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of the end of the period covered by the report, we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)). Based on that evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2022 our disclosure controls and procedures were effective at the reasonable assurance level.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. The framework used by management in making that assessment was the criteria set forth in the document entitled "Internal Control – Integrated Framework 2013" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that assessment, our Chief Executive Officer and Chief Financial Officer has determined and concluded that, as of December 31, 2022, our internal control over financial reporting were effective.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to the permanent exemption of the Securities and Exchange Commission that permits us to provide only management's report in this Annual Report.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during the most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following table sets forth information concerning our directors and executive officers as of December 31, 2022. The biographical description of each director includes the specific experience, qualifications, attributes and skills that the board of directors would expect to consider if it were making a conclusion currently as to whether such person should serve as a director.

Name	Age	Position(s)	Director/Officer Since
David Perry	55	Executive Chairman and Class I Director	October 2021
Frank Karbe	54	Chief Executive Officer, President and Class II Director	June 2022
Dr. Mark Berman	47	Chief Medical Officer	October 2021
Kristin Wynholds	50	Chief Product Officer	October 2021
Mark Heinen	53	Head of Finance and Interim Chief Financial Officer	October 2021
Dr. Richard Carmona	73	Class I Director	October 2021
Andrew Armanino	57	Class III Director	October 2021
Geoffrey Parker	58	Class II Director	October 2021
Dr. Risa Lavizzo-Mourey	68	Class III Director	October 2021
Dr. Elder Granger	68	Class III Director	November 2021
Dr. Suying Liu	34	Class II Director	July 2020

Executive Officers

Frank Karbe is our Chief Executive Officer, a position he has held since June 2022. Mr. Karbe previously served as the Principal Financial and Accounting Officer of Myovant Sciences Ltd. from September 2016 to August 2021. Mr. Karbe was appointed as Myovant Sciences, Inc.'s Chief Financial Officer in April 2017 and was subsequently appointed as President and Chief Financial Officer in February 2020. From September 2014 to July 2016, Mr. Karbe served as President of The Color Run, a global mass participation events platform, where he was responsible for leading the operational and financial functions. From January 2004 to June 2014, Mr. Karbe was the Executive Vice President and Chief Financial Officer of Exelixis, Inc., a biotechnology company. During his tenure at Exelixis, Mr. Karbe was responsible for leading the finance organization, internal and external communications, business development, information technology, corporate strategy and various other operational functions. Prior to joining Exelixis in 2004, Mr. Karbe worked as an investment banker for Goldman Sachs & Co., where he served most recently as Vice President in the healthcare group advising clients on corporate finance and mergers and acquisitions. Prior to joining Goldman Sachs in 1997, Mr. Karbe held various positions in the finance department of The Royal Dutch/Shell Group in Europe. Mr. Karbe has served as a director of Aduro Biotech, Inc. from April 2019 to October 2020 and Arbutus Biopharma Corporation from 2010 to 2018, and currently serves as a director of Phantom Pharmaceuticals, Inc. Mr. Karbe received his Diplom-Kaufmann from the WHU-Otto Beisheim Graduate School of Management, Koblenz, Germany.

Dr. Mark Berman is our Chief Medical Officer, a position he has held since the closing of our business combination and with Legacy BTX since 2019. Previously, Dr. Berman was the Head of Health of Legacy BTX from 2015 to 2019. Prior to that, Dr. Berman practiced as an internal and lifestyle medicine physician at One Medical. Dr. Berman studied physical therapy at McGill University and received his M.D. from Yale University. He completed residency at Harvard University's Brigham and Women's Hospital and a clinical research fellowship at University of California, San Francisco, where he was a Doris Duke Clinical Research Fellow. He is a fellow and served as a director of the American College of Lifestyle Medicine from 2013 until 2016. Currently, Dr. Berman oversees all of our clinical development and delivery and leads regulatory, research, and publication efforts. Mr. Berman served as the special assistant to the CEO and president for Childhood Obesity at the Robert Wood Johnson Foundation from 2007 to 2009. Dr. Berman is a social entrepreneur whose work focuses on cardiometabolic health, plant-based diets, and digital therapeutics.

Kristin Wynholds is our Chief Product Officer, a position she has held since the closing of our business combination and with Legacy BTX since 2019. Previously, Ms. Wynholds was the Head of Design at Legacy BTX from 2018 to 2019. Prior to working with us, she spent 7 years as a Principal Product Designer at Carbon Five, a product development consultancy, from 2011 to 2018. Ms. Wynholds is a Silicon Valley native who has spent two decades helping startups, as well as growth and enterprise companies, creating compelling, user-centered products. She has been involved with or led more than 30 digital product launches for companies in diverse fields, such as communications, finance, fashion, and healthcare. Some notable companies include Skype, The Gap, Thomson Reuters, Moodys, Coinbase, Stanford Health and Grand Rounds. Ms. Wynholds has a B.A. degree in clinical psychology from University of California, Santa Barbara.

Mark Heinen is our Head of Finance and interim Chief Financial Officer, a position he has held since the closing of our business combination and with Legacy BTX since January 2021. Mr. Heinen is a finance veteran with over a decade of experience in high level accounting and financial oversight roles across multiple fields, including cloud computing and database management. Mr. Heinen previously held the Chief Financial Officer position at Omnigo LLC, in 2020. Prior to that, Mr. Heinen was the SVP, Global Corporate Controller and interim Chief Financial Officer at Trintech Inc. from 2017 to 2020. Prior to his Trintech Inc. role, Mr. Heinen was the acting CFO at Daegis Inc. from 2013 to 2016. In his CFO roles, Mr. Heinen has overseen the sale and acquisition of both public and private companies. Mr. Heinen has over 25 years of finance and accounting experience in both publicly traded and private companies. Mr. Heinen has a B.B.A. in Accounting and an M.B.A. from the University of Oklahoma.

Directors

Our board of directors is divided into three staggered classes of directors and each director is assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the year 2025 for Class I directors, 2023 for Class II directors and 2024 for Class III directors.

- the Class I directors are Dr. Richard Carmona and David Perry, and their terms will expire at the annual meeting of stockholders to be held in 2025;
- the Class II directors are Dr. Suying Liu, Frank Karbe and Geoffrey Parker, and their terms will expire at the annual meeting of stockholders to be held in 2023; and
- the Class III directors are Dr. Risa Lavizzo-Mourey, Andrew Armanino and Dr. Elder Granger, and their terms will expire at the annual meeting of stockholders to be held in 2024.

At each annual meeting of stockholders, the successors to directors whose terms will then expire shall serve from the time of election and qualification until the third annual meeting following election and until their successors are duly elected and qualified. A resolution of the board of directors may change the authorized number of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in control or management of our company.

David Perry is a co-founder of Legacy BTX and served as the chairman of Legacy BTX's board of directors since 2015 and as executive chairman of our board of directors since the closing of our business combination. Mr. Perry, has been the founder or founding CEO of three multi- billion-dollar companies in his career. He was the founding CEO at Anacor Pharmaceuticals where he led the company from its inception in 2002 until 2014, a time period that included an initial public offering in 2010 and the development of two drugs to treat infections (Tavaborole) and inflammation (Eucrisa) that were subsequently approved by the FDA, along with multiple programs to treat neglected diseases. Pfizer purchased Anacor for $5.2 billion in 2016. Most recently, he was the CEO of Indigo Agriculture where he led the company in raising over $1.2 billion, becoming the first agriculture technology company to be valued at over $1 billion. Indigo was ranked #1 on CNBC's Most Disruptive Companies list in 2019. Earlier in his career, Mr. Perry was the founder and CEO of the business-to-business e-commerce pioneer Chemdex in 1997, which he subsequently took public in 1999. Mr. Perry also previously served as a director on the board of Evelo Biosciences, Inc. Mr. Perry has a B.S.E. in Chemical Engineering from the University of Tulsa and an MBA from Harvard Business School. Due to his experience in management, operations, fundraising and launching companies, especially in the life sciences space, we believe Mr. Perry is well equipped to be a director of the Company.

Dr. Richard Carmona has served as a member of our board of directors since the closing of our business combination and served as a member of Legacy BTX's board of directors since 2017. Dr. Carmona has been chief of health innovations of Canyon Ranch Inc., a life-enhancement company, since August 2017. He previously served as vice chairman of Canyon Ranch, chief executive officer of the Canyon Ranch health division, and president of the nonprofit Canyon Ranch Institute from October 2006 to August 2017. He is the first distinguished professor of public health at the Mel and Enid Zuckerman College of Public Health at the University of Arizona. Prior to joining Canyon Ranch, Dr. Carmona served as the 17th Surgeon General of the United States from 2002 through 2006, achieving the rank of Vice Admiral. Previously, he was chairman of the State of Arizona Southern Regional Emergency Medical System, a professor of Surgery, Public Health, and Family and Community Medicine at the University of Arizona, and Surgeon and Deputy Sheriff of the Pima County, Arizona Sheriff's Department. Dr. Carmona served in the United States Army and the Army's Special Forces. Dr. Carmona previously served as a director of the Clorox Company and Axon Enterprise, Inc. (formerly Taser International) and he currently serves as a director of Herbalife Ltd. (October 2013 to present) and McKesson Corporation (September 2021 to present). Dr. Carmona has dedicated his career of more than 50 years toward helping individual and public health in various positions including nurse, trauma surgeon, police officer, public health official, and combat-decorated Special Forces Vietnam veteran. Due to the depth and breadth of experience and knowledge that Dr. Carmona brings to the board of directors we believe Dr. Carmona is well equipped to be a director of the Company.

Andrew Armanino has served as a member of our board of directors since the closing of our business combination and served as a member of Legacy BTX's board of directors since March 2021. Mr. Armanino is currently the chairman of the board of directors of Moore Global International, an accounting and business advisory network of independent accounting firms. He is also a member of the board of directors of Armanino Foundation, a community service organization and serves on the American Institute of CPAs council, and a member of the board of directors of the California Bank of Commerce. Mr. Armanino was the Managing Partner and Chief Executive Officer of Armanino LLP, a 1,500-person public accounting firm, from 2005 to 2018, at which time he retired and is no longer affiliated with the firm. He has a B.S. in accounting from Santa Clara University. We believe Mr. Armanino is well equipped to be a director of the Company due to the depth and breadth of his business, accounting, and management experience. Mr. Armanino's significant accounting experience provides in-depth knowledge of generally accepted accounting principles and auditing standards to our board of directors. With years of providing services to small and medium-sized businesses, he brings valuable insights to our board of directors.

Geoffrey Parker has served as a member of our board of directors since the closing of our business combination and served as a member of Legacy BTX's board of directors since March 2021. Mr. Parker is currently the Chief Financial Officer and Chief Operating Officer of Tricida, Inc. (Nasdaq: TCDA). Mr. Parker joined Tricida in 2017. Prior to that, Mr. Parker was Chief Financial Officer of Anacor Pharmaceuticals, Inc. from September 2010 to May 2015 and a Managing Director at Goldman Sachs where he led the West Coast Healthcare Investment Banking group from April 1997 to April 2009. Mr. Parker serves as a director on the board of directors of Perrigo Company plc, where he serves as a member of the audit committee. Previously, Mr. Parker served as a director on the board of directors at ChemoCentryx, Inc., Genomic Health, Sunesis Pharmaceuticals, Inc., and Genoptix, Inc. Mr. Parker has a B.A. in a double major of economics and engineering sciences from Dartmouth College and an MBA from the Stanford Graduate School of Business. We believe Mr. Parker is well equipped to be a director of the Company due to his extensive management, financial and operations experience, especially in the life science sector.

Dr. Risa Lavizzo-Mourey has served as a member of our board of directors since the closing of our business combination and served as a member of Legacy BTX's board of directors since April 2021. Dr. Lavizzo-Mourey was a professor at the University of Pennsylvania from 1986 until 2021 and served as the Robert Wood Johnson Foundation Professor of Health Equity and Health Policy from 2018 to 2021. Dr. Lavizzo-Mourey was the Chief Executive Officer of the Robert Wood Johnson Foundation from 2003 to 2017, where she spearheaded initiatives to reverse the childhood obesity epidemic, create an affordable and inclusive healthcare system, and address social factors associated with adverse health impacts. Dr. Lavizzo-Mourey also has extensive government experience in a wide range of roles from 1985 to 1998, including as a Co-Chair of the White House Health Care Reform Task Force and as an Advisory Committee Member on the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. Dr. Lavizzo-Mourey has served as an independent director for Intel (NYSE: INTC) since 2018, where she has served as a member of the nominating and governance committee, as an independent director for Merck (NYSE: MRK) since 2020, where she has served as a member of the compensation and benefits and governance committees, and as an independent director for General Electric (NYSE: GE) since 2017, where she has served on the governance and public affairs committee. Dr. Lavizzo-Mourey got her B.S. at the State University of New York, Stony Brook, her M.D. at Harvard University, and her MBA at the University of Pennsylvania. We believe Dr. Lavizzo-Mourey is well equipped to be a director of the Company due to her wealth of knowledge and experience, including in functional and thought leadership, across the healthcare spectrum, and her work as a primary care physician and shaping health policy on a national level. Dr. Lavizzo-Mourey has demonstrated a passion for cognitive behavioral therapy, having been the leader behind Robert Wood Johnson Foundation's strategic shift towards the behavioral space.

