

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-39864

**BETTER THERAPEUTICS, INC.**

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**548 Market St. #49404**

**San Francisco, CA**

(Address of principal executive offices)

**85-3472546**

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

**94104**

(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	The Nasdaq Stock Market LLC

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

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

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

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

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

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

As of November 3, 2023, the registrant had 47,403,398 shares of common stock, \$0.0001 par value per share, outstanding.

## Table of Contents

	<u>Page</u>
<a href="#"><u>Special Note Regarding Forward-Looking Statements</u></a>	2
<b>PART I.</b> <a href="#"><u>FINANCIAL INFORMATION</u></a>	4
Item 1. <a href="#"><u>Financial Statements</u></a>	4
<a href="#"><u>Condensed Balance Sheets</u></a>	4
<a href="#"><u>Condensed Statements of Operations and Comprehensive Loss</u></a>	5
<a href="#"><u>Condensed Statements of Stockholders' (Deficit)/Equity</u></a>	6
<a href="#"><u>Condensed Statements of Cash Flows</u></a>	7
<a href="#"><u>Notes to Condensed Financial Statements</u></a>	8
Item 2. <a href="#"><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></a>	18
Item 3. <a href="#"><u>Quantitative and Qualitative Disclosures About Market Risk</u></a>	30
Item 4. <a href="#"><u>Controls and Procedures</u></a>	30
<b>PART II.</b> <a href="#"><u>OTHER INFORMATION</u></a>	31
Item 1. <a href="#"><u>Legal Proceedings</u></a>	31
Item 1A. <a href="#"><u>Risk Factors</u></a>	31
Item 2. <a href="#"><u>Unregistered Sales of Equity Securities and Use of Proceeds</u></a>	73
Item 3. <a href="#"><u>Defaults Upon Senior Securities</u></a>	73
Item 4. <a href="#"><u>Mine Safety Disclosures</u></a>	73
Item 5. <a href="#"><u>Other Information</u></a>	74
Item 6. <a href="#"><u>Exhibits</u></a>	75
<a href="#"><u>Signatures</u></a>	76

## SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

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

- our 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 AspyreRx™ (formerly 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 AspyreRx 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 additional 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 AspyreRx and our other 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 AspyreRx and our other 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 AspyreRx and our other product candidates, if authorized for marketing;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- expectations regarding the use of proceeds from our financings;
- potential delisting from the Nasdaq Capital Market;
- 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 conflicts in Ukraine and Israel, and public health events on the foregoing; and
- other risks and uncertainties including those discussed in Part II, Item 1A - Risk Factors in this Quarterly Report.

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

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2023 (unaudited)	December 31, 2022 (audited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 6,598	\$ 15,740
Prepaid expenses	674	2,496
Other current assets	73	210
Total current assets	<u>7,345</u>	<u>18,446</u>
Capitalized software development costs, net	2,792	3,888
Property and equipment, net	102	121
Other long-term assets	483	488
Total Assets	<u>\$ 10,722</u>	<u>\$ 22,943</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 2,308	\$ 3,035
Accrued payroll	1,886	2,301
Other accrued expenses	2,158	3,626
Current portion of long-term debt	6,586	4,532
Total current liabilities	<u>12,938</u>	<u>13,494</u>
Long-term debt, net of current portion and debt issuance costs	7,721	10,348
Total liabilities	<u>20,659</u>	<u>23,842</u>
Commitments and contingencies (Note 8)		
Stockholders' deficit:		
Common stock, \$0.0001 par value per share, 200,000,000 shares authorized as of September 30, 2023 and December 31, 2022 and 40,577,987 and 23,851,022 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	4	2
Additional paid-in capital	124,370	110,602
Accumulated deficit	<u>(134,311)</u>	<u>(111,503)</u>
Total Stockholders' Deficit	<u>(9,937)</u>	<u>(899)</u>
Total Liabilities and Stockholders' Deficit	<u>\$ 10,722</u>	<u>\$ 22,943</u>

The accompanying notes are in integral part of these Financial Statements

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 1,833	\$ 5,477	\$ 7,462	\$ 13,391
Sales and marketing	1,392	1,557	5,200	5,284
General and administrative	2,116	3,962	8,629	11,265
Total operating expenses	<u>5,341</u>	<u>10,996</u>	<u>21,291</u>	<u>29,940</u>
Loss from operations	(5,341)	(10,996)	(21,291)	(29,940)
Interest expense, net	(518)	(406)	(1,512)	(1,052)
Loss before provision for income taxes	(5,859)	(11,402)	(22,803)	(30,992)
Provision for income taxes	3	3	5	3
Net loss	<u>\$ (5,862)</u>	<u>\$ (11,405)</u>	<u>\$ (22,808)</u>	<u>\$ (30,995)</u>
Net loss per share, basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.48)</u>	<u>\$ (0.73)</u>	<u>\$ (1.32)</u>
Weighted-average shares used in computing net loss per share	<u>38,495,150</u>	<u>23,693,154</u>	<u>31,214,093</u>	<u>23,533,290</u>

The accompanying notes are in integral part of these Financial Statements

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance as of December 31, 2022	23,851,022	\$ 2	\$ 110,602	\$ (111,503)	\$ (899)
Net loss	—	—	—	(9,357)	(9,357)
Issuance of common stock under equity incentive plans	1,250	—	—	—	—
Share-based compensation	—	—	423	—	423
Balance as of March 31, 2023	23,852,272	\$ 2	\$ 111,025	\$ (120,860)	\$ (9,833)
Net loss	—	—	—	(7,589)	(7,589)
Issuance of common stock, net of issuance costs	7,878,786	1	6,099	—	6,100
Issuance of common stock under equity incentive plans	66,043	—	41	—	41
Share-based compensation	—	—	493	—	493
Balance as of June 30, 2023	31,797,101	\$ 3	\$ 117,658	\$ (128,449)	\$ (10,788)
Net loss	—	—	—	(5,862)	(5,862)
Issuance of common stock, net of issuance costs	8,780,886	1	6,278	—	6,279
Share based compensation	—	—	434	—	434
Balance as of September 30, 2023	40,577,987	\$ 4	\$ 124,370	\$ (134,311)	\$ (9,937)

  

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of December 31, 2021	23,602,718	\$ 2	\$ 108,461	\$ (71,743)	\$ 36,720
Net loss	—	—	—	(9,662)	(9,662)
Issuance of common stock under equity incentive plans	5,882	—	1	—	1
Share-based compensation	—	—	366	—	366
Balance as of March 31, 2022	23,608,600	\$ 2	\$ 108,828	\$ (81,405)	\$ 27,425
Net loss	—	—	—	(9,928)	(9,928)
Issuance of common stock under equity incentive plans	124,370	—	145	—	145
Share-based compensation	—	—	412	—	412
Balance as of June 30, 2022	23,732,970	\$ 2	\$ 109,385	\$ (91,333)	\$ 18,054
Net loss	—	—	—	(11,405)	(11,405)
Issuance of common stock	11,093	—	6	—	6
Share based compensation	—	—	597	—	597
Balance as of September 30, 2022	23,744,063	\$ 2	\$ 109,988	\$ (102,738)	\$ 7,252

The accompanying notes are in integral part of these Financial Statements

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

	<b>Nine Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (22,808)	\$ (30,995)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,393	2,008
Share-based compensation expense	1,315	1,375
Loss on write-off of property and equipment	—	9
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,965	3,560
Accounts payable	(727)	(268)
Accrued expenses and other liabilities	(1,884)	1,718
Net cash used in operating activities	<u>(19,746)</u>	<u>(22,593)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(31)	(92)
Capitalized internal-use software costs	(927)	(728)
Net cash used in investing activities	<u>(958)</u>	<u>(820)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from the issuance of shares under the PIPE and registered direct investment	13,223	—
Payment of costs directly attributable to the issuance of common stock in connection with the PIPE and registered direct investment	(844)	—
Proceeds from exercise of common stock options	—	27
Proceeds from the issuance of shares under the employee stock purchase plan	41	125
Proceeds from the issuance of long-term debt	—	5,000
Payment on long-term debt	(858)	—
Net cash provided by financing activities	<u>11,562</u>	<u>5,152</u>
Net change in cash and cash equivalents	<u>(9,142)</u>	<u>(18,261)</u>
Cash and cash equivalents, beginning of period	15,740	40,566
Cash and cash equivalents, end of period	<u>\$ 6,598</u>	<u>\$ 22,305</u>
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid for interest	<u>\$ (1,054)</u>	<u>\$ (870)</u>

The accompanying notes are in integral part of these Financial Statements

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

***Description of Business***

The Company's mission is to advance human health through the power of behavior change.

Better Therapeutics, Inc. (the "Company" or "Better"), a Delaware corporation, is a prescription digital therapeutics ("PDT") company developing U.S Food and Drug Administration ("FDA") regulated cognitive behavioral therapy ("CBT") that is accessed via an app on a patient's smartphone to address the root causes of cardiometabolic diseases ("CMDx"). The Company's clinically validated PDTs are intended to be prescribed by physicians and reimbursed by payers like traditional medicines. The mechanism of action embedded in its PDTs is a novel form of CBT developed by Better Therapeutics, targeting the specific behaviors that cause and contribute to the progression of the diseases it seeks to treat. The CBT delivered by its PDTs is designed to enable changes in neural pathways of the brain so that lasting changes in behavior become possible.

The Company's first commercial product, AspyreRx™ (formerly BT-001), was authorized by the FDA to treat Type 2 Diabetes ("T2D"), in July 2023 and launched commercially in October 2023. AspyreRx is the first FDA-authorized digital behavioral therapeutic delivering CBT for the treatment of a cardiometabolic disease. The Company's pipeline also includes programs for the treatment of hypertension, hyperlipidemia, Metabolic Dysfunction-Associated Steatotic Liver Disease ("MASLD"), Metabolic Dysfunction-Associated Steatohepatitis ("MASH") and chronic kidney disease. 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 and medical devices.

AspyreRx is a prescription-only digital treatment indicated to provide cognitive behavioral therapy to patients 18 years or older with T2D. The device targets behavior to aid in the treatment of T2D adjunctively with standard-of-care in patients who are under the care of a healthcare provider. AspyreRx was reviewed through the FDA's *de novo* pathway and its authorization created a new class of diabetes digital behavioral therapeutic devices. The Company envisions AspyreRx becoming part of the standard-of-care for adult patients with T2D given the clinical evidence supporting its efficacy and safety, its broad label to treat all adult patients with T2D across the entire disease spectrum, its mechanism of action in-line with existing treatment guidelines, its broad accessibility to anyone with a smartphone and the potential cost savings the utilization of AspyreRx can generate for payers and health systems.

In September 2023, the Company completed enrollment in its real-world evidence studies to evaluate the long-term effectiveness and healthcare utilization changes associated with the use of AspyreRx for the treatment of T2D. The randomized, controlled, multi-site studies enrolled patients for a treatment period of at least 12 months. Change in A1c and healthcare resource utilization will be evaluated and compared to standard of care. The study seeks to provide payers and providers with long-term data related to usage and outcomes in a real-world like setting.

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 MASLD and MASH (formerly known as NAFLD/NASH). The results of this study were published in the peer reviewed journal Gastro Hep Advances in October 2023. 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 submit a request to the FDA for Breakthrough Device Designation for its investigational CBT-based treatment platform by the end of 2023.

The Company has combined medical, behavioral and data sciences to develop a clinically validated software-based therapeutics platform targeting behavioral change at scale. The Company's 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. AspyreRx and its other PDTs, if authorized by the FDA, are intended to be prescribed by physicians and reimbursed by health insurance providers.

The Company is a remote, "fully distributed" company, and does not have offices.

### ***Financings***

On April 6, 2023, the Company entered into a Securities Purchase Agreement with certain investors pursuant to which it issued and sold an aggregate of 7,878,786 shares of its common stock to such investors, for an aggregate purchase price of approximately \$6.5 million in private placement (the "April Private Placement"). The April Private Placement closed on April 10, 2023.

On July 25, 2023, the Company entered into a Securities Purchase Agreement with certain investors pursuant to which it issued and sold 2,897,654 shares of its common stock for an aggregate purchase price of \$2.1 million in a private placement (the "July Private Placement"). The July Private Placement closed on July 27, 2023.

On July 25, 2023, the Company also entered into a Securities Purchase Agreement with a single investor pursuant to which it issued and sold 3,859,649 shares of its common stock for an aggregate purchase price of \$2.2 million in a registered direct offering (the "July Registered Direct Offering"). The July Registered Direct Offering closed on July 27, 2023.

The Company used the net proceeds from the April Private Placement, July Private Placement and July Registered Direct Offering to support the execution of key milestones, including commercial launch of the FDA authorized AspyreRx.

### ***"At-the-Market" Offering***

On May 11, 2023, the Company entered into an ATM Sales Agreement (the "Sales Agreement") with Virtu Americas LLC ("Virtu") pursuant to which the Company may issue and sell up to an aggregate amount of \$6.9 million in shares of its common stock (the "ATM Shares") from time to time, at its discretion, through Virtu as its sales agent or principal. Subject to the terms of the Sales Agreement, Virtu may sell the ATM Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act of 1933, as amended the ("Securities Act"), including, without limitation, sales made through the Nasdaq Capital Market or on any other existing trading market for the Company's common stock. The Company may sell the ATM Shares in amounts and at times to be determined by the Company from time to time subject to the terms and conditions of the Sales Agreement, but it has no obligation to sell any ATM Shares under the Sales Agreement. The Company or Virtu may suspend or terminate the offering upon notice to the other party and subject to other conditions.