Dr. Elder Granger has served as a member of our board of directors since November 2021. He is a U.S. Army Major General (Retired) and has served as the President and Chief Executive Officer of THE 5Ps, LLC, a healthcare, education, and leadership consulting firm, since August 2009. He served in the U.S. Army for over 35 years before retiring in June 2009 and was the Deputy Director and Program Executive Officer of TRICARE Management Activity, Office of the Assistant Secretary of Defense (Health Affairs) in Washington, D.C. from December 2005 to June 2009. He is board certified by the American College of Physician Executives, American College of Healthcare Executives, American Board of Medical Quality, and American Board of Internal Medicine, National Association of Corporate Directors, and holds numerous medical certifications. Dr. Granger currently serves on the board of directors of Cigna Corporation (NYSE: CI) since 2018 and DLH Holdings Corp (Nasdaq: DLHC) since 2014, and he previously served on the board of directors of Express Scripts Holding Company (from 2015 to 2018) and Cerner Corporation (Nasdaq: CERN). He received his Bachelor of Science Degree from Arkansas State University in 1976 and earned his medical degree from University of Arkansas School of Medicine in 1980. We believe Dr. Granger is well-equipped to serve as a director of the Company due to his extensive experience in health care management and operations, including health policy, planning, budgeting, compliance, and execution related to the health program for uniformed service members around the globe. Dr. Granger has unique leadership and policy experience through his career with the U.S. Army and the commercial sector.

Dr. Suying Liu has served as a member of our board of directors since inception and previously served as the chairman and chief executive officer of MCAD. Dr. Liu was a director of PLBY Group, Inc. (Nasdaq: PLBY) from the closing of its business combination with Mountain Crest Acquisition Corp (Nasdaq: MCAC) in February 2021 through August 2021. Dr. Liu has been serving as the Chief Executive Officer, the Chief Financial Officer, and the Chairman of Mountain Crest Acquisition Corp. III (Nasdaq: MCAE) since March 2021. He also has been serving as the Chairman, Chief Executive Officer, and Chief Financial Officer of Mountain Crest Acquisition Corp. IV (Nasdaq: MCAF) since March 2021 and of Mountain Crest Acquisition Corp. V (Nasdaq: MCAG) since April 2021. He served as the Head of Corporate Strategy of Hudson Capital Inc. (Nasdaq: HUSN) between May 2020 and September 2020, where he led the company's strategic development for both general operations and specific growth areas. Between November 2018 and April 2020, Dr. Liu served as the Chief Strategist of Mansion Capital LLC, a privately-held real estate investment firm with brokerage and property management operations serving clients from both North America and Asia for their investments in the U.S. real estate market. Prior to joining Mansion Capital, Dr. Liu was an investment strategist at J.P. Morgan Chase & Co. from July 2015 to October 2018, providing investment strategies to major Wall Street institutions spanning private equity, hedge funds and insurance companies, with a primary focus in commercial mortgages. Dr. Liu began his career in academia, teaching a variety of degree programs from bachelor's to executive education at Washington University Olin Business School between January 2013 and May 2015 while completing his doctoral studies, for which he received a PhD in finance in May 2015. Dr. Liu obtained a master's in finance in December 2012 and his BA in economics and mathematics summa cum laude in May 2010 from Washington University in St. Louis. We believe Dr. Liu is qualified to serve on our board of directors based on his diverse experience in corporate and investment strategies.

There are no family relationships between or among any of our directors or executive officers. The principal occupation and employment during the past five years of each of our directors was carried on, in each case except as specifically identified in this Annual Report, with a corporation or organization that is not a parent, subsidiary or other affiliate of us. There is no arrangement or understanding between any of our directors and any other person or persons pursuant to which he is to be selected as a director. There are no material legal proceedings to which any of our directors is a party adverse to us or any of our subsidiaries or in which any such person has a material interest adverse to us or our subsidiary.

Director Independence

The Nasdaq listing rules require that a majority of our board of directors be independent. An "independent director" is defined generally as a person other than an executive officer or employee of us or any other individual having a relationship which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Our board of directors has determined that each individual who serves on our board of directors, other than David Perry, Frank Karbe and Dr. Suying Liu, qualifies as an independent director under Nasdaq listing standards.

Board Meetings and Attendance

Our board of directors held six meetings during the fiscal year ended December 31, 2022. Each of the directors attended at least 75% of the meetings of the board of directors and the committees of the board of directors on which he or she served during the fiscal year ended December 31, 2022 (in each case, which were held during the period for which he or she was a director and/or a member of the applicable committee). The Company encourages its directors to attend the annual meeting of stockholders.

Committees of the Board of Directors

Our board of directors has three standing committees: an audit committee, a compensation committee and a nominating and corporate governance committee. Each committee operates pursuant to a written charter. In addition, each committee reviews and assesses the adequacy of its charter and submits its charter to the board of directors for approval. Copies of each committee's charter are posted on our website at www.bettertx.com under the "Investor Relations" section. The information contained on or that can be accessed through our website is not incorporated by reference into this Annual Report, and you should not consider such information to be part of this Annual Report.

Audit Committee

The members of our audit committee are Andrew Armanino, Geoffrey Parker and Dr. Elder Granger, and Andrew Armanino serves as the chairperson of the audit committee. Under the Nasdaq listing rules and applicable SEC rules, the audit committee is required to have at least three members. The Nasdaq listing rules and Rule 10A-3 of the Exchange Act also require that the audit committee of a listed company be composed solely of independent directors for audit committee purposes, and each member of our audit committee qualifies as an independent director for audit committee purposes under applicable rules. Each of Andrew Armanino, Geoffrey Parker and Dr. Elder Granger is financially literate and Andrew Armanino qualifies as an "audit committee financial expert" as defined in applicable SEC rules. During the fiscal year ended December 31, 2022, the audit committee met four times. The audit committee's responsibilities include:

- selecting a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- helping to ensure the independence and performance of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing policies on risk assessment and risk management;
- reviewing related party transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality-control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving (or, as permitted, pre-approving) all audit and all permissible non-audit service to be performed by the independent registered public accounting firm.

Compensation Committee

The members of our compensation committee are Dr. Risa Lavizzo-Mourey and Dr. Richard Carmona, all of whom are independent directors, and Dr. Risa Lavizzo-Mourey serves as the chairperson of the compensation committee. During the fiscal year ended December 31, 2022, the compensation committee met seven times. The compensation committee's responsibilities include:

- reviewing and approving, or recommending that our board of directors approve, the compensation of our executive officers other than the Chief Executive Officer;
- reviewing and recommending to our board of directors the compensation of our directors;
- reviewing and approving, or recommending that our board of directors approve, the terms of compensatory arrangements with our executive officers;
- administering our stock and equity incentive plans;
- selecting independent compensation consultants and assessing whether there are any conflicts of interest with any of the committee's compensation advisors;
- reviewing and approving, or recommending that our board of directors approve, incentive compensation and equity plans and any other compensatory arrangements for our executive officers and other senior management, as appropriate;

- reviewing and establishing general policies relating to compensation and benefits of our employees; and
- reviewing our overall compensation policies and processes.

Our compensation committee considers matters related to individual compensation. The compensation committee also reviews and approves grants and awards under our incentive-based compensation plans and equity-based plans, other than with respect to our Chief Executive Officer, Executive Chairman and our directors. In the case of our Chief Executive Officer and Executive Chairman, the compensation committee reviews and approves the corporate goals and objectives to be considered in determining their compensation, conducts an evaluation of their performance in light of those goals and objectives and then makes a recommendation for compensation to the board of directors based on that evaluation. For all other officers other than the Chief Executive Officer and Executive Chairman, the compensation committee reviews and recommends to the board of directors policies and procedures for the grant of equity based awards, including a compensation matrix consisting of bands for grants and awards under equity-based plans to employees at each level.

In 2022, the compensation committee retained the services of an independent compensation consultant and considered its input on certain compensation matters as the compensation committee deemed appropriate. The compensation committee may establish and delegate authority to one or more subcommittees consisting of one or more of its members to carry out its responsibilities.

Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are Geoffrey Parker and Dr. Richard Carmona, all of whom are independent directors, and Geoffrey Parker serves as the chairperson of the nominating and corporate governance committee. During fiscal year ended December 31, 2022, the nominating and corporate governance committee met four times. The nominating and corporate governance committee's responsibilities include:

- identifying, evaluating and selecting, or recommending that our board of directors approve, nominees for election to our board of directors;
- evaluating the performance of our board of directors and of individual directors;
- reviewing developments in corporate governance practices;
- evaluating the adequacy of our corporate governance practices and reporting;
- reviewing management succession plans; and
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters.

We believe that the composition and functioning of our nominating and corporate governance committee complies with all applicable requirements of the Sarbanes-Oxley Act and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us. Our board of directors may from time to time establish other committees.

Identifying and Evaluating Director Nominees

Our board of directors is responsible for selecting its own members. The board of directors delegates the selection and nomination process to the nominating and corporate governance committee, with the expectation that other members of the board of directors, and of management, will be requested to take part in the process as appropriate.

Generally, our nominating and corporate governance committee identifies candidates for director nominees in consultation with management, through the use of search firms or other advisors, through the recommendations submitted by stockholders or through such other methods as the nominating and corporate governance committee deems to be helpful to identify candidates. Once candidates have been identified, our nominating and corporate governance committee confirms that the candidates meet all of the criteria for director nominees established by the nominating and corporate governance committee and approved by the board of directors. The nominating and corporate governance committee may gather information about the candidates through interviews, detailed questionnaires, background checks or any other means that the nominating and corporate governance committee deems to be appropriate in the evaluation process. The nominating and corporate governance committee then meets as a group to discuss and evaluate the qualities and skills of each candidate, both on an individual basis and taking into account the overall composition and needs of our board of directors. Based on the results of the evaluation process, the nominating and corporate governance committee recommends candidates for the board of directors' approval as director nominees for appointment or election to the board of directors.

Minimum Qualifications and Board Diversity

Our nominating and corporate governance committee will consider, among other things, the following minimum qualifications, skills and attributes when recommending candidates for the board's selection as director nominees for the board and as candidates for appointment to the board's committees: a nominee shall have experience at a strategic or policymaking level in a business, government, non-profit or academic organization of high standing; a nominee shall be highly accomplished in his or her respective field, with superior credentials and recognition; a nominee shall be well regarded in the community and shall have a long-term reputation for high ethical and moral standards; a nominee shall have sufficient time and availability to devote to our affairs, particularly in light of the number of boards of directors on which such nominee may serve; and, to the extent a nominee serves or has previously served on other boards, the nominee shall have a demonstrated history of actively contributing at board meetings.

In evaluating prospective director candidates, our nominating and corporate governance committee will also consider all facts and circumstances that it deems appropriate or advisable, including, among other things, diversity, including, but not limited to, race, gender, national origin, the skills of the proposed director candidate, his or her depth and breadth of professional experience or other background characteristics, his or her independence and the needs of the board of directors. While we have no formal policy regarding board diversity, we believe that the varied perspectives and experiences resulting from having a diverse board of directors enhances the quality of our decision-making. We also believe diversity can help the board identify and respond more effectively to the needs of patients, stockholders, employees and other stakeholders.

The nominating and corporate governance committee will consider director candidates recommended by stockholders. The policy adopted by the nominating and corporate governance committee provides that candidates recommended by stockholders are given appropriate consideration in the same manner as other candidates.

Non-Employee Director Meetings

In addition to the meetings of the committees of the board of directors described above, in connection with board of directors' meetings, the non-employee directors met five times in executive session during the fiscal year ended December 31, 2022.

Communication with the Board of Directors

Any interested party with concerns about the Company may report such concerns to the board of directors or the Chairperson of our board of directors or nominating and corporate governance committee, by submitting a written communication to the attention of such director at the following address:

c/o Better Therapeutics, Inc.
548 Market Street, #49404
San Francisco, California 94104
United States

You may submit your concern anonymously or confidentially by postal mail. You may also indicate whether you are a stockholder or other interested party.

A copy of any such written communication may also be forwarded to the Company's legal counsel and a copy of such communication may be retained for a reasonable period of time. The director may discuss the matter with the Company's legal counsel, with independent advisors, with non-employee directors or with the Company's management, or may take other action or no action as the director determines in good faith, using reasonable judgment, and applying his or her own discretion.

Communications may be forwarded to other directors if they relate to important substantive matters and include suggestions or comments that may be important for other directors to know. In general, communications relating to corporate governance and long-term corporate strategy are more likely to be forwarded than communications relating to ordinary business affairs, personal grievances and matters as to which we receive repetitive or duplicative communications.

The audit committee oversees the procedures for the receipt, retention, and treatment of complaints received by the Company regarding accounting, internal accounting controls or audit matters, and the confidential, anonymous submission by employees of concerns regarding questionable accounting, internal accounting controls or auditing matters.

Role of Our Board of Directors in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure, and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures. The audit committee also has the responsibility to review with management the process by which risk assessment and management is undertaken, monitor compliance with legal and regulatory requirements, and review the adequacy and effectiveness of our internal controls over financial reporting. Our nominating and corporate governance committee is responsible for periodically evaluating our company's corporate governance policies and systems in light of the governance risks that our company faces and the adequacy of our company's policies and procedures designed to address such risks. Our compensation committee assesses and monitors whether any of our compensation policies and programs is reasonably likely to have a material adverse effect on our company.