In July 2023, the Company issued and sold 2,023,583 shares of its common stock in "at-the-market" offerings pursuant to the Sales Agreement for an aggregate purchase price of \$2.4 million. The Company used the net proceeds from the July ATM sales to support the execution of key milestones, including commercial launch of the FDA authorized AspyreRx. On July 25, 2023, the Company delivered written notice to Virtu that it was suspending and terminating the prospectus related to the common stock issuable pursuant to the terms of the Sales Agreement. In August 2023, the Company filed a new ATM prospectus supplement related to the ATM shares. As a result, the Company may issue and sell up to an aggregate of \$3.5 million in ATM Shares from time to time pursuant to the Sales Agreement.

### ***Basis of Presentation***

The financial statements and accompanying notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding interim financial reporting. Certain information and disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments consisting of normal recurring accruals considered necessary for fair presentation have been included. Operating results for the three and nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the year ended December 31, 2023. Accordingly, these interim financial statements should be read in conjunction with the audited financial statements and accompanying notes for the years ended December 31, 2022 and 2021.

### ***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.

### ***Nasdaq Delisting Notice***

On April 5, 2023, the Company received a deficiency letter (the "April Letter") from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market ("Nasdaq") notifying the Company that it was not in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market. The April Letter further noted that as of its date, the Company did not have a market value of listed securities of \$35 million, or net income from continued operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years, the alternative quantitative standards for continued listing on the Nasdaq Capital Market. In accordance with Nasdaq rules, the Company was provided 45 calendar days, or until May 19, 2023, to submit a plan to regain compliance (the "Compliance Plan"), with an extension of 180 calendar days to evidence compliance with the Stockholders' Equity Requirement if the Compliance Plan is acceptable to the Staff. On April 24, 2023, the Company received a letter from Nasdaq notifying the Company that it had regained compliance with Nasdaq's continued listing standards by demonstrating compliance with Nasdaq's alternative standard of market value of listed securities in excess of \$35 million under Nasdaq Listing Rule 5550(b)(2) and that the matter was closed.

On June 16, 2023 the Company received deficiency letters (the "June Letters") from the Staff notifying the Company that it was not in compliance with the minimum bid price requirement and the market value of listed securities requirement for continued listing on the Nasdaq Capital Market. The June Letters noted that, as of their date, the bid price of the Company's common stock was below \$1 per share and the Company's market value of listed securities was below \$35 million, in each case for 30 consecutive business days. In accordance with Nasdaq rules, the Company has been provided 180 calendar days, or until December 13, 2023, to regain compliance. The June Letters are only a notification of deficiency, not of imminent delisting, and have no current effect on the listing or trading of the Company's securities on the Nasdaq Capital Market.

### ***Liquidity and Capital Resources***

The Company has been in the development stage and its activities have consisted principally of raising capital, performing research and development and preparing for the commercial launch of AspyreRx. Since inception the Company has incurred significant losses from operations. As of September 30, 2023, the Company had cash of \$6.6 million and an accumulated deficit of \$134.3 million. In April 2023, the Company completed a private placement of shares of the Company's common stock for an aggregate purchase price of \$6.5 million. In July 2023, the Company issued and sold 2,023,583 shares of its common stock in "at-the-market" offerings pursuant to the Sales Agreement for an aggregate purchase price of \$2.4 million. Also in July 2023, the Company issued and sold 2,897,654 shares of common stock in a private placement for an aggregate purchase price of \$2.1 million and issued and sold 3,859,649 shares of common stock in a registered direct offering for an aggregate purchase price of \$2.2 million. In October 2023 the Company issued and sold 6,825,411 shares of its common stock in "at-the-market" offerings pursuant to the Sales Agreement for an aggregate purchase price of \$2.9 million (See Note 10). The Company incurred a net loss of \$22.8 million and used \$19.7 million of cash in operating activities during the nine months ended September 30, 2023. The Company's primary use of cash is to fund operating expenses, which predominantly relate to the commercial launch of AspyreRx 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.

**BETTER THERAPEUTICS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
(Unaudited)

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 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, 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 future product candidates, as well as to build the sales, marketing and distribution infrastructure that it believes will be necessary to commercialize AspyreRx and its future product candidates, if approved, the Company will require substantial additional funding in the future. Under its current operating plan and taking into account the proceeds raised under its ATM program in October 2023, the Company believes it has sufficient capital to fund its operations into the first quarter of 2024. 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 its 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 effects of the COVID-19 pandemic and economic and political developments, including the conflicts in Ukraine and Israel, rising interest rates 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 public health events and economic and political developments on financial markets and the global economy.

### ***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 and valuation allowance for deferred tax assets. Actual results could be different from these estimates. To the extent there are material differences between these estimates, judgments, or assumptions and actual results, the Company's financial statements will be affected.

### ***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 include 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.

### **Recent Accounting Pronouncements**

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 does not expect ASU 2020-06 to have an impact on its financial statements.

Other accounting standards that have been issued or proposed by FASB that do not require adoption until a future date are not expected to have a material impact on the financial statements upon adoption. The Company does not discuss recent pronouncements that are not anticipated to have an impact on or are unrelated to its financial condition, results of operations, cash flows or disclosures.

### **Note 2. Debt**

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 and is secured by substantially all of the Company's assets. Payments due for the term loan were interest-only until March 1, 2023 after which principal became payable 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 thousand 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 \$285 thousand and \$281 thousand for the nine months ended September 30, 2023 and 2022, 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 (as defined below), (ii) \$10.0 million when the Company achieves certain positive clinical trial results sufficient to submit a *de novo* classification request with respect to AspyreRx 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 AspyreRx 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. Additionally, the Company did not receive net cash proceeds of at least \$40 million prior to March 15, 2023 and therefore the associated borrowing is no longer available. As of September 30, 2023 and December 31, 2022, the outstanding debt balance, net of unamortized debt issuance costs and including the accrued end of term charge was \$14.3 million and \$14.9 million, respectively. The interest rate was 14.2% and 13.2% as of September 30, 2023 and December 31, 2022, and there was \$167 thousand and \$168 thousand of accrued interest included in other liabilities on the accompanying balance sheets as of September 30, 2023 and December 31, 2022.

On April 5, 2023, the Company entered into the First Amendment (the "Amendment") to the Loan Agreement with Hercules Capital. The Amendment provides for a cessation of amortization payments under the Loan Agreement until August 1, 2023 or, if certain benchmarks are hit, November 1, 2023. The Amendment also provides a security interest in the intellectual property of the Company and its subsidiaries which is required to be released by Hercules Capital on the achievement of certain benchmarks. Additionally, the Amendment waives the prepayment penalty under the Loan Agreement for any prepayment in full prior to December 31, 2023. As of July 10, 2023, with the FDA authorization of AspyreRx, the Company met the requirements for the cessation of amortization payments under the Loan Agreement until November 1, 2023.

**BETTER THERAPEUTICS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
(Unaudited)

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.

**Note 3. Accrued Liabilities**

	<b>September 30, 2023</b>	<b>December 31, 2022</b>
Due to service providers	\$ 1,753	\$ 1,335
Due to professionals	238	506
Financed insurance	-	963
Accrued interest	167	168
Other	-	654
Other accrued liabilities	<u>\$ 2,158</u>	<u>\$ 3,626</u>

**Note 4. 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.

**Note 5. 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):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
Net loss	\$ (5,862)	\$ (11,405)	\$ (22,808)	\$ (30,995)
Weighted-average common stock outstanding	38,505,212	23,739,731	31,250,175	23,667,335
Less: weighted-average shares of common stock subject to vesting	(10,062)	(46,577)	(36,082)	(134,045)
Weighted-average shares of common stock outstanding used in the calculation of basic and diluted net loss per share attributable to shareholders	38,495,150	23,693,154	31,214,093	23,533,290
Loss per share attributable to common shareholders, basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.48)</u>	<u>\$ (0.73)</u>	<u>\$ (1.32)</u>

As of September 30, 2023 and 2022 potentially dilutive securities of 5,108,585 and 3,932,550 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive.

**BETTER THERAPEUTICS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
(Unaudited)

**Note 6. 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 and Unrestricted Stock Awards. A total of 903 thousand shares of the Company's common stock have been reserved for issuance pursuant to the 2020 plan. Following the closing of the Company's business combination with Mountain Crest Acquisition Corp. II (the "Business Combination"), no further shares have been issued under the 2020 Plan.

In October 2021, the Company adopted the Better Therapeutics Inc. 2021 Stock Option and Incentive Plan (the "2021 Plan") to grant equity based incentives to officers, directors, consultants and employees. The equity-based incentives include, Incentive Stock Options, Non-Qualified Stock Options, Stock appreciation rights, Restricted Stock Awards, Unrestricted Stock Awards, Cash-based Awards and Dividend Equivalent Rights. A total of 3.6 million shares of common stock were initially reserved for issuance. Additionally, on each January 1 beginning January 1, 2022, the number of shares of common stock reserved and available for issuance under the 2021 Plan will be automatically 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. As of September 30, 2023, the Company had a total of 1.9 million shares reserved for issuance under the 2021 Plan.

In October 2021, the Company adopted the Better Therapeutics, Inc. 2021 Employee Stock Purchase Plan (the "ESPP") to provide eligible employees with opportunities to purchase shares of the Company's common stock. A total of 280 thousand shares of common stock were initially reserved for issuance. Additionally, on each January 1 beginning January 1, 2021, the number of shares of common stock reserved for issuance under the ESPP will be automatically increased by the lesser of (i) 560 thousand shares of common stock, (ii) one percent (1%) of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (iii) such lesser number of shares of common stock as determined by the Administrator of the ESPP. As of September 30, 2023, the Company had a total of 501 thousand shares reserved for issuance under the ESPP.

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 thousand shares of common stock have been initially reserved for issuance under the Inducement Plan. As of September 30, 2023, the Company had a total of 400 thousand shares 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 (in thousands, except share and per share data):

	<b>Options Outstanding</b>			
	<b>Shares Subject to Options Outstanding</b>	<b>Weighted- Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life (Years)</b>	<b>Aggregate Intrinsic Value</b>
Balance as of December 31, 2022	3,999,223	\$ 3.95	9.3	\$ 64
Granted	984,560	1.07		
Exercised	(1,544)	0.50		
Forfeited	(583,154)	4.19		
Balance as of September 30, 2023	4,399,085	\$ 3.28	8.3	\$ 0

**BETTER THERAPEUTICS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
(Unaudited)

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 nine months ended September 30, 2023, was \$0.49 per share. As of September 30, 2023, total unrecognized compensation expense related to unvested stock options was \$2.1 million which is expected to be recognized over a weighted-average period of 4.84 years.

The fair value of each option award granted is estimated on the grant date. The grant date fair value of options with service and performance-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 our common stock. The assumptions used to determine the fair value of the option awards represent the Company's best estimates. These estimates involve inherent uncertainties and the application of our judgment. The related stock-based compensation expense is recognized on a straight-line basis over the requisite service period of the awards, which is generally four years.

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

	<b>Nine Months Ended September 30, 2023</b>
Expected Term (Years)	6.02
Expected Volatility	41 %
Risk-free interest rate	4.09 %
Dividend Yield	—

In July 2022, the Company granted options with performance-based vesting conditions to the Company's new Chief Executive Officer ("CEO"), which entitled the CEO 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 1.85 million shares in the aggregate. As of September 30, 2023, 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 remaining period of 7.3 years.

***Restricted Stock***

During the nine months ended September 30, 2023, 23 thousand shares of common stock vested and converted into unrestricted common stock. As of September 30, 2023 there were 7 thousand shares of restricted stock outstanding.

Total stock-based compensation expense for time-based restricted stock of \$2 thousand is expected to be recognized on a straight-line basis over approximately the next 3 months for the unvested restricted stock outstanding as of September 30, 2023.

***Restricted Stock Units***

In April 2023, the Company issued time-based restricted stock units ("RSUs") that vest in 2 equal annual installments. RSU activity for the periods presented is as follows:

	<b>Restricted Stock Units</b>
Balance as of December 31, 2022	—
Granted	822,700
Vested	—
Forfeited	(113,200)
Balance as of September 30, 2023	709,500

**BETTER THERAPEUTICS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
(Unaudited)

For the nine months ended September 30, 2023, the Company recognized \$0.2 million in restricted stock compensation expense. Unamortized compensation costs of \$0.5 million is being recognized over a weighted average term of 1.48 years. The weighted average grant date fair value of the RSUs granted during the nine months ended September 30, 2023 was \$0.90 per share.

***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 nine months ended September 30, 2023, the Company issued 66 thousand shares and recorded \$159 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 (in thousands):

	<b>Nine Months Ended</b>	
	<b>September 30, 2023</b>	
	<b>2023</b>	<b>2022</b>
Research and development	\$ 507	\$ 414
Sales and marketing	87	52
General and administrative	721	887
Total equity-based compensation expense	<u>\$ 1,315</u>	<u>\$ 1,353</u>

For the nine months ended September 30, 2023 and 2022, \$35 thousand and \$22 thousand of stock based compensation expense was included as part of capitalized internal-use software costs, respectively.

**Note 7. Income Taxes**

The effective tax rate was zero percent for the nine months ended September 30, 2023 and 2022, respectively. The effective tax rate differs from the Company's statutory tax rate of 21%, primarily due to a change in the valuation allowance for deferred assets as of September 30, 2023 and 2022, respectively.

**Note 8. 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. As of September 30, 2023, the Company has an estimated accrued liability of \$1.1 million related to a disputed change order with one of its vendors. This accrual is based on management's estimate of probable outcome, however the amount remains in dispute and could ultimately exceed the amount presently accrued.

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.