Code of Ethics

Our board of directors has adopted a Code of Business Conduct and Ethics (our "code of ethics") that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive and senior financial officers. The full text of our code of ethics is available under the "Investors - Governance - Documents & Charters" section of our website at www.bettertx.com under the "Investor Relations" section.

We intend to disclose future amendments to certain provisions of our code of ethics, or waivers of certain provisions as they relate to our directors and executive officers, at the same location on our website or in public filings. The information on our website is not intended to form a part of or be incorporated by reference into this Annual Report.

Item 11. Executive Compensation.

Executive Compensation Overview

This section discusses the material components of the executive compensation program offered to our "named executive officers" for 2022, which consisted of each individual who served as our Chief Executive Officer during 2022 and two most highly compensated executive officers during 2022 other than our Chief Executive Officers. Such executive officers consist of the following persons:

- Frank Karbe, our Chief Executive Officer;
- Kevin Appelbaum, Co-Founder & Former Chief Executive Officer;
- Dr. Mark Berman, our Chief Medical Officer; and
- Kristin Wynholds, our Chief Product Officer.

Our executive compensation programs are designed to:

- attract, motivate, incentivize and retain employees who contribute to our long-term success;
- provide short-term incentive compensation packages to our executives that are competitive and reward the achievement of our business objectives; and
- effectively align our executives' interests with those of our stockholders by focusing on long-term equity incentives that correlate with the growth of sustainable long-term value for our stockholders.

Our compensation committee is primarily responsible for the executive compensation programs for our executive officers. Our Chief Executive Officer makes compensation recommendations to the compensation committee for the respective executive officers that report to him, and typically attends compensation committee meetings. Our Chief Executive Officer makes such recommendations (other than with respect to himself) regarding base salary and short-term and long-term incentives for our executive officers based on company-wide results and an executive officer's individual contribution toward these results. Our compensation committee then reviews the recommendations and other data, including various compensation survey data and publicly-available data of our peers, and makes decisions as to the target total direct compensation for each executive officer, including our Chief Executive Officer, as well as each individual compensation element. The compensation committee reviews the performance of our Chief Executive Officer and makes recommendations to the board of directors with respect to his compensation. The board of directors retains the authority to make compensation decisions relative to our Chief Executive Officer. While our Chief Executive Officer typically attends meetings of the compensation committee, the compensation committee meets outside the presence of our Chief Executive Officer when discussing his compensation and when discussing certain other matters, as well.

Our compensation committee is authorized to retain the services of one or more executive compensation advisors, as it sees fit, in connection with the establishment of our executive compensation programs and related policies. The compensation committee engages Pay Governance LLC, a national compensation consulting firm with compensation expertise relating to the technology and biotechnology industries, to provide it with market information, analysis and other advice relating to executive and non-executive compensation on an ongoing basis. Pay Governance LLC assists in developing an appropriate group of peer companies to help us determine the appropriate level of overall compensation for our executive officers, and assesses each separate element of compensation, with a goal of ensuring that the compensation we offer to our executive officers, individually as well as in the aggregate, is competitive and fair. We do not believe the retention of, and the work performed by Pay Governance LLC, creates any conflict of interest.

2022 Summary Compensation Table

The following table presents information regarding the total compensation awarded to, earned by and paid to our named executive officers for services rendered to the Company in all capacities in the fiscal years ended December 31, 2022 and 2021, respectively.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Frank Karbe, Chief Executive Officer	2022	246,474(1)			909,929	110,913(3)		1,267,316
Kevin Appelbaum, Co-Founder & Former Chief Executive Officer	2022	272,064(1)	-	194,432(4)	198,246	-	571,331(5)	1,236,073
	2021	462,250	-	-	675,111	707,500		1,844,861
Dr. Mark Berman, Chief Medical Officer	2022	421,875(1)	-	-	98,413	151,875(3)		672,163
	2021	360,500	-	-	250,062	215,875		826,437
Kristin Wynholds, Chief Product Officer	2022	381,667(1)	-	-	98,413	137,400(3)		617,480
	2021	329,375	-	-	219,681	257,125		806,181

(1) In March 2022, we increased Mr. Appelbaum's, Dr. Berman's and Ms. Wynholds' annual base salaries from $520,000 to $540,000, from $410,000 to $425,000 and from $350,000 to $390,000, respectively. In addition, the amounts reported for Mr. Karbe and Mr. Appelbaum each reflect such named executive officer's partial year of service to the Company in 2022, as Mr. Karbe commenced employment with and Mr. Appelbaum departed from the Company in July 2022. Accordingly, such named executive officer's base salaries were prorated to reflect their time in service with the Company.

(2) The amounts reported represent the aggregate grant date fair value of the stock options granted to our named executive officers calculated in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the stock options reported in this column are set forth in Note 2 of our financial statements included elsewhere in this Annual Report. The amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the actual economic value that may be received by our named executive officers upon the exercise of the stock options or any sale of the underlying shares of our common stock. The amounts reported for Mr. Karbe's 2022 stock option awards subject to performance-based vesting conditions are calculated based on probable achievement of performance outcomes. The grant date fair value of such awards assuming the maximum achievement of performance outcomes is the same as the grant fair value of the awards assuming probable achievement of the performance outcomes, which are estimated to be $531,225 for the Performance Option (as defined below) and $31,449 for the Supplemental Performance Option (as defined below). In addition, the 2022 value in this column for Mr. Applebaum includes the incremental fair value, computed in accordance with FASB ASC Topic 718, with respect to the amendments to Mr. Applebaum's options in connection with his departure from the Company to provide for certain acceleration of vesting (as described in more detail below) and an extension of his options' post-termination exercise periods until the second anniversary of the date of his departure.

(3) Amounts include bonuses earned by our named executive officers under our short-term cash incentive program, based on both the Company's achievement of certain corporate performance goals and the named executive officer's individual performance during the 2022 fiscal year. For Mr. Karbe, his annual bonus amount was prorated to reflect his partial year of service with the Company during 2022. In addition, because of his departure from the Company in 2022, Mr. Appelbaum's annual bonus for 2022 was forfeited.

(4) The amount reported reflects the incremental fair value, computed in accordance with FASB ASC Topic 718, with respect to the amendments to Mr. Applebaum's performance-based restricted stock awards in connection with his departure from the Company to provide for certain acceleration of vesting (as described below).

(5) The amount reported reflects the value of severance paid to and/or accrued in connection with Mr. Appelbaum's departure from the Company, which includes $540,000 for cash severance, $31,331 for COBRA continuation coverage and $194,432 for the value of acceleration of vesting of his equity awards (minus any incremental fair value for amendments to Mr. Appelbaum's equity awards related to such acceleration of vesting, as reported in the Stock Awards column).

Narrative Disclosure to the Summary Compensation Table

Base Salaries

Each of the named executive officers is paid a base salary commensurate with his or her skill set, experience, performance, role and responsibilities. From January 1, 2022 until March 2022, the annual base salaries for Mr. Appelbaum, Dr. Berman and Ms. Wynholds were $520,000, $410,000 and $350,000, respectively. Effective March, 2022, the annual base salaries for Mr. Appelbaum, Dr. Berman and Ms. Wynholds were increased to $540,000, $425,000 and $390,000, respectively. Mr. Appelbaum departed from the Company in July 2022. Mr. Karbe commenced employment in July 2022 and his annualized base salary was $500,000. Mr. Karbe's and Mr. Appelbaum's salaries for 2022 were pro-rated for their partial year of service with the Company during 2022.

Cash Bonuses

For the 2022 fiscal year, the target annual bonuses for Mr. Appelbaum, Mr. Karbe, Dr. Berman and Ms. Wynholds were 50%, 50%, 40% and 40%, respectively, of the applicable named executive officer's annual base salary.

For 2022, our named executive officers were eligible to earn an annual bonus under our short-term cash incentive program based on both achievement of certain corporate performance objectives and individual performance in 2022. Following the end of the 2022 performance year, our board of directors determined that such corporate performance and individual objectives were achieved at 90%, resulting in payment amounts of $110,913, $151,875 and $137,400 to Mr. Karbe, Dr. Berman and Ms. Wynholds, respectively. Because of his departure from the Company in 2022, Mr. Appelbaum did not earn an annual bonus for 2022. In addition, the amount paid to Mr. Karbe was prorated to reflect his partial year of service with the Company during 2022.

Equity Compensation

During the fiscal year 2022, we granted stock options to each of our named executive officers, as shown in more detail in the "Outstanding Equity Awards at Fiscal 2022 Year-End Table" below.

401(k) Plan

We maintain a 401(k) Plan, a tax-qualified retirement plan that provides eligible employees, including our named executive officers, with an opportunity to save for retirement on a tax-advantaged basis. Plan participants are able to defer eligible compensation subject to applicable annual limits under the Internal Revenue Code of 1986, as amended (the "Code"). Employees' pre-tax or Roth contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Employees are immediately and fully vested in their contributions. We may make matching contributions on a discretionary basis, but did not make any matching contributions in fiscal years 2022 or 2021. Our 401(k) plan is intended to be qualified under Section 401(a) of the Code with our 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code.

Perquisites and Personal Benefits

We generally do not provide perquisites or personal benefits to our named executive officers.

Employment Arrangements with our Named Executive Officers

We have entered into employment agreements or offer letters with each of our named executive officers. In addition, we adopted an executive severance plan in connection with the business combination (the "Executive Severance Plan"), which provides for certain payments and benefits in the event of a termination of employment, including an involuntary termination of employment in connection with a change in control of the Company. All of the named executive officers other than Mr. Karbe and Mr. Appelbaum participate in the Executive Severance Plan and the terms of the Executive Severance Plan replace the severance provisions in such named executive officers' offer letters, if any.

Employment Agreements and Offer Letters

The material terms of the applicable employment agreement and offer letters with Mr. Karbe, Mr. Appelbaum, Dr. Berman, and Ms. Wynholds are described below.

Frank Karbe. On the same day as Mr. Appelbaum's departure (as described below), the Company entered into an employment agreement with Frank Karbe (the "Karbe Employment Agreement") to appoint him as President and Chief Executive Officer of the Company effective as of July 5, 2022.

Pursuant to the Karbe Employment Agreement, Mr. Karbe is entitled to receive an initial annual base salary of $500,000 and is eligible to receive an annual performance bonus with a target annual bonus amount of 50% of his annual base salary. Mr. Karbe's bonus for 2022 will be pro-rated based on the Effective Date and length of Mr. Karbe's employment with the Company during 2022.

Further, the Board approved the grant to Mr. Karbe as of the Effective Date of (i) a time-based option to purchase 472,200 shares of common stock, with 25% of the option shares vesting on the first anniversary of the Effective Date and the balance vesting in equal monthly installments over the next three years, subject to his continued employment with the Company through each vesting date, (ii) a performance-based option to purchase 708,300 shares of common stock, vesting upon the satisfaction of both a time-based vesting condition and certain performance-based vesting conditions, (the "Performance Option") and (iii) a performance-based option to purchase 472,200 shares of common stock, vesting upon the achievement of certain performance milestones (the "Supplemental Performance Option"). Upon a "change in control", as defined in the Karbe Employment Agreement, subject to Mr. Karbe's continued employment through such date, all unvested and outstanding performance-based equity awards (other than the Supplemental Performance Option) will immediately accelerate and become fully vested and exercisable as of such date, and the Supplemental Performance Option shall be immediately forfeited as of such date.

In addition, pursuant to the Karbe Employment Agreement, if (i) Mr. Karbe's employment is terminated without "cause," or (ii) he resigns for "good reason," in each case outside of the "change in control period," as each term is defined in the Karbe Employment Agreement, Mr. Karbe will be entitled to receive the following severance benefits, subject to his execution of an irrevocable separation agreement and release within 60 days after the date of termination: (A) continuation of his then current base salary for a period of 12 months following his termination of employment, (B) his full target bonus for the then-current year, payable over 12 months, (C) monthly payments equal to the monthly employer contribution that the Company would have made to provide health insurance to Mr. Karbe had he remained employed by the Company for up to 12 months and (D) acceleration of vesting of 25% of his then-outstanding and unvested time-based equity awards and vesting of any performance-based awards for which performance milestones or conditions are achieved within six months of such termination date.

If (1) Mr. Karbe's employment is terminated without "cause" or (2) he resigns for "good reason", in each case within the "change in control period," in lieu of the benefits described above, Mr. Karbe will be entitled to receive the following severance benefits, subject to his execution of an irrevocable separation agreement and release within 60 days after the date of termination: (a) a lump sum payment equal to two times his then current annual base salary, (b) a lump sum payment equal to two times his full then-current target annual bonus opportunity for the then-current year (or his target bonus in effect immediately prior to the change in control, if higher), (c) monthly payments equal to the monthly employer contribution that the Company would have made to provide health insurance to Mr. Karbe had he remained employed by the Company for up to 24 months and (d) 100% acceleration of vesting of then-outstanding and unvested equity awards (other than the Supplemental Performance Option).

Kevin Appelbaum. We entered into an executive employment agreement with Mr. Appelbaum effective as of April 6, 2021, with certain provisions thereof effective as of the closing of our business combination (the "Appelbaum Employment Agreement"), for the position of President and Chief Executive Officer. The Appelbaum Employment Agreement provided for the terms and conditions of Mr. Appelbaum's employment and set forth his initial annual base salary of $520,000, his target bonus amount equal to 50% of his annual base salary, transaction and other bonuses subject to the consummation of our business combination, his eligibility to participate in our equity incentive plans, and his eligibility to participate in our benefit plans generally.

Pursuant to the Appelbaum Employment Agreement, if (i) Mr. Appelbaum's employment was terminated without "cause" outside of the "change in control period", (ii) he resigned for "good reason" outside of the "change in control period" or (iii) he resigned upon a "good leaver termination", as each term is defined in the Appelbaum Employment Agreement, Mr. Appelbaum would have been entitled to receive the following severance benefits, subject to his execution of an irrevocable separation agreement and release within 60 days after the date of termination: (A) continuation of his then current base salary for a period of 12 months following his termination of employment, (B) reimbursement for COBRA premiums for himself and his dependents for up to 12 months following his termination of employment and (C) six months' acceleration of vesting of outstanding time-based equity awards and for performance-based vesting awards, the vesting of a number of shares equal to the number of shares that would have vested pursuant to such performance-based vesting awards subject to the Company's achievement of the applicable performance-based vesting conditions described therein within the six-month period following the date of termination.

Upon the consummation of a "change in control" (as defined in the Appelbaum Employment Agreement) and subject to Mr. Appelbaum's continued employment with the Company through such date, all shares subject to performance-based vesting would have converted to time-based vesting awards at target without proration, which would have vested in substantially equal monthly installments each month following the consummation of such change in control over (i) the remainder of the applicable performance period set forth in the underlying award agreement, or (ii) twenty-four (24) consecutive months following the consummation of such change in control, if no such performance period is contained in the underlying award agreement.

If Mr. Appelbaum's employment was terminated without "cause" or he resigns for "good reason", in each case within 12 months following a "change in control" (i.e., the change in control period) as each term is defined in the Appelbaum Employment Agreement, in lieu of the benefits described above, Mr. Appelbaum would have been entitled to receive the following severance benefits, subject to his execution of an irrevocable separation agreement and release within 60 days after the date of termination: (1) a lump sum payment equal to 24 months of his then current base salary, (2) 200% of his then-current target bonus opportunity, (3) reimbursement for COBRA premiums for himself and his dependents for up to 24 months following his termination of employment and (4) 100% acceleration of vesting of outstanding equity awards.

The payments and benefits provided under the Appelbaum Employment Agreement in connection with a change in control may not be eligible for federal income tax deduction for the Company pursuant to Section 280G of the Code. These payments and benefits may also be subject to an excise tax under Section 4999 of the Code. If the payments or benefits payable to each executive in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to him.

On June 7, 2022, the Company and Mr. Appelbaum agreed that Mr. Appelbaum would cease serving as President and Chief Executive Officer of the Company and as a member of our board of directors effective as of July 5, 2022 (the "Effective Date"). In connection with Mr. Appelbaum's departure, the Company entered into a Separation Agreement and Release (the "Separation Agreement") with Mr. Appelbaum, pursuant to which, following the Effective Date, Mr. Appelbaum would be eligible to receive the following, subject to the execution of an effective release of claims against the Company and our affiliates and continued compliance with applicable restrictive covenants: (i) 12 months' base salary continuation, (ii) monthly payments equal to the monthly employer contribution that the Company would have made to provide health insurance to Mr. Appelbaum had he remained employed by the Company for up to 12 months from the Effective Date and (iii) immediate vesting of certain outstanding stock-based equity awards, in each case beginning on the Effective Date.

Dr. Mark Berman. We entered into an offer letter with Dr. Berman, dated as of November 23, 2015 (the "Berman Offer Letter"). The Berman Offer Letter provides for Dr. Berman's employment and sets forth the term of his employment, his positions and duties, his eligibility to receive equity compensation, and his eligibility to participate in our benefit plans generally. Dr. Berman is subject to our standard confidential information agreement.

Kristin Wynholds. We entered into an offer letter with Ms. Wynholds, dated as of October 9, 2018 (the "Wynholds Offer Letter"). The Wynholds Offer Letter provides for Ms. Wynholds' employment and sets forth the term of her employment, her positions and duties, her eligibility to receive equity compensation, and her eligibility to participate in our benefit plans generally. Ms. Wynholds is subject to our standard confidential information agreement.

Executive Severance Plan

The Executive Severance Plan provides that upon a termination of employment by us other than for "cause" (as defined in the Executive Severance Plan), death or "disability" (as defined in the Executive Severance Plan), or upon a resignation by an eligible participant for "good reason" (as defined in the Executive Severance Plan), in either case outside of the "change in control period" (i.e., the period beginning on the date of a "change in control" (as defined in the Executive Severance Plan) and ending on the one-year anniversary of the change in control), the participant will be entitled to receive, subject to the execution and delivery of a separation agreement and release containing, among other provisions, an effective release of claims in favor of the Company and reaffirmation of the "restrictive covenants agreement" (as defined in the Executive Severance Plan), (i) a severance amount equal to 9 months of the participant's annual base salary in effect immediately prior to such termination, payable over 9 months, (ii) up to 9 monthly cash payments equal to the monthly employer contribution that we would have made to provide health insurance for the applicable participant if he or she had remained employed by us, based on the premiums as of the date of termination.

The Executive Severance Plan also provides that upon a termination of employment by us other than for cause, death or disability or upon a resignation by an eligible participant for good reason, in either case within the change in control period, the participant will be entitled to receive, in lieu of the payments and benefits described above and subject to the execution and delivery of an a separation agreement and release containing, among other provisions, an effective release of claims in favor of the Company and reaffirmation of the restrictive covenants agreement, (i) a lump sum cash severance amount equal to 100% of the participant's annual base salary in effect immediately prior to such termination (or the participant's annual base salary in effect for the year immediately prior to the year of termination, if higher), (ii) a lump sum amount equal to 100% of the participant's annual target bonus in effect immediately prior to such termination (or the participant's annual target bonus in effect immediately prior to the change in control, if higher), (iii) a lump sum amount equal to the monthly employer contribution that we would have made to provide health insurance for the participant if he or she had remained employed by us for 12 months following the date of termination, based on the premiums as of the date of termination, and (iv) for all outstanding and unvested equity awards of the Company that are subject to time-based vesting held by the participant, full accelerated vesting of such awards; provided, that any outstanding and unvested equity awards subject to performance conditions may become vested, exercisable and/or nonforfeitable to the extent specified in the applicable award agreement; provided further, that if the treatment of outstanding and unvested equity awards subject to performance conditions is not addressed in the applicable award agreement, then the performance conditions applicable to such equity awards will be deemed satisfied at the maximum level specified in the terms of the applicable award agreement.

The payments and benefits provided under the Executive Severance Plan in connection with a change in control may not be eligible for a federal income tax deduction by us pursuant to Section 280G of the Code. These payments and benefits may also subject an eligible participant to an excise tax under Section 4999 of the Code. If the payments or benefits payable to an eligible participant in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a greater net after-tax benefit to the applicable participant.

Outstanding Equity Awards at 2022 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2022.

	Option awards[1]							Stock awards [2]			
	Grant date	Vesting commencement date	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: number of Securities Underlying Unexercised Unearned Options (#)	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)(3)	Equity incentive plan awards: number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: market or payout value of unearned shares, units or other rights that have not vested ($)(3)
Frank Karbe	7/5/2022	7/5/2022	—	472,200 (4)	708,300 (5)	1.68	7/5/2032	—	—	—	—
	7/5/2022	7/5/2022	—	—	472,200 (6)	1.68	7/5/2032	—	—	—	—
Kevin Appelbaum	4/6/2021	4/6/2021	98,704	98,704 (7)	—	11.38	4/6/2031	—	—	—	—
Dr. Mark Berman	2/4/2019	12/7/2018	—	—	—	—	—	29,601 (8)	32,709	—	—
	4/6/2021	4/6/2021	36,574	51,167 (7)	—	11.38	4/6/2023	—	—	—	—
	4/1/2022	4/1/2022	—	116,700 (4)	—	1.97	4/1/2032	—	—	—	—
Kristin Wynholds	8/14/2020	2/1/2020	20,134	8,291(4)	—	0.47	8/13/2030	—	—	—	—
	4/6/2021	4/6/2021	32,126	49,955(7)	—	11.38	4/5/2031	—	—	—	—
	4/1/2022	4/1/2022	—	116,700 (4)	—	1.97	4/1/2032	—	—	—	—

(1) Unless otherwise specified, each equity award granted prior to our business combination in 2021 was granted under and is subject to the terms of our 2020 Stock Option and Grant Plan (the "2020 Plan") and all other awards granted following our business combination were granted under and subject to our 2021 Plan. Such awards are subject to certain acceleration of vesting provisions as set forth in the Executive Severance Plan or the named executive officer's employment agreement, as applicable.

(2) Each stock award was granted pursuant to individual restricted stock agreements between the Company and each applicable named executive officer. The stock awards represent the unvested common unit awards converted into Legacy BTX restricted stock in connection with its corporate reorganization in 2020. The grant date listed for such awards represent the original grant date of the equity award (i.e., the grant date of common units under our 2015 Equity Incentive Plan (the "2015 Plan"). Such awards are subject to certain acceleration of vesting provisions as set forth in the Executive Severance Plan or the named executive officer's employment agreement, as applicable.

(3) Based on the closing price of $1.105 per share of our common stock as of December 31, 2022.

(4) 25% of the shares subject to the equity award vest upon the one-year anniversary of the vesting commencement date and 1/48 of the shares subject to the equity award vest each month thereafter, subject to the named executive officer's continued service relationship with the Company through each applicable date.

(5) The shares subject to this award shall vest upon the achievement of both a time-based vesting condition and a performance-based vesting condition, such that such shares will satisfy the time-based vesting condition in four equal annual tranches following the vesting commencement date subject to Mr. Karbe's continued employment with us through each such date, and the shares will satisfy the performance-based vesting conditions in four equal parts (the "Performance Condition"). The Performance Condition will be satisfied 25% upon the occurrence of any of the following, in each case, prior to the fourth anniversary of the vesting commencement date: (i) the completion of a bona fide equity financing or partnership transaction with an unrelated third party with net aggregate cash proceeds or upfront net aggregate cash payment, respectively, of at least $40 million, (ii) the grant by the FDA of the *de novo* Classification Request (as defined in the Karbe Employment Agreement), (iii) the completion of a bona fide equity financing or partnership transaction with an unrelated third party with net aggregate cash proceeds or upfront net aggregate cash payment, respectively, of at least $60 million or (iv) the achievement of $5 million in cumulative net sales of our products and services as determined in accordance with GAAP.

(6) 50% of the shares subject to this award shall vest upon (i) our initial achievement of the Stock Price Hurdle (as defined in the Karbe Employment Agreement) equal to at least $30 million and (ii) our initial achievement of Revenue (as defined in the Karbe Employment Agreement) equal to at least $100 million, and the remaining 50% of the shares subject to this award shall vest upon (i) our initial achievement of a Stock Price Hurdle equal to at least $200 and (ii) our initial achievement of Revenue equal to at least $1 billion, in each, subject to Mr. Karbe's continued employment with us through each such date.

(7) 25% of the shares subject to the equity award vest upon the first year anniversary of the vesting commencement date, and 1/48th of the shares subject to the equity award vest each month thereafter, subject to the named executive officer's continued service relationship with the Company through each applicable date. Pursuant to the Separation Agreement, 98,704 shares are currently vested and outstanding.

(8) 494 of the shares to the equity award vest each month for the first 11 months following the vesting commencement date, and the remainder of the shares vest in 48 equal monthly installments commencing on January 3, 2020, subject to continued service relationship through each applicable vesting date. Upon the occurrence of the sale of the Company, all unvested shares will automatically vest.

Employee benefit and equity compensation plans and arrangements

2020 Stock Option and Grant Plan

Our 2020 Plan, allowed for the grant of incentive stock options to our employees and any of our subsidiary corporations' employees, and for the grant of incentive stock options, nonqualified stock options, restricted stock, unrestricted stock, and restricted stock units awards to our employees, officers, directors and consultants of ours and our subsidiary corporations. Our 2020 Plan was terminated in connection with the closing of our business combination (the "Closing"), and accordingly, no shares were available for future issuance under the 2020 Plan following the Closing. Our 2020 Plan will continue to govern outstanding awards granted thereunder.

Under the 2020 Plan, we had reserved for issuance an aggregate of 902,775 shares of our common stock. The number of shares of common stock reserved for issuance is subject to adjustment in the event of a stock dividend, stock split or combination of shares (including a reverse stock split), recapitalization or other change in our capital structure that constitutes an equity restructuring and no more than 902,775 shares may be issued pursuant to incentive stock options.

The 2020 Plan is administered by our board of directors or a committee appointed by it. The plan administrator has full power to, among other things, select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to accelerate the time at which a stock award may be exercised or vest, to amend the 2020 Plan and to determine the specific terms and conditions of each award, subject to the provisions of the 2020 Plan. The plan administrator may exercise its discretion to reduce the exercise price of outstanding options under the 2020 Plan or effect repricing through cancellation of such outstanding and by granting such holders new awards in replacement of the cancelled options.