**BETTER THERAPEUTICS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
(Unaudited)

**Note 9. Restructuring**

On March 23, 2023, the 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. Cash disbursements for expenses associated with the restructuring were substantially completed in the second quarter of 2023. Additionally, during the three months ended September 30, 2023, the Company reduced a previously recorded payroll accrual of \$1.5 million related to expenses incurred in 2022 as management determined this payroll accrual would not be paid. The following table provides a summary related to the Company's restructuring activity, recorded in accrued payroll on the accompanying balance sheets, as of September 30, 2023:

	<b>Employee Severance and Related Benefits</b>	
Balance at December 31, 2022	\$	-
Charges		430
Payments		(430)
Balance at September 30, 2023	\$	<u>—</u>

**Note 10. Subsequent Events**

In October 2023, the Company issued and sold 6,825,411 shares of its common stock in "at-the-market" offerings pursuant to the Sales Agreement for an aggregate purchase price of \$2.9 million. The Company intends to use the proceeds to support the commercial launch of the FDA authorized AspyreRx.

On October 16, 2023 the Company announced the commercial launch of AspyreRx.

On October 30, 2023, the Company's stockholders approved a proposed amendment to the Company's Second Amended and Restated Certificate of Incorporation to effect a reverse stock split of the Company's outstanding common stock at a ratio of not less than 1-for-10 and not greater than 1-for-25, subject to and as determined by the Company's board of directors. The primary reason the Company sought stockholder approval of the reverse stock split was to attempt to increase the per share market price of its common stock to exceed the minimum closing bid price requirement for continued listing on The Nasdaq Capital Market.

## Item 2. 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 elsewhere in this Quarterly Report. Unless otherwise specified all dollar amounts are in U.S. Dollars.

### Overview

Our mission is to advance human health through the power of behavior change.

We are a prescription digital therapeutics ("PDT") company developing a U.S. Food and Drug Administration ("FDA") regulated cognitive behavioral therapy ("CBT") that is accessed via an app on a patient's smartphone to address the root causes of cardiometabolic diseases ("CMDx"). Our clinically validated PDTs are intended to be prescribed by physicians and reimbursed by payers like traditional medicines. The mechanism of action embedded in our PDTs is a novel form of CBT developed by Better Therapeutics, targeting the specific behaviors that cause and contribute to the progression of 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 first commercial product, AspyreRx™ (formerly BT-001), was authorized by the FDA to treat Type 2 diabetes ("T2D"), in July 2023, and launched commercially in October 2023. AspyreRx is the first FDA-authorized digital behavioral therapeutic delivering CBT for the treatment of a cardiometabolic disease. Our pipeline also includes programs for the treatment of hypertension, hyperlipidemia, Metabolic Dysfunction-Associated Steatotic Liver Disease ("MASLD"), Metabolic Dysfunction-Associated Steatohepatitis ("MASH") and chronic kidney disease. 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 and medical devices.

AspyreRx is a prescription-only digital treatment indicated to provide cognitive behavioral therapy to patients 18 years or older with T2D. The device targets behavior to aid in the treatment of T2D adjunctively with standard-of-care in patients who are under the care of a healthcare provider. AspyreRx was reviewed through the FDA's *de novo* pathway and its authorization created a new class of diabetes digital behavioral therapeutic devices. We envision AspyreRx becoming part of the standard-of-care for adult patients with T2D given the clinical evidence supporting its efficacy and safety, its broad label to treat all adult patients with T2D across the disease spectrum, its mechanism of action in-line with existing treatment guidelines, its broad accessibility to anyone with a smartphone and the potential cost savings the utilization of AspyreRx can generate for payers and health systems.

Like other prescription therapies, successful commercialization will require physicians to write prescriptions for their patients and for payers to reimburse the cost of those prescriptions. We are pursuing a focused go-to-market strategy and intend to launch AspyreRx initially in 6 geographies with a small commercial team, targeting high prescribing providers identified as innovators and early adopters, as well as the top health systems and payer organizations that overlap, with the goal to generate early, meaningful, commercial traction in these areas. We intend to expand our commercial footprint after we have established commercial traction in our initial target geographies.

The treatment and other healthcare costs associated with T2D consumes over \$400 billion each year in the U.S., and that number is growing each year driven by rising prevalence of the disease, which is projected to grow from 37 million patients in 2019 to 55 million by 2030, as well as the introduction of expensive new drugs. We have completed an extensive healthcare economic study which demonstrates the potential of AspyreRx to improve health outcomes and reduce costs to insurers.

We have conducted primary market research into the potential for reimbursement coverage of AspyreRx by representative payer groups and, with FDA authorization, have conducted post authorization meetings with several payers. As a result of the market research and payer meetings to date, we believe widespread reimbursement coverage can be established. These findings have been further supported by independent research studies, such as the one conducted by Xcenda and presented at the AMCP Nexus meeting in October 2022. To ensure eligible patients have affordable access to AspyreRx regardless of insurance coverage while payer coverage is ramping up, we are offering a cash-pay program for a limited time. We expect to announce our first coverage decisions in Q4 2023 and further expand coverage through 2024.

Treatment guidelines for T2D typically start with instructions for physicians to counsel patients on changes in diet and exercise. Since AspyreRx offers providers a clinically proven behavioral therapy that targets behaviors around diet, exercise and other disease driving behaviors, is valuable at any stage of the disease, is delivered in an easily accessible, engaging and affordable way, and is already part of the foundation of treatment under the current clinical guidelines for treatment of T2D, we believe AspyreRx has the potential to become part of the standard-of-care for the treatment of T2D. We project that peak annual sales of AspyreRx may potentially exceed \$1 billion per year.

In September 2023, we also completed enrollment in our real-world evidence studies to evaluate the long-term effectiveness and healthcare utilization changes associated with the use of AspyreRx for the treatment of T2D. The randomized, controlled, multi-site studies enrolled patients for a treatment period of at least 12 months. Change in A1c and healthcare resource utilization will be evaluated and compared to standard of care. The study seeks to provide payers and providers with long-term data related to usage and outcomes in a real-world like setting.

We further 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 MASLD and MASH (former known as NAFLD/NASH). The results of this study were published in the peer reviewed journal *Gastro Hep Advances* in October 2023. 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 submit a request to the FDA for Breakthrough Device Designation for our investigational CBT-based treatment platform by the end of 2023. We plan to use data from the LivVita study and exploratory endpoints embedded in the BT-001 pivotal trial that generated additional proof-of-concept data in hypertension and hyperlipidemia, to inform the potential expansion of our digital therapeutics platform into other cardiometabolic diseases beyond T2D.

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.