Stock options could have been granted under our 2020 Plan. The exercise price per share of all options must equal at least 100% of the fair market value per share of our common stock on the date of grant. The term of an incentive stock option may not exceed ten years. An incentive stock option granted to a participant who owns more than 10% of the total combined voting power of all classes of our stock on the date of grant, or any subsidiary corporations, may not have a term in excess of five years and must have an exercise price of at least 110% of the fair market value per share of our common stock on the date of grant. The plan administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or certain other property or other considerations acceptable to the plan administrator. After a participant's termination of service, the participant generally may exercise his or her options, to the extent vested as of such date of termination, for 90 days after termination. If termination is due to death or disability, the option generally will remain exercisable, to the extent vested as of such date of termination, until the one-year anniversary of such termination. However, in no event may an option be exercised later than the expiration of its term. If termination is for cause, then an option automatically expires upon the date of the optionee's termination.

Restricted stock could have been granted under our 2020 Plan. Restricted stock awards are grants of shares of our common stock that are subject to various restrictions, including restrictions on transferability and forfeitures provisions. Shares of restricted stock will vest, and the restrictions on such shares will lapse, in accordance with terms and conditions established by the plan administrator.

Unrestricted stock could have been granted under our 2020 Plan. Unrestricted stock awards may have been granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Restricted stock units could have been granted under our 2020 Plan. A restricted stock unit is an award that covers a number of shares of our common stock that may be settled upon vesting in cash, by the issuance of the underlying shares or a combination of both. The plan administrator determines the terms and conditions of restricted stock units, including the number of units granted, the vesting criteria (which may include accomplishing specified performance criteria or continued service to us) and the form and timing of payment.

Our 2020 Plan generally does not allow for the transfer or assignment of awards, other than, at the discretion of the plan administrator, by gift to an immediate family member, to trusts for the benefit of family members, or to partnerships in which such family members are the only partners, and only the recipient of an award may exercise such an award during his or her lifetime.

In the event of certain changes in our capitalization, the exercise prices of and the number of shares subject to outstanding options, and the purchase price of and the numbers of shares subject to outstanding awards will be proportionately adjusted, subject to any required action by the Board or our stockholders.

The 2020 Plan provides that upon the effectiveness of a "sale event," as defined in the 2020 Plan, an acquirer or successor entity may assume, continue or substitute for the outstanding awards under the 2020 Plan. To the extent that awards granted under the 2020 Plan are not assumed or continued or substituted by the successor entity, all options and all other awards granted under the 2020 Plan shall terminate. In the event of such termination, individuals holding options will be permitted to exercise such options (to the extent exercisable) prior to the sale event. In addition, in connection with the termination of the 2020 Plan upon a sale event, we may make or provide for a cash payment equal to (A) in the case of vested and exercisable options, the difference between (1) the per share cash consideration payable to stockholders (as determined by the plan administrator) in the sale event times the number of shares subject to the options being cancelled and (2) the aggregate exercise price of the options and (B) in the case of restricted stock and restricted stock unit awards, the per share cash consideration payable to stockholders in the sale event multiplied by the number of shares of stock subject to such stock awards (payable at the time of the sale event or upon the later vesting of the awards). In the event of the forfeiture of shares of restricted stock issued under our 2020 Plan, such shares of restricted stock shall be repurchased from the holder at a price per share equal to the original per share purchase price paid by the recipient of such shares. Additionally, the Board may resolve, in its sole discretion, to subject any assumed options or payments in respect of options to any escrow, holdback, indemnification, earn-out or similar provisions in the transaction agreements as such provisions apply to holders of our common stock. The Board has determined not to grant any further awards under the 2020 Plan after the Closing. As of 12/31/2022, options to purchase up to 530,611 shares of common stock were outstanding under the 2020 Plan.

2015 Equity Incentive Plan

The 2015 Plan, was adopted by the board of directors of Better Therapeutics, LLC in June 2015. In connection with the Company's corporate reorganization in 2020, all awards for common units and profits interest units (as defined in the 2015 Plan) were cancelled and exchanged for common stock and restricted stock of Legacy BTX under its 2020 Plan. Following the Company's corporate reorganization in 2020, no further grants of any awards were or will be made under the 2015 Plan.

Employees, directors and consultants of Better Therapeutics, LLC and its subsidiaries were eligible to participate in the 2015 Plan.

The board of directors of Better Therapeutics, LLC administered the 2015 Plan. The plan administrator had the authority to select award recipients, determine the size, types and terms of awards, interpret the plan and prescribe, amend and rescind rules and make all other determinations necessary or desirable for the administration of the 2015 Plan.

The 2015 Plan originally reserved 1,664,097 common units available for issuance as awards under such plan. If awards were forfeited due to a failure to vest, the underlying common units were available for future grant under the 2015 Plan. Awards issued under the 2015 Plan were granted subject to the terms and conditions of the Limited Liability Company Agreement of Better Therapeutics, LLC, or the operating agreement, as well as the terms and conditions of the 2015 Plan.

In the event of any recapitalization, reorganization, merger, split-up, spin-off, subdivision of common units, repurchase, or exchange of common units or other securities of Better Therapeutics, LLC, or other change in capital structure of Better Therapeutics, LLC affecting the common units, the plan administrator will adjust the number and class of common units that may be delivered under the 2015 Plan, and/or the number, class and distribution threshold of common units covered by each outstanding award. In the event of a "sale of the business" (as defined in the operating agreement), the 2015 Plan provided each outstanding award will be subject to the operating agreement and to the agreement governing the sale of the business, which may provide for one of the following: (i) that awards will be assumed or substituted by the successor corporation; (ii) that outstanding awards will (A) be terminated in exchange for cash and/or property per profits interest unit equal to the value of a common unit in the sale of the business, minus the distribution threshold or (B) be replaced with other rights or pertly selected by the plan administrator in its sole discretion; (iii) any combination of the foregoing. No awards remain outstanding under the 2015 Plan.

Awards under the 2015 Plan were generally not transferrable other than by will or by the laws of descent and distribution. Awards under the 2015 Plan were subject to the transfer restrictions set forth in the operating agreement (the "Operating Agreement") and any special forfeiture conditions, rights of repurchase, rights of first refusal or other transfer restrictions as determined by the board of directors of Better Therapeutics, LLC.

The board of directors of Better Therapeutics, LLC had the authority to amend or modify the 2015 Plan at any time; provided, that any amendment that adversely affected rights under any outstanding award would have required consent by the holder of such award. The 2015 Plan was terminated in connection with the Company’s corporate reorganization in 2020.

Better Therapeutics, Inc. 2021 Stock Option and Incentive Plan

Our 2021 Plan was adopted by the board of directors prior to the Closing, subject to stockholder approval, and became effective upon the date immediately prior to the Closing (the "2021 Plan Effective Date"). The 2021 Plan allows us to make equity and equity-based incentive awards to officers, employees, directors and consultants. The Board anticipates that providing such persons with a direct stake in the Company will assure a closer alignment of the interests of such individuals with those of the Company and our stockholders, thereby stimulating their efforts on the Company’s behalf and strengthening their desire to remain with the Company.

We have initially reserved 3,600,000 shares of common stock of the Company for the issuance of awards under the 2021 Plan (the "Initial Limit"). The 2021 Plan provides that the number of shares reserved and available for issuance under the 2021 Plan will automatically increase each January 1, beginning on January 1, 2022, by 5% of the outstanding number of shares of common stock of the Company on the immediately preceding December 31, or such lesser amount as determined by the plan administrator (the "Annual Increase"). This limit is subject to adjustment in the event of a reorganization, recapitalization, reclassification, stock split, stock dividend, extraordinary cash dividend, reverse stock split or other similar change in the Company’s capitalization. The maximum aggregate number of shares of common stock of the Company that may be issued upon exercise of incentive stock options under the 2021 Plan shall not exceed the Initial Limit cumulatively increased on January 1, 2022 and on each January 1 thereafter by the lesser of the Annual Increase or 3,600,000 shares of common stock of the Company. Shares underlying any awards under the 2021 Plan or 2020 Plan that are forfeited, canceled, held back upon exercise of an option or settlement of an award to cover the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock or otherwise terminated (other than by exercise) will be added back to the shares available for issuance under the 2021 Plan and, to the extent permitted under Section 422 of the Code and the regulations promulgated thereunder, the shares that may be issued as incentive stock options.

The 2021 Plan contains a limitation whereby the value of all awards under the 2021 Plan and all other cash compensation paid by the Company to any non-employee director may not exceed $750,000 in any calendar year; provided, however, that such amount will be $1,000,000 for the first calendar year a non-employee director is initially appointed to the Company’s Board of Directors.

The 2021 Plan may be administered by the compensation committee of the Company's board of directors, the Company's Board of Directors or such other similar committee pursuant to the terms of the 2021 Plan. The plan administrator, which initially is the compensation committee of the board of directors, has full power to, among other things select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2021 Plan. The plan administrator may delegate to a committee consisting of one or more officers, including the chief executive officer, the authority to grant stock options and other awards to employees who are not subject to the reporting and other provisions of Section 16 of the Exchange Act and not members of the delegated committee, subject to certain limitations and guidelines. Persons eligible to participate in the 2021 Plan are officers, employees, non-employee directors and consultants of the Company and our subsidiaries as selected from time to time by the plan administrator in its discretion.

The 2021 Plan permits the granting of both options to purchase common stock of the Company intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. Options granted under the 2021 Plan will be non-qualified options if they fail to qualify as incentive stock options or exceed the annual limit on incentive stock options. Incentive stock options may only be granted to employees of the Company and our subsidiaries.

Non-qualified options may be granted to any persons eligible to receive awards under the 2021 Plan. The option exercise price of each option will be determined by the plan administrator but generally may not be less than 100% of the fair market value of the common stock of the Company on the date of grant or, in the case of an incentive stock option granted to a ten percent stockholder, 110% of such share's fair market value. The term of each option will be fixed by our plan administrator and may not exceed ten years from the date of grant. The plan administrator will determine at what time or times each option may be exercised, including the ability to accelerate the vesting of such options.

Upon exercise of options, the option exercise price must be paid in full either in cash, by certified or bank check or other instrument acceptable to the plan administrator or by delivery (or attestation to the ownership) of shares of common stock of the Company that are beneficially owned by the optionee free of restrictions or were purchased in the open market. Subject to applicable law, the exercise price may also be delivered by a broker pursuant to irrevocable instructions to the broker from the optionee. In addition, the plan administrator may permit non-qualified options to be exercised using a "net exercise" arrangement that reduces the number of shares issued to the optionee by the largest whole number of shares with fair market value that does not exceed the aggregate exercise price.

The plan administrator may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock of the Company, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price generally may not be less than 100% of the fair market value of common stock of the Company on the date of grant. The term of each stock appreciation right will be fixed by the plan administrator and may not exceed ten years from the date of grant. The plan administrator will determine at what time or times each stock appreciation right may be exercised.

The plan administrator may award restricted shares of common stock of the Company and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. The plan administrator may also grant shares of common stock of the Company that are free from any restrictions under the 2021 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant. The plan administrator may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock of the Company.

The plan administrator may grant cash-based awards under the 2021 Plan to participants, subject to the achievement of certain performance goals. The 2021 Plan requires the plan administrator to make appropriate adjustments to the number of shares of common stock that are subject to the

2021 Plan, to certain limits in the 2021 Plan, and to any outstanding awards to reflect stock dividends, stock splits, extraordinary cash dividends and similar events.

The 2021 Plan provides that upon the effectiveness of a "sale event," as defined in the 2021 Plan, an acquirer or successor entity may assume, continue or substitute for the outstanding awards under the 2021 Plan. To the extent that awards granted under the 2021 Plan are not assumed or continued or substituted by the successor entity, all awards granted under the 2021 Plan shall terminate and in such case except as may be otherwise provided in the relevant award agreement, all stock options and stock appreciation rights with time-based vesting conditions or restrictions that are not vested and/or exercisable immediately prior to the effective time of the sale event shall become fully vested and exercisable as of the effective time of the sale event, all other awards with time-based vesting conditions or restrictions shall become fully vested and nonforfeitable as of the effective time of the sale event, and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in connection with a sale event in the Board's discretion or to the extent specified in the relevant award agreement. In the event of such termination, individuals holding options and stock appreciation rights will, for each such award, either (a) receive a payment in cash or in kind for each share subject to such award that is exercisable in an amount equal to the per share cash consideration payable to stockholders in the sale event less the applicable per share exercise price (provided that, in the case of an option or stock appreciation right with an exercise price equal to or greater than the per share cash consideration payable to stockholders in the sale event, such option or stock appreciation right shall be cancelled for no consideration) or (b) be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified period of time prior to the sale event. The plan administrator shall also have the option (in its sole discretion) to make or provide for a payment, in cash or in kind, to the grantees holding other awards in an amount equal to the per share cash consideration payable to stockholders in the sale event multiplied by the number of vested shares under such awards.

Participants in the 2021 Plan are responsible for the payment of any federal, state or local taxes that the Company or our subsidiaries are required by law to withhold upon the exercise of options or stock appreciation rights or vesting of other awards. The plan administrator may cause any tax withholding obligation of the Company or our subsidiaries to be satisfied, in whole or in part, by the applicable entity withholding from shares of common stock of the Company to be issued pursuant to an award a number of shares with an aggregate fair market value that would satisfy the withholding amount due. The plan administrator may also require any tax withholding obligation of the Company or our subsidiaries to be satisfied, in whole or in part, by an arrangement whereby a certain number of shares issued pursuant to any award are immediately sold and proceeds from such sale are remitted to the Company or our subsidiaries in an amount that would satisfy the withholding amount due.

The 2021 Plan generally does not allow for the transfer or assignment of awards, other than by will or by the laws of descent and distribution or pursuant to a domestic relations order; however, the plan administrator may permit the transfer of non-qualified stock options by gift to an immediate family member, to trusts for the benefit of family members, or to partnerships in which such family members are the only partners.

The plan administrator may amend or discontinue the 2021 Plan and the plan administrator may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may materially and adversely affect rights under an award without the holder's consent. Certain amendments to the 2021 Plan will require the approval of the Company's stockholders.

No awards may be granted under the 2021 Plan after the date that is ten years from the 2021 Plan Effective Date. As of December 31, 2022, options to purchase up to 3,268,612 shares of common stock were outstanding under the 2021 Plan.

Better Therapeutics, Inc. 2021 Employee Stock Purchase Plan

An aggregate of 280,000 shares are reserved and available for issuance under our 2021 ESPP. The 2021 ESPP provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022, by the lesser of 560,000 shares of common stock of the Company, 1% of the outstanding number of shares of the common stock of the Company on the immediately preceding December 31, or such lesser amount as determined by the plan administrator. If our capital structure changes because of a stock dividend, subdivision of outstanding shares or similar event, the number of shares that can be issued under the 2021 ESPP will be appropriately adjusted.

The 2021 ESPP may be administered by the person or persons appointed by the board of directors. The plan administrator, which initially is the compensation committee of the board of directors, has full authority to make, administer and interpret such rules and regulations regarding the 2021 ESPP as it deems advisable.

Any employee of the Company or one of our subsidiaries that has been designated to participate in the 2021 ESPP is eligible to participate in the 2021 ESPP so long as the employee is customarily employed for more than 20 hours a week. No person who owns or holds, or as a result of participation in the 2021 ESPP would own or hold, common stock of the Company or options to purchase common stock of the Company, that together equal to 5% or more of total combined voting power or value of all classes of stock of the Company or any parent or subsidiary is entitled to participate in the 2021 ESPP. No employee may exercise an option granted under the 2021 ESPP that permits the employee to purchase common stock of the Company having a value of more than $25,000 (determined using the fair market value of the stock at the time such option is granted) in any calendar year.

Participation in the 2021 ESPP is limited to eligible employees who authorize payroll deductions equal to a whole percentage of base pay to the 2021 ESPP. Employees may authorize payroll deductions, with a minimum of 1% of base pay and a maximum of 15% of base pay. Once an employee becomes a participant in the 2021 ESPP, that employee will automatically participate in successive offering periods, as described below, until such time as that employee withdraws from the 2021 ESPP, becomes ineligible to participate in the 2021 ESPP, or his or her employment ceases.

Unless otherwise determined by the compensation committee, each offering of the Company's common stock under the 2021 ESPP will be for a period of 24 months, which we refer to as an "offering period." Each offering will consist of one or more purchase periods. Offerings under the 2021 ESPP will generally begin on the first trading day occurring on or after each December 1 and will end on the last trading day occurring on or before the November 30 that is two years later. Further, separate offerings under the 2021 ESPP will generally begin on the first trading day occurring on or after each June 1 and will end on the last trading day occurring on or before the May 31 that is two years later. Unless the plan administrator determines otherwise, each offering will be divided into four purchase periods. Shares are purchased on the last business day of each purchase period, with that day being referred to as an "exercise date." The plan administrator may establish different offering periods or exercise dates under the 2021 ESPP.

Unless as otherwise determined by the plan administrator, participants will only be permitted to participate in one offering at a time. Unless the plan administrator, in its sole discretion, chooses otherwise prior to an offering date, and to the extent an offering has more than one purchase period and to the extent permitted by applicable law, if the fair market value of the common stock on any exercise date in an offering is lower than the fair market value of the common stock on the offering date, then all participants in such offering automatically will be withdrawn from such offering immediately after the exercise of their option on such exercise date and automatically re-enrolled in the immediately following offering as of the first day thereof and the preceding offering will terminate.

On the exercise date of each purchase period, the employee is deemed to have exercised the option, at the exercise price for the lowest of (i) a number of shares of common stock of the Company determined by dividing such employee's accumulated payroll deductions or contributions on such exercise date by the exercise price; (ii) a number of shares of common stock of the Company determined by dividing $25,000 by the fair market value of the common stock on the first day of the offering; or (iii) such lesser number as established by the plan administrator in advance of the offering. The exercise price is equal to the lesser of (i) 85% the fair market value per share of common stock of the Company on the first day of the offering period or (ii) 85% of the fair market value per share of common stock of the Company on the exercise date.

In general, if an employee is no longer a participant on an exercise date, the employee's option will be automatically terminated, and the amount of the employee's accumulated payroll deductions will be refunded.

Except as may be permitted by the plan administrator in advance of an offering, a participant may not increase or decrease the amount of his or her payroll deductions during any purchase period but may increase or decrease his or her payroll deduction with respect to the next purchase period by filing a new enrollment form at least 15 business days before the next purchase period. A participant may also increase or decrease the amount of his or her payroll deductions with respect to the next offering period by filing a new enrollment form at least 15 business days before such offering period. A participant may withdraw from an offering period at any time without affecting his or her eligibility to participate in future offering periods. If a participant withdraws from an offering period, that participant may not again participate in the same offering period, but may enroll in subsequent offering periods. An employee's withdrawal will be effective as of the beginning of the next payroll period immediately following the date that the plan administrator receives the employee's written notice of withdrawal under the 2021 ESPP.

In the case of and subject to the consummation of a "sale event," the plan administrator, in its discretion, and on such terms and conditions as it deems appropriate, is hereby authorized to take any one or more of the following actions under the 2021 ESPP or with respect to any right under the 2021 ESPP or to facilitate such transactions or events: (a) to provide for either (i) termination of any outstanding option in exchange for an amount of cash, if any, equal to the amount that would have been obtained upon the exercise of such option had such option been currently exercisable or (ii) the replacement of such outstanding option with other options or property selected by the plan administrator in its sole discretion; (b) to provide that the outstanding options under the 2021 ESPP shall be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for similar options covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices;(c) to make adjustments in the number and type of shares of common stock of the Company (or other securities or property) subject to outstanding options under the 2021 ESPP and/or in the terms and conditions of outstanding options and options that may be granted in the future; (d) to provide that the offering and any applicable purchase period with respect to which an option relates will be shortened by setting a new exercise date on which such offering or applicable purchase period will end; and (e) to provide that all outstanding options shall terminate without being exercised and all amounts in the accounts of participants shall be promptly refunded.

The 2021 ESPP will automatically terminate on the 10-year anniversary of the 2021 ESPP effective date. The Company Board of Directors may, in its discretion, at any time, terminate or amend the 2021 ESPP.

Senior Executive Cash Incentive Bonus Plan

Our board of directors adopted the Senior Executive Cash Incentive Bonus Plan (the "Bonus Plan"), effective as of the Closing. The Bonus Plan provides for cash bonus payments based upon the attainment of performance targets established by our compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to our company, or corporate performance goals, as well as individual performance objectives.

The compensation committee may select corporate performance goals from among the following: research, preclinical, non-clinical, developmental, publication, clinical or regulatory milestones; scientific or technological advances; R&D capabilities; cash flow (including, but not limited to, operating cash flow and free cash flow); revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of the Company's common stock; economic value-added; acquisitions or strategic transactions, including licenses, collaborations, joint ventures or promotion arrangements; financing or other capital raising transactions; operating income (loss); return on capital, assets, equity, or investment; stockholder returns; return on sales; total shareholder return; gross or net profit levels; productivity; expense; efficiency; margins; operating efficiency; satisfaction of, or other achievement metrics relating to, key third parties; working capital; earnings (loss) per share of the Company's common stock; bookings, new bookings or renewals; sales or market shares; number of prescriptions or prescribing physicians; coverage decisions; leadership development, employee retention, and recruiting and other human resources matters; operating income and/or net annual recurring revenue, any of which may be (A) measured in absolute terms or compared to any incremental increase, (B) measured in terms of growth, (C) compared to another company or companies or to results of a peer group, (D) measured against the market as a whole and/or as compared to applicable market indices and/or (E) measured on a pre-tax or post-tax basis (if applicable).

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive officer. The corporate performance goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the corporate performance goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each such performance period, but no later than two and one-half months after the end of the fiscal year in which the performance period ends. Subject to the rights contained in any agreement between the executive officer and us, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment, unless otherwise determined by the compensation committee. The Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion and provides the compensation committee with discretion to adjust the size of the award as it deems appropriate.

DIRECTOR COMPENSATION

Non-Employee Director Compensation Policy

In connection with our business combination, we approved the non-employee director compensation policy described below, which is designed to align compensation with our business objectives and the creation of stockholder value, while enabling us to attract, retain, incentivize and reward directors who contribute to the long-term success of the Company.

Under the policy, our non-employee directors are eligible to receive cash retainers (which will be prorated for partial years of service) and equity awards as set forth below:

Annual Retainer for Board Membership		
Annual service on the board of directors	$	40,000
Additional retainer for annual service as non-executive chairperson	$	30,000
Additional retainer for annual service as a lead director of the board of directors	$	15,000
Additional Annual Retainer for Committee Membership		
Annual service as audit committee chairperson	$	15,000
Annual service as member of the audit committee (other than chair)	$	7,500
Annual service as compensation committee chairperson	$	10,000
Annual service as member of the compensation committee (other than chair)	$	5,000
Annual service as nominating and governance committee chairperson	$	8,000
Annual service as member of the nominating and governance committee (other than chair)	$	4,000

In addition, our policy provides that, upon initial election or appointment to our board of directors, each new non-employee director will be granted a non-statutory stock option to purchase 30,000 shares of our common stock (the "Director Initial Grant"). The Director Initial Grant will vest 1/3 on the first anniversary of the grant date and then in substantially equal monthly installments over the next two years. On the date of each annual meeting of stockholders of the Company following the completion of our business combination, each non-employee director who will continue as a non-employee director following such meeting will be granted an annual award of a non-statutory stock option to purchase 15,000 shares of our common stock (the "Director Annual Grant"). If a new non-employee director joins the board of directors between annual meetings of stockholders, then such non-employee director will be granted, at the next annual meeting of stockholders, a pro-rata portion of the Director Annual Grant based on the time between such director's appointment and our next annual meeting of stockholders. The Director Annual Grant will vest in full on the earlier of the one-year anniversary of the grant date or on the date of our next annual meeting of stockholders. The Director Initial Grant and Director Annual Grant are subject to full acceleration vesting upon the sale of the Company. All of the foregoing stock options would be granted with a per share exercise price equal to the fair market value of a share of our common stock on the date of grant and would have a 10 year term.

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any non-employee director of the Company in a calendar year period will not exceed $750,000 in the first calendar year such individual becomes a non-employee director and $1,000,000 in any other calendar year.

We will reimburse all reasonable out-of-pocket expenses incurred by directors for their attendance at meetings of the board of directors or any committee thereof.

Employee directors will receive no additional compensation for their service as a director.

Executive Chairman and Other Agreements

In connection with but prior to the consummation of our business combination, we entered into an executive chairperson agreement with Mr. Perry (the "Perry Agreement"), providing for standard terms of employment as the executive chairman of our board of directors, including an initial $260,000 annual base salary, eligibility to participate in the health and welfare benefits offered to full-time employees and the initial grant of a nonqualified stock option to purchase 28,300 shares of our common stock (the "Initial Option"), which will vest 1/3 on the first anniversary of the grant date and in equal monthly installments over the next two years, subject to Mr. Perry's continued service as a member of the board of directors on each applicable vesting date; provided, that the Initial Option shall fully vest in the event of a sale event (as defined in the Perry Agreement). In addition to the Initial Option, on each of the Company's annual meeting of stockholders, if Mr. Perry continues thereafter to be a member of the board of directors, he will receive a grant of a non-statutory stock option to purchase 11,800 shares of our common stock on the date of such annual meeting (the "Annual Grant"). The Annual Grant will vest in full on the earlier of (i) the one-year anniversary of the grant date or (ii) the Company's next annual meeting of stockholders, subject to Mr. Perry's continued service as a member of our board of directors on such vesting date; provided, that the Annual Grant shall fully vest in the event of a sale event. The Perry Agreement requires Mr. Perry to execute the Company's standard form of restrictive covenants agreement.

On June 7, 2022, the Company and Mr. Appelbaum agreed that Mr. Appelbaum would cease serving as President and Chief Executive Officer of the Company and as a member of our board of directors effective as the Effective Date. In addition, on June 8, 2022, the Board appointed Mr. Karbe as a director to the Board effective as of the Effective Date, to fill the vacancy created by Mr. Appelbaum's departure and to hold office until the 2023 annual meeting of stockholders, or until his earlier resignation or removal.

Director Compensation Table

The following table presents the total compensation for each person who served as a director of our board of directors during fiscal year 2022.