We believe we are differentiated from other PDT companies in several important ways, which we believe has the potential to result in better commercial 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 (about 50% of patients diagnosed with T2D have uncontrolled blood sugar levels despite being on standard of care medication); 2) because T2D ranks among the most costly therapeutic areas for payers, and given the rapidly rising prevalence of the disease as well as escalating expenses for payers, in part driven by the introduction of expensive new medications, we believe we get a different level of attention from payers than prior PDT companies seeking to obtain payer coverage, 3) we ran the largest randomized control trial to date for a PDT intending to lower blood sugar, generating clinical evidence against the same clinical endpoints used in drug development for T2D; 4) the FDA granted us a broad label, authorizing the treatment of all adult T2D patients from first diagnosis across all stages of the disease; 5) our FDA authorized and 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; 6) our therapy has the potential to generate health economic benefits and the utilization of our PDTs has the potential to demonstrate cost savings for payers; and 7) we have a team with extensive industry experience in developing and commercializing therapeutics and medical devices. 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 PDT trial for an intervention aimed at glycemic control and included a diverse, nationally representative population of 668 patients with a body mass index  $\geq 25$  mg/m<sup>2</sup>, 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. Participants were 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 set a high bar to demonstrate efficacy and 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 or more), 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.

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 MASLD and MASH, 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. MASLD and MASH 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 MASLD or MASH.

We are engaging in business development efforts to maximize the value of AspyreRx and our platform in non-dilutive ways. We are exploring opportunities to partner with pharmaceutical, medical device, and technology companies that have a strategic interest in digital health or have the organizational infrastructure to support the successful commercialization of AspyreRx and our platform. Opportunities may also exist to co-develop novel combination products with a pharmaceutical company operating in the cardiometabolic space. In September 2023, the FDA issued draft guidance titled "Regulatory Considerations for Prescription Drug Use-Related Software," which provides clarity about the agency's views and intent to consider the combined effectiveness of pharmaceuticals and digital therapeutic solutions when making drug labeling decisions. We believe the FDA draft guidance has the potential to support our business development efforts and may be particularly relevant in the context of a new subgroup analysis data which was announced in October 2023 and which revealed that adjunctive use of AspyreRx with standard of care, including GLP-1 receptor agonists, led to a substantially greater clinical improvement compared to control participants who did not incorporate AspyreRx into their regimen.

We have combined medical, behavioral and data sciences to develop a clinically validated software-based therapeutics platform targeting behavioral 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. AspyreRx and our other PDTs, if authorized by the FDA, are intended to be prescribed by physicians and reimbursed by health insurance providers.

## Recent Events

### *ATM Program*

On May 11, 2023, we entered into an "at-the-market" ("ATM") sales agreement (the "Sales Agreement") with Virtu Americas LLC ("Virtu") pursuant to which we may issue and sell up to an aggregate of \$6.9 million in shares of our common stock (the "ATM Shares") from time to time, at our discretion, through Virtu as our sales agent or principal. Subject to the terms of the Sales Agreement, Virtu may sell the ATM Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act, including, without limitation, sales made through the Nasdaq Capital Market or on any other existing trading market for our common stock. We may sell the ATM Shares in amounts and at times to be determined by us from time to time subject to the terms and conditions of the Sales Agreement, but we have no obligation to sell any ATM Shares under the Sales Agreement. We or Virtu may suspend or terminate the offering upon notice to the other party and subject to other conditions. In July 2023, we issued and sold 2,023,583 shares of our common stock in "at-the-market" offerings pursuant to the Sales Agreement for an aggregate purchase price of \$2.4 million.

In July 2023, we delivered written notice to Virtu that we were suspending and terminating the prospectus related to the common stock issuable pursuant to the terms of the Sales Agreement.

In August 2023, we filed a new ATM prospectus supplement related to the ATM shares. As a result, we may issue and sell up to an aggregate of \$3,476,781 in ATM Shares from time to time pursuant to the Sales Agreement.

As of October 25, 2023, we have sold 8,848,994 shares of our common stock at a weighted average price of \$0.60 per share in the ATM pursuant to the Sales Agreement, resulting in net proceeds of approximately \$5.2 million to us, after deducting sales commissions and other offering costs. We intend to use the net proceeds from the sale of the ATM Shares to support the commercial launch of AspyreRx.

### *Financings*

On April 6, 2023, we entered into a Securities Purchase Agreement with certain investors pursuant to which we offered and sold an aggregate of 7,878,786 shares of our common stock for an aggregate purchase price of approximately \$6.5 million (the "April Private Placement"). The April Private Placement closed on April 10, 2023.

On July 25, 2023, we entered into a Securities Purchase Agreement with certain investors pursuant to which we issued and sold 2,897,654 shares of our common stock for an aggregate purchase price of \$2.1 million in a private placement (the "July Private Placement"). The July Private Placement closed on July 27, 2023.

On July 25, 2023, we also entered into a Securities Purchase Agreement with a single investor pursuant to which we issued and sold 3,859,649 shares of our common stock for an aggregate purchase price of \$2.2 million in a registered direct offering (the "July Registered Direct Offering"). The July Registered Direct Offering closed on July 27, 2023.

We used the net proceeds from the April Private Placement, July Private Placement and the July Registered Direct Offering to support the commercial launch of AspyreRx.

### *Nasdaq Deficiency Notice*

On June 16, 2023, we received written notices from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") notifying us that we were not in compliance with the minimum bid price requirement as well as the market value of listed securities requirement for continued listing on the Nasdaq Capital Market. These notices do not impact our listing on The Nasdaq Capital Market at this time. Both notification letters state that we have 180 calendar days, or until December 13, 2023, to regain compliance. There is the possibility for an additional 180-day compliance period to regain compliance with the minimum bid price compliance requirement provided that the Company is in compliance with all other Nasdaq listing standards. However, no additional compliance period is applicable to the market value of listed securities or alternative standards noncompliance.

At our special meeting of stockholders held on October 30, 2023, our stockholders approved a proposed amendment to our Second Amended and Restated Certificate of Incorporation to effect a reverse stock split of our outstanding common stock at a ratio of not less than 1-for-10 and not greater than 1-for-25, subject to and as determined by our board of directors. The primary reason we sought stockholder approval of the reverse stock split was to attempt to increase the per share market price of our common stock to exceed the minimum closing bid price requirement for continued listing on The Nasdaq Capital Market. We will also consider available options to resolve the market value of listed securities deficiency and regain compliance with all applicable Nasdaq rules.

In the event we do not regain compliance with the Nasdaq listing rules prior to the expiration of the compliance or any grace period, we will receive written notice that our securities are subject to delisting unless we timely request a hearing before a Nasdaq Hearings Panel to present a plan of compliance. There can be no assurance that the Panel will grant our request for a grace period to demonstrate compliance, or we will be successful in executing our plan of compliance, and we may be delisted from Nasdaq as a result.

### **Impact of Macroeconomic Events**

Economic uncertainty in various global markets caused by political instability and conflict, such as the ongoing conflicts in Ukraine and Israel, and economic challenges caused by public health events, including the effects of COVID-19 pandemic, have led to market disruptions, including significant volatility in commodity prices, credit and capital market instability and supply chain interruptions, which have caused record inflation globally. Our business, financial condition and results of operations could be materially and adversely affected by further negative impacts on the global economy and capital markets resulting from these global economic conditions, particularly if such conditions are prolonged or worsen. Although, to date, our business has not been materially impacted by these global economic and geopolitical conditions, it is impossible to predict the extent to which our operations may be impacted in the short and long term. The extent and duration of these market disruptions, whether as a result of the military conflict between Russia and Ukraine and effects of the Russian sanctions, the conflict in Israel, geopolitical tensions, record inflation or otherwise, are impossible to predict. Any such disruptions may also magnify the impact of other risks described in this Quarterly Report.