Neither Mr. Karbe nor Mr. Appelbaum received any additional compensation from the Company for his services on the board of directors. The compensation received by Messrs. Karbe and Appelbaum as named executive officers is set forth above in "Executive Compensation — 2022 Summary Compensation Table."

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Andrew Armanino (2)	55,000	—	10,499	—	65,499
Dr. Richard Carmona (3)	49,000	—	10,499	—	59,499
Dr. Elder Granger (4)	47,500	—	10,499	—	57,999
Dr. Risa Lavizzo-Mourey (5)	50,000	—	10,499	—	60,499
Dr. Suying Liu (6)	40,000	—	10,499	—	50,499
Geoffrey Parker (7)	55,500	—	10,499	—	65,999
David Perry (8)	—	—	10,499	260,000 (9)	270,499

(1) The amounts reported represent the aggregate grant date fair value of the stock options granted to our directors calculated in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the stock options reported in this column are set forth in Note 2 of our financial statements included elsewhere in this annual report. The amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the actual economic value that may be received by our directors upon the exercise of the stock options or any sale of the underlying shares of our common stock.

(2) As of December 31, 2022 Mr. Armanino held options to purchase 43,300 shares of our common stock.

(3) As of December 31, 2022 Dr. Carmona held options to purchase 43,300 shares of our common stock.

(4) As of December 31, 2022 Dr. Granger held options to purchase 43,300 shares of our common stock.

(5) As of December 31, 2022 Dr. Lavizzo-Mourey held options to purchase 43,300 shares of our common stock.

(6) As of December 31, 2022 Dr. Liu held options to purchase 43,300 shares of our common stock.

(7) As of December 31, 2022 Mr. Parker held options to purchase 43,300 shares of our common stock.

(8) As of December 31, 2022 Mr. Perry held options to purchase 43,300 shares of our common stock.

(9) The amount represents the salary received by Mr. Perry as the executive chairman of our board of directors.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Security ownership of certain beneficial owners

The following table sets forth certain information known to us regarding the beneficial ownership of our common stock as of December 31, 2022 for each of our named executive officers, executive officers, directors, all executive officers and directors as a group and each person known by us to be the beneficial owner of more than 5% of our common stock. Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security. Under those rules, beneficial ownership includes securities that the individual or entity has the right to acquire, such as through the exercise of warrants or stock options or the vesting of restricted stock units, within 60 days of December 31, 2022. Shares subject to warrants or options that are currently exercisable or exercisable within 60 days of December 31, 2022 or subject to restricted stock units that vest within 60 days of December 31, 2022 are considered outstanding and beneficially owned by the person holding such warrants, options or restricted stock units for the purpose of computing the percentage ownership of that person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Except as noted by footnote, and subject to community property laws where applicable, based on the information provided to us, we believe that the persons and entities named in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them. Unless otherwise noted, the business address of each of our directors and executive officers is c/o Better Therapeutics, Inc., 548 Market Street, #49404, San Francisco, California 94104. The percentage of beneficial ownership of our shares of common stock is calculated based on 23,851,022 shares of common stock outstanding as of December 31, 2022.

Name and Address of Beneficial Owners	Number of Shares	%
Greater than 5% holders:		
David P. Perry 2015 Trust[1]	10,892,607	45.6%
Kevin Appelbaum Revocable Trust[2]	2,511,673	10.5%
Mountain Crest Capital LLC[3]	1,388,250	5.8%
Named Executive Officers and Directors:		
David Perry[1]	10,892,607	45.6%
Frank Karbe[4]	50,000	*
Dr. Mark Berman [5]	272,169	1.1%
Kristin Wynholds[6]	156,068	*
Dr. Richard Carmona[7]	166,189	*
Andrew Armanino[8]	177,232	*
Geoffrey Parker[9]	105,903	*
Dr. Risa Lavizzo-Mourey[10]	22,570	*
Mark Heinen[11]	110,718	*
Dr. Suying Liu[12]	12,570	*
Dr. Elder Granger[13]	12,783	*
All directors and officers as a group (11 persons)	11,978,809	50.2%

* Less than 1%.

(1) Consists of (i) 10,464,015 shares held by the David P. Perry 2015 Trust, over which David P. Perry is the sole trustee and has sole voting and dispositive power, (ii) 101,536 shares held by Mr. Perry, (iii) 293,150 shares held by Mr. Perry's spouse, Georgianna Maule-Ffinch, (iv) 21,336 shares held by Donald R. Leo, Trustee of Pensus Limited Trust dated 06/12/2010 for the benefit of Georgianna Maule-Ffinch and (v) includes 12,570 shares which Mr. Perry has the right to acquire through exercise of stock options within 60 days from December 31, 2022.

(2) Consists of (i) 2,406,719 shares held by Kevin Appelbaum, or his successor(s), as Trustee of the Kevin Appelbaum Revocable Trust under Revocable Trust Declaration dated May 16, 2020, as amended, over which Mr. Appelbaum has sole voting and dispositive power, (ii) 6,250 shares held by Mr. Appelbaum and (iii) includes 98,704 shares which Mr. Appelbaum has the right to acquire through the exercise of stock options within 60 days of November 1, 2022.

(3) Information based on the Schedule 13G filed with the SEC on February 10, 2022 by Mountain Crest Capital LLC and Dong Liu. Consists of shares held by Mountain Crest Capital LLC, of which Mr. Dong Liu is the sole Managing Member and has sole voting and dispositive power. The address of Mountain Crest Capital LLC is 311 West 43rd Street, 12th Floor, New York, New York 10036. See also note (11) below.

(4) Consists of 50,000 shares held by Mr. Karbe.

(5) Includes 40,230 shares which Dr. Berman has the right to acquire through the exercise of stock options within 60 days from December 31, 2022.

(6) Includes 57,249 shares which Ms. Wynholds has the right to acquire through exercise of stock options within 60 days from December 31, 2022.

(7) Includes 12,570 shares which Dr. Carmona has the right to acquire through exercise of stock options within 60 days of December 31, 2022.

(8) Consists of (i) 151,328 shares held by Andrew J. Armanino III and Denise M. Armanino Family Trust, over which Mr. Armanino and his spouse, Denise M. Armanino, have shared voting and dispositive power, (ii) 13,334 shares held by Mr. Armanino and (iii) includes 12,570 shares which Mr. Armanino has the right to acquire through the exercise of stock options within 60 days from December 31, 2022.

(9) Consists of (i) 53,333 shares held by Geoffrey M. Parker and Jill G. Parker Rev Trust dtd 1/27/00, over which Mr. and Mrs. Parker have shared voting and dispositive power, (ii) 40,000 shares held by Mr. Parker and (iii) includes 12,570 shares which Mr. Parker has the right to acquire through exercise of stock options within 60 days from December 31, 2022.

(10) Includes 12,570 shares which Dr. Lavizzo-Mourey has the right to acquire through exercise of stock options within 60 days from December 31, 2022.

(11) Consists of (i) 70,000 shares held by Mr. Heinen, (ii) 2,280.605 shares held by Mr. Heinen's daughter and (iii) includes 22,715 shares which Mr. Heinen has the right to acquire through exercise of stock options within 60 days from December 31, 2022.

(12) Includes 12,570 shares which Dr. Liu has the right to acquire through exercise of stock options within 60 days from December 31, 2022. On October 28, 2021, Dr. Liu resigned from his Managing Member position at Mountain Crest Capital LLC, which owns 1,388,250 shares of our common stock. He disclaims any beneficial ownership except to the extent of his pecuniary interests in these shares. See also note (3) above.

(13) Includes 11,783 shares which Dr. Granger has the right to acquire through exercise of stock options within 60 days from December 31, 2022.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2022 with respect to shares of our common stock that may be issued under our existing equity compensation plans.

	Number of securities to be issued upon exercise of outstanding options , warrants and rights #(a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders [1]	3,799,223	4.09	2,098,650(3)(4)
Equity compensation plans not approved by the security holders [2]	200,000	1.43	400,000
Total	3,999,223	3.96	2,498,650

(1) Consists of our 2020 Plan, our 2021 Stock Option and Incentive Plan (the "2021 Plan"), and our 2021 ESPP. Following the closing of our business combination, we have not and will not grant any awards under our 2020 Plan, but all outstanding awards under such plan will continue to be governed by their existing terms. The shares of common stock underlying any awards granted under the 2020 Plan or 2021 Plan that are forfeited, canceled, reacquired by us prior to vesting, satisfied without the issuance of stock, or otherwise terminated (other than by exercise) and the shares of common stock that are withheld upon exercise of a stock option or settlement of such award to cover the exercise price or tax withholding will be added to the shares of common stock available for issuance under the 2021 Plan.

(2) Consists of our 2022 Inducement Plan adopted by the Company on November 30, 2022. The Inducement Plan is be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company (or following a bona fide period of non-employment with the Company), as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. The terms and conditions of the Inducement Plan are substantially similar to the Company's 2021 Plan with the exception that incentive stock options may not be granted under the Inducement Plan.

(3) Consists of shares available for future issuance under the 2021 ESPP and the 2021 Plan. As of December 31, 2022, 328,243 shares of common stock were available for issuance under the 2021 ESPP and 1,770,407 shares of common stock were available for issuance under the 2021 Plan.

(4) The 2021 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022, by 5% of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by our compensation committee. The 2021 ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2022, by the least of 560,000 shares of our common stock, 1% of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by our compensation committee. The number in the table does not include the increases made on January 1, 2023.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our officers and directors, and persons who own, or are part of a group that owns, more than ten percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. Officers, directors and greater than ten percent stockholders are required by regulation of the SEC to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of reports furnished to us, all reports required by Section 16(a) of the Exchange Act to be filed by our directors and executive officers and all beneficial owners of more than ten percent of our common stock outstanding to report transactions in our securities in fiscal year 2022 were timely filed.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Other than compensation and employment-related arrangements, including those described under the sections entitled "Executive Compensation" and "Director Compensation" in this Annual Report, and the transactions described below, since January 1, 2021, there has not been and there is not currently proposed, any transaction or series of similar transactions to which:

- we were, or will be, a participant;
- the amount involved exceeded, or will exceed, $120,000; and
- in which any director, executive officer, holder of 5% or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of the foregoing persons, had, or will have, a direct or indirect material interest.

Amended and Restated Registration Rights Agreement

In connection with our business combination, we entered in to an amended and restated registration rights agreement (the "Amended and Restated Registration Rights Agreement"), with Kevin Appelbaum Revocable Trust, an affiliate of Kevin Appelbaum, our former director and Chief Executive Officer and beneficial owner of more than 5% of our common stock, and David P. Perry 2015 Trust (the "Perry Trust"), an affiliate of David Perry, the Executive Chairman of our board of directors and beneficial owner of more than 5% of our common stock, Mountain Crest Capital LLC ("MCAD Sponsor"), a beneficial owner of more than 5% of our common stock, and certain affiliates of the MCAD Sponsor. The Amended and Restated Registration Rights Agreement amended and restated the Registration Rights Agreement dated January 7, 2021 by and among the Company, the MCAD Sponsor and its affiliates. The Amended and Restated Registration Rights Agreement required us to, among other things, file a resale registration statement on behalf of the stockholders no later than 30 days from the closing of the business combination. The Registration Rights Agreement also provided certain demand registration rights and piggyback registration rights to the stockholders, subject to underwriter cutbacks and issuer blackout periods. We agreed to pay certain fees and expenses relating to registrations under the Amended and Restated Registration Rights Agreement.

PIPE Subscription Agreements and Resale Registration Rights

In connection with our business combination, we entered into Subscription Agreements with certain PIPE investors for $50,000,000 in PIPE investment, including $100,000 subscribed by the Perry Trust and $13,500,000 subscribed by entities managed by Farallon Capital Management LLC ("Farallon"), a beneficial owner of more than 5% of our common stock as a result of such investment. The PIPE investment was consummated with the closing of the business combination. Pursuant to the Subscription Agreements, we agreed to file a registration statement registering the resale of the shares of common stock purchased in the private placement by the PIPE investors with the SEC no later than 30 calendar days following the closing of the business combination.

Private Placement

In connection with MCAD’s initial public offering on January 12, 2021, the MCAD Sponsor and Chardan Capital Markets, LLC ("Chardan"), purchased, pursuant to a written purchase agreement with MCAD, 185,000 private placement units for a total purchase price of $1,850,000, of which 135,000 private units were purchased by the MCAD Sponsor and 50,000 private units were purchased by Chardan. The private units were identical to the units sold in MCAD's initial public offering. Additionally, simultaneously with the sale of the over-allotment option, we consummated the private sale of an additional 15,000 private placement units, generating gross proceeds of $150,000. The Sponsor and Chardan agreed not to transfer, assign or sell any of the private placement units or underlying securities (except to the same permitted transferees as the insider shares and provided the transferees agree to the same terms and restrictions as the permitted transferees of the insider shares must agree to, each as described above) until the closing of the business combination.

Stock Purchase Agreement for the Sale of MCAD Shares

MCAD, the MCAD Sponsor and the Perry Trust entered into a stock purchase agreement pursuant to which the MCAD Sponsor transferred 200,000 shares of MCAD’s common stock held by the MCAD Sponsor to the Perry Trust upon the closing of the business combination for $1.8 million.