### **Update to Previously Reported Financial Information**

The financial statements as of June 30, 2023 and December 31, 2022 included in this Quarterly Report include a payroll accrual of \$1.5 million related to expenses incurred during 2022. Management has determined that this payroll accrual will not be paid out and therefore reversed such amount during the quarter ended September 30, 2023.

### **Components of Results of Operations**

#### ***Revenue***

We expect that our primary sources of revenue will be through reimbursement coverage for our treatments by commercial insurers, Medicare, Medicaid and the Veterans Administration in the U.S. In the near term we are offering a cash pay option as we work to obtain broad reimbursement coverage for our first PDT for treating T2D, AspyreRx. We expect to pursue obtaining favorable rates and broad reimbursement coverage through demonstrating and generating a comprehensive set of evidence to substantiate the value of AspyreRx 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 AspyreRx and our other product candidates is highly uncertain. As a result, the timing and the amount of revenue we expect to recognize from monetizing our product candidates may vary based on various factors.

We are engaging in business development efforts to maximize the value of AspyreRx 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 contract research organizations ("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, AspyreRx.

We expect our research and development expenses may increase in the future as we continue to invest in research and development activities related to developing our platform and our other product candidates, as our other 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 support the commercialization of AspyreRx. Our sales and marketing efforts are expected to focus on targeting payers, patients and health care providers 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 (as defined herein) entered into in 2021, offset by interest earned on excess cash.

## Results of Operations

Comparisons of the three and nine months ended September 30, 2023 and 2022.

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2023	2022	Change	% Change	2023	2022	Change	% Change
Operating expenses:								
Research and development	\$ 1,833	\$ 5,477	\$ (3,644)	(67)%	\$ 7,462	\$ 13,391	\$ (5,929)	(44)%
Sales and marketing	1,392	1,557	(165)	(11)%	5,200	5,284	(84)	(2)%
General and administrative	2,116	3,962	(1,846)	(47)%	8,629	11,265	(2,636)	(23)%
Total operating expenses	5,341	10,996	(5,655)	(51)%	21,291	29,940	(8,649)	(29)%
Loss from operations	(5,341)	(10,996)	5,655	(51)%	(21,291)	(29,940)	8,649	(29)%
Interest expense, net	(518)	(406)	(112)	28%	(1,512)	(1,052)	(460)	44%
Loss before provision for income taxes	(5,859)	(11,402)	5,543	(49)%	(22,803)	(30,992)	8,189	(26)%
Provision for income taxes	3	3	—	N/M	5	3	2	N/M
Net loss	\$ (5,862)	\$ (11,405)	\$ 5,543	(49)%	\$ (22,808)	\$ (30,995)	\$ 8,187	(26)%

N/M – The percentage change is not meaningful

### Research and Development Expenses

Research and development expenses were \$1.8 million for the three months ended September 30, 2023, compared to \$5.5 million for the three months ended September 30, 2022. The decrease was primarily due to a \$2.0 million decrease in clinical study costs as a result of the completion of the BT-001 pivotal trial in the third quarter of 2022, a \$1.8 million decrease in personnel related costs due to the restructuring that occurred in the first quarter of 2023 and other costs savings measures.

Research and development expenses were \$7.5 million for the nine months ended September 30, 2023, compared to \$13.4 million for the nine months ended September 30, 2022. The decrease was primarily due to a \$3.2 million decrease in clinical study costs as a result of the completion of the BT-001 pivotal trial in the third quarter of 2022, a \$2.1 million decrease in personnel and consulting related costs due to the restructuring that occurred in the first quarter of 2023 and other cost savings measures.

### Sales and Marketing Expenses

Sales and marketing expenses were \$1.4 million for the three months ended September 30, 2023 and \$1.6 million for the three and nine months ended September 30, 2022. The change was driven by an increase of \$0.2 million in personnel related costs as we prepared for the commercial launch of AspyreRx. This was offset by a \$0.3 million decrease in costs related to our real-world evidence study as we completed enrollment in the study.

Sales and marketing expenses were \$5.2 million for the nine months ended September 30, 2023 and \$5.3 million for the nine months ended September 30, 2022. The change was driven by a \$0.7 million increase in personnel related costs associated with the commercial launch of AspyreRx offset by a \$0.4 million decrease in costs related to our real-world evidence study, and a \$0.3 million severance charge in the second quarter of 2022.

### General and Administrative Expenses

General and administrative expenses were \$2.1 million for the three months ended September 30, 2023, compared to \$4.0 million for the three months ended September 30, 2022. The decrease was primarily related to a \$1.1 million decrease in personnel and consulting costs related to the cost savings initiatives implemented earlier this year, and a \$0.7 million decrease in business insurance costs.

General and administrative expenses were \$8.6 million for the nine months ended September 30, 2023, compared to \$11.3 million for the nine months ended September 30, 2022. The overall decrease in general and administrative expenses was primarily related to a \$2.0 million decrease in business insurance cost and a \$0.7 million decrease in personnel related costs due to the cost savings initiatives implemented earlier this year.

### *Interest Expense, Net*

Interest expense, net was \$0.5 million for the three months ended September 30, 2023 compared to \$0.4 million for the three months ended September 30, 2022. The increase in interest expense net, was the result of higher interest rates under our secured term loan agreement with Hercules Capital, Inc. ("Hercules Capital").

Interest expense, net was \$1.5 million for the nine months ended September 30, 2023 compared to \$1.1 million for the nine months ended September 30, 2022. The increase in interest expense, net was the result of higher interest rates and an additional \$5.0 million borrowed under our secured term loan agreement with Hercules Capital.

### **Liquidity and Capital Resources**

We have primarily funded our operations through the sale of common stock, preferred stock, convertible notes, simple agreements for future equity, borrowing under our secured term loan agreement with Hercules Capital and funding from our business combination with Mountain Crest Acquisition Corp. II.

On August 18, 2021, we entered into a secured term loan agreement (the "Loan Agreement") with 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, and is secured by substantially all of our assets. Payments due for the term loan were interest-only until March 1, 2023, after which principal became payable 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 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, we will be required to pay an end of term charge of the greater of (a) \$893 thousand and (b) 5.95% of the aggregate outstanding principal upon repayment of the loan. We are 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 \$285 thousand and \$281 thousand for the nine months ended September 30, 2023 and 2022, respectively. We are permitted to borrow the loans in four tranches based on the completion of certain milestones which include, as set forth more fully in the 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 AspyreRx and have initiated a second pivotal trial prior to September 15, 2022, (iii) \$10.0 million when we have received FDA approval for the marketing of AspyreRx for the improvement of glycemic control and initiated a pivotal trial for a new indication in people with T2D and received, prior to March 15, 2023, net cash proceeds of at least \$40.0 million from equity financings, and (iv) \$15.0 million on or before June 15, 2023, subject to Hercules Capital's approval. In October 2021, we borrowed \$10.0 million under the 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. Additionally, we did not receive net cash proceeds of at least \$40 million prior to March 15, 2023 and therefore the associated borrowing is no longer available. As of September 30, 2023 and December 31, 2022, the outstanding debt balance, net of unamortized debt issuance costs and including the accrued end of term charge was \$14.3 million and \$14.9 million, respectively. The interest rate was 14.2% and 13.2% as of September 30, 2023 and December 31, 2022, and there was \$167 thousand and \$168 thousand of accrued interest included in other liabilities on the accompanying balance sheets as of September 30, 2023 and December 31, 2022, respectively.

On April 5, 2023, we entered into the First Amendment (the "Amendment") to the Loan Agreement with Hercules Capital. The Amendment provides for a cessation of amortization payments under the Loan Agreement until August 1, 2023 or, if certain benchmarks are hit, November 1, 2023. The Amendment also provides a security interest in the intellectual property of the Company and its subsidiaries which is required to be released by Hercules Capital on the achievement of certain benchmarks. Additionally, the Amendment waives the prepayment penalty under the Loan Agreement for any prepayment in full prior to December 31, 2023. As of July 10, 2023, with the FDA authorization of AspyreRx, we met the requirements for the cessation of amortization payments under the Loan Agreement until November 1, 2023.

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 our financial statements included elsewhere in the Quarterly Report, our liquidity and capital resource issues could lead to the failure of a financial covenant in the year ending December 31, 2023 without additional funding.

In April 2023, we offered and sold an aggregate of 7,878,786 shares of our common stock for an aggregate purchase price of approximately \$6.5 million.

In May 2023, we entered into the Sales Agreement, with Virtu Americas LLC, pursuant to which we may issue and sell up to an aggregate of \$6.9 million in ATM Shares from time to time, at our discretion, through Virtu as our sales agent or principal. In July 2023, we delivered written notice to Virtu that we were suspending and terminating the prospectus related to the common stock issuable pursuant to the terms of the Sales Agreement. In August 2023, we filed a new ATM prospectus supplement related to the ATM shares. As a result, we may issue and sell up to an aggregate of \$3,476,781 in ATM Shares from time to time pursuant to the Sales Agreement. As of October 25, 2023, we have sold 8,848,994 shares of our common stock at a weighted average price of \$0.60 per share in the ATM pursuant to the Sales Agreement, resulting in net proceeds of approximately \$5.2 million to us, after deducting sales commissions and other offering costs. We intend to use the net proceeds from the sale of the ATM Shares to support the commercial launch of AspyreRx and the completion of other strategic initiatives.

In July 2023, we entered into a Securities Purchase Agreement with certain investors pursuant to which we issued and sold 2,897,654 shares of our common stock for an aggregate purchase price of \$2.1 million in a private placement

In July 2023, we also entered into a Securities Purchase Agreement with a single investor pursuant to which we issued and sold 3,859,649 shares of our common stock for an aggregate purchase price of \$2.2 million in a registered direct offering.

We used the net proceeds from the April Private Placement, July Private Placement and the July Registered Direct Offering to support the commercial launch of AspyreRx.

As of September 30, 2023, we had \$6.6 million in cash, and an accumulated deficit of \$134.3 million. Our primary use of cash is to fund operating expenses, which predominantly relate to activities to support the commercial launch of AspyreRx 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 commercialization of AspyreRx and the development and potential commercialization of our product candidates and ongoing internal research and development programs. At this time, we cannot reasonably estimate the nature, timing or aggregate amount of costs for our development, potential commercialization, and internal research and development programs. However, in order to complete our planned product development, and to complete the process of obtaining regulatory authorization or clearance for our product candidates, as well as to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product and other product candidates, if authorized by the FDA, we will require substantial additional funding in the future. In the event that additional financing is required from outside sources, we may not be able to raise it on terms acceptable to us, or at all. If we are unable to raise additional capital when desired, our business, results of operations, and financial condition would be adversely affected. Under our current operating plan, we believe we have sufficient capital to fund our operations into the first quarter of 2024. These factors raise substantial doubt regarding our ability to continue as a going concern.

### **Summary Statement of Cash Flows**

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

	<b>Nine Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Cash used in operating activities	\$ (19,746)	\$ (22,593)
Cash used in investing activities	(958)	(820)
Cash provided by financing activities	11,562	5,152
Net (decrease) in cash and cash equivalents	<u>\$ (9,142)</u>	<u>\$ (18,261)</u>

### *Cash Used in Operating Activities*

During the nine months ended September 30, 2023, net cash used in operating activities was \$19.7 million, which consisted of a net loss of \$22.8 million, a net change of \$0.6 million in our net operating assets and liabilities and \$3.7 million in non-cash charges. The net change in our operating assets and liabilities was primarily due to a net decrease in prepaid expenses and other assets of \$2.0 million and a decrease in accounts payable and accrued expenses of \$2.6 million. The non-cash charges of \$3.7 million consisted of depreciation and amortization expense and share-based compensation expense.

During the nine months ended September 30, 2022, net cash used in operating activities was \$22.6 million, which consisted of a net loss of \$31.0 million, a net change of \$5.0 million in our net operating assets and liabilities and \$3.4 million in non-cash charges. The net change in our operating assets and liabilities was primarily due a net decrease in account payable and accrued expenses of \$1.5 million and a decrease in prepaid expenses and other assets of \$3.6 million. The non-cash charges of \$3.4 million consisted of depreciation and amortization expense, share-based compensation expense, and loss on fixed asset disposal.

### *Cash Used in Investing Activities*

During the nine months ended September 30, 2023, cash used in investing activities was \$1.0 million and was primarily related to capitalized internal-use software costs and capital expenditures.

During the nine months ended September 30, 2022, cash used in investing activities was \$820 thousand and was primarily related to capitalized internal-use software cost and capital expenditures.

### *Cash Provided by Financing Activities*

During the nine months ended September 30, 2023, cash provided by financing activities was \$11.6 million related to proceeds from the issuance of common stock and the issuance of shares under the employee stock purchase plan, offset by payments on long-term debt.

During the nine months ended September 30, 2022, cash provided by financing activities was \$5.2 million related to proceeds received from the issuance of long-term debt, the issuance of shares under the employee stock purchase plan and the exercise of common stock options.

### *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 September 30, 2023.

### *Off-Balance Sheet Arrangements*

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

### **Critical Accounting Policies and Estimates**

There have been no significant changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations," disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022 (our "2022 Annual Report").

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

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

### ***Impairment of Long-Lived Assets***

We review long-lived assets for impairment when circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of these assets is measured