SAFE Financings

From August 14, 2020 to September 7, 2021, Legacy BTX issued SAFEs to the following affiliates of David Perry or his immediate family members: $22,101,878 in aggregate purchase amount to the Perry Trust and $1,015,738 in purchase amount to Belinda Barclay-White. Of such SAFEs, $8,672,617 were issued upon the exchange of then-outstanding convertible promissory notes as described above.

From August 24, 2020 to September 7, 2021, Legacy BTX issued SAFEs to Andrew Armanino, a member of our board of directors, or the following affiliates of Andrew Armanino or his immediate family members: $100,000 in purchase amount to the Andrew J. Armanino III and Denise M. Armanino Family Trust, $100,000 in purchase amount to Matt Armanino, and $300,000 in purchase amount to Andrew Armanino. Of such SAFEs, $300,000 were issued upon the exchange of then-outstanding convertible promissory notes as described above.

From April 7, 2021 to September 9, 2021, Legacy BTX sold and issued SAFEs to the following other related parties: $250,000 in purchase amount to Geoffrey M. Parker and Jill G. Parker Rev Trust, an affiliate of Geoffrey M. Parker, a director of the Company; $100,000 in purchase amount to Dr. Mark Berman, an executive officer of the Company; $50,000 in purchase amount to Mark Heinen, an officer of the Company; $5,000,000 in purchase amount to Farallon.

Policies and Procedures for Related Person Transactions

Our written related person transaction policy sets forth the following policies and procedures for the review and approval or ratification of related person transactions.

A "Related Person Transaction" is a transaction, arrangement or relationship in which we or any of our subsidiaries was, is or will be a participant, the amount of which involved exceeds $120,000, and in which any related person had, has or will have a direct or indirect material interest. A "Related Person" means:

- any person who is, or at any time during the applicable period was, one of our officers or one of our directors;
- any person who is known by us to be the beneficial owner of more than five percent (5%) of our voting stock;
- any immediate family member of any of the foregoing persons, which means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, daughter-in-law, brother-in-law or sister-in-law of a director, officer or a beneficial owner of more than five percent (5%) of the Company's voting stock, and any person (other than a tenant or employee) sharing the household of such director, officer or beneficial owner of more than five percent (5%) of the Company's voting stock; and
- any firm, corporation or other entity in which any of the foregoing persons is a partner or principal or in a similar position or in which such person has a ten percent (10%) or greater beneficial ownership interest.

The audit committee of our board of directors reviews and approves transactions with directors, officers and holders of 5% or more of the Company’s capital stock and their immediate family members, each a related party. Prior to a transaction, the material facts as to the related party’s relationship or interest in the transaction are disclosed to the board of directors prior to their consideration of such transaction, and the transaction is not considered approved by the board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. If advance review by the audit committee is not feasible, then the related person transaction shall be reviewed at the audit committee’s next regularly scheduled meeting.

The audit committee may review and pre-approve a list of related party transactions and each of the pre-approved transactions shall not be subject to further review by the audit committee under the terms of this policy. In connection with each regularly scheduled meeting of the audit committee, a summary of any new related party transactions deemed pre-approved (other than director and executive compensation arrangements) shall be provided to the audit committee for its review. If a related party transaction will be ongoing, the audit committee may establish guidelines for the Company’s management to follow in its ongoing dealings with the related person. Thereafter, on at least an annual basis, the audit committee will review and assess such ongoing related party transaction and confirm that the ongoing dealings with the related person have been in compliance with the guidelines established by the audit committee.

Item 14. Principal Accounting Fees and Services.

Our independent registered accounting firm is Elliott Davis, LLC, Greenville, South Carolina, PCAOB ID Number 149.

Independent Registered Public Accounting Firm Fees

The following is a summary and description of aggregate fees agreed to be paid by the Company for professional services rendered by Elliott Davis, LLC for the fiscal years ended December 31, 2022 and 2021.

	Year Ended December 31,	
Fee Category	**2022**	**2021**
Audit Fees[1]	$ 229,500	$ 124,500
Audit Related Fees [2]	-	98,000
Tax Fees [3]	-	-
Other Fees	-	-
Total	$ 229,500	$ 222,500

The following is a summary and description of aggregate fees agreed to be paid by the Company for professional services rendered by Marcum LLC, our prior independent auditors, for the fiscal year ended December 31, 2021.

Fee Category	Years Ended December 31, 2021
Audit Fees[1]	$ 57,000
Audit Related Fees [2]	42,000
Tax Fees [3]	7,000
Other Fees	-
Total	$ 106,000

(1) "Audit Fees" consist of fees for professional services provided in connection with the annual audits of our financial statements and internal control over financial reporting, review of our quarterly financial statements, accounting matters directly related to the annual audits, professional services in connection with SEC registration statements, periodic reports (including Form 8-Ks), and other documents filed with the SEC or other documents issued in connection with securities offerings, and professional services provided in connection with other statutory or regulatory filings.

(2) "Audit Related Fees" consist of fees for professional services provided in connection with MCAD's initial public offering and the business combination.

(3) "Tax Fees" consist of fees for services related to tax compliance.

All audit fees relating to the audit for the fiscal years ended December 31, 2022 and 2021 were approved in advance by the audit committee. All audit and non-audit services to be provided by our independent auditors were, and will continue to be, pre-approved by the audit committee.

The audit committee has considered the nature and amount of fees billed by Elliott Davis, LLC and Marcum LLC and believes that the provision of services for activities unrelated to the audit was compatible with maintaining their independence.

Pre-Approval Policies and Procedures

Our audit committee has adopted procedures requiring the pre-approval of all non-audit services performed by our independent registered public accounting firm in order to assure that these services do not impair the auditor's independence. These procedures generally approve the performance of specific services subject to a cost limit for all such services. This general approval is to be reviewed, and if necessary modified, at least annually. Management must obtain the specific prior approval of the audit committee for each engagement of the independent registered public accounting firm to perform other audit-related or other non-audit services. The audit committee does not delegate its responsibility to approve services performed by the independent registered public accounting firm to any member of management.

The standard applied by the audit committee in determining whether to grant approval of any type of non-audit service, or of any specific engagement to perform a non-audit service, is whether the services to be performed, the compensation to be paid for such services and other related factors are consistent with the independent registered public accounting firm's independence under guidelines of the SEC and applicable professional standards. Relevant considerations include whether the work product is likely to be subject to, or implicated in, audit procedures during the audit of our financial statements, whether the independent registered public accounting firm would be functioning in the role of management or in an advocacy role, whether the independent registered public accounting firm's performance of the service would enhance our ability to manage or control risk or improve audit quality, whether such performance would increase efficiency because of the independent registered public accounting firm's familiarity with our business, personnel, culture, systems, risk profile and other factors, and whether the amount of fees involved, or the non-audit services portion of the total fees payable to the independent registered public accounting firm in the period would tend to reduce the independent registered public accounting firm's ability to exercise independent judgment in performing the audit.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) (1) For a list of the financial statements included herein, see Index to the Financial Statements on page F-1 of this Annual Report, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the financial statements or the notes thereto.

(3) The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report are listed in the Exhibit Index below. The exhibits listed in the Exhibit Index are incorporated by reference herein.

(b) Exhibits

Exhibit Index

Exhibit Number	Description
2.1+	Agreement and Plan of Merger, dated as of April 6, 2021, by and among MCAD, Merger Sub and BTX, as amended by the Amendment to Agreement and Plan of Merger, dated as of August 30, 2021 and the Second Amendment to Agreement and Plan of Merger, dated as of September 27, 2021 (incorporated by reference to Annex A to our Proxy Statement/Prospectus for Special Meeting filed pursuant to Rule 424(b)(3)) filed with the SEC on October 12, 2021).
3.1	Second Amended and Restated Certificate of Incorporation of Better Therapeutics, Inc., filed October 28, 2021 (incorporated by reference to Exhibit 3.1 to our Form 8-K filed with the SEC on November 3, 2021).
3.2	Amended and Restated Bylaws of Better Therapeutics, Inc., effective October 28, 2021 (incorporated by reference to Exhibit 3.2 of our Form 8-K filed with the SEC on November 3, 2021).
4.1	Amended and Restated Registration Rights Agreement, dated as of October 28, 2021 by and among Better Therapeutics, Inc., and each of the other shareholders party thereto. (incorporated by reference to Exhibit 10.16 of our Form 8-K filed with the SEC on November 3, 2021).
4.2	Subscription Agreement dated October 28, 2021 by and among MCAD and Cowen and Company, LLC. (incorporated by reference to Exhibit 10.17 of our Form 8-K filed with the SEC on November 3, 2021).
4.3	Form of Subscription Agreement, dated as of April 6, 2021, by and among MCAD and certain institutional and accredited investors (incorporated by reference to Exhibit 10.3 to our Form 8-K filed with the SEC on April 7, 2021).
4.4	Description of the Registrant's Securities (incorporated by reference to Exhibit 4.4 to our Annual Report on Form 10-K filed with the SEC on March 28, 2022).
10.1†	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the SEC on November 3, 2021).
10.2†	2021 Option and Incentive Plan, as amended, and forms of award agreements thereunder (incorporated by reference to Exhibit 10.2 of our Form 8-K filed with the SEC on November 3, 2021).
10.3†	2020 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.3 of our Form 8-K filed with the SEC on November 3, 2021).
10.4†*	2022 Inducement Plan.
10.5†	Executive Severance Plan (incorporated by reference to Exhibit 10.16 to our Registration Statement on Form S-4 filed with the SEC on April 23, 2021, as amended through amendment no. 5 thereto).
10.6†	Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.5 of our Form 8-K filed with the SEC on November 3, 2021).
10.7†	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.6 of our Form 8-K filed with the SEC on November 3, 2021).
10.8†	Form of Director Indemnification Agreement (incorporated by reference to Exhibit 10.7 of our Form 8-K filed with the SEC on November 3, 2021).
10.9†	Form of Officer Indemnification Agreement (incorporated by reference to Exhibit 10.8 of our Form 8-K filed with the SEC on November 3, 2021).
10.10†	Executive Chairperson Offer Letter by and between Better Therapeutics, Inc. and David P. Perry, dated as of October 28, 2021 (incorporated by reference to Exhibit 10.9 of our Form 8-K filed with the SEC on November 3, 2021).
10.11†	Offer Letter by and between Better Therapeutics OpCo, Inc. (successor to Nutrition Development Group LLC) and Mark Berman, dated as of November 23, 2015 (incorporated by reference to Exhibit 10.17 to our Registration Statement on Form S-4 filed with the SEC on April 23, 2021, as amended through amendment no. 5 thereto).
10.12†	Offer Letter by and between Better Therapeutics OpCo, Inc. (successor to Better Therapeutics LLC) and Kristin Wynholds, dated as of October 9, 2018 (incorporated by reference to Exhibit 10.18 to our Registration Statement on Form S-4 filed with the SEC on April 23, 2021, as amended through amendment no. 5 thereto).
10.13†	Offer Letter by and between Better Therapeutics OpCo, Inc. (formerly, Better Therapeutics, Inc.) and Mark Heinen, dated as of May 7, 2021 (incorporated by reference to Exhibit 10.21 to our Registration Statement on Form S-4 filed with the SEC on April 23, 2021, as amended through amendment no. 5 thereto).
10.14†	Separation Agreement and Release by and among Better Therapeutics, Inc., Better Therapeutics OpCo, Inc., Kevin Appelbaum and other parties listed thereto, effective as of July 5, 2022 (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the SEC on June 13, 2022).

10.15†	Employment Offer Letter by and among Better Therapeutics, Inc., Better Therapeutics OpCo, Inc., and Frank Karbe, dated as of July 5, 2022 (incorporated by reference to Exhibit 10.2 of our Form 8-K filed with the SEC on June 13, 2022).
10.16	Loan and Security Agreement by and between Better Therapeutics OpCo, Inc. (formerly, Better Therapeutics, Inc.) and Hercules Capital, Inc. dated August 18, 2021 (incorporated by reference to Exhibit 10.23 to our Registration Statement on Form S-4 filed with the SEC on April 23, 2021, as amended through amendment no. 5 thereto).
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 of our Form 8-K filed with the SEC on November 3, 2021).
23.1*	Consent of Elliott Davis, LLC, independent registered public accounting firm.
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.
** Furnished herewith. This certification is being furnished solely to accompany this report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filings of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
+ Certain schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.
† Management contract or compensation plan or arrangement.

(c) Financial Statement Schedules

No financial statements have been submitted because they are not required or are not applicable or because the information required is included in the financial statements or the notes thereto.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

BETTER THERAPEUTICS, INC.

Date: March 30, 2023

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

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

Name	Title	Date
/s/Frank Karbe Frank Karbe	Director, President and Chief Executive Officer (Principal Executive Officer)	March 30, 2023
/s/David P. Perry David P. Perry	Executive Chairman and Director	March 30, 2023
/s/Mark Heinen Mark Heinen	Head of Finance and Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 30, 2023
/s/Richard Carmona Richard Carmona	Director	March 30, 2023
/s/Geoffrey Parker Geoffrey Parker	Director	March 30, 2023
/s/Andrew Armanino Andrew Armanino	Director	March 30, 2023
/s/Risa Lavizzo-Mourey Risa Lavizzo-Mourey	Director	March 30, 2023
/s/Suying Liu Suying Liu	Director	March 30, 2023
/s/Elder Granger Elder Granger	Director	March 30, 2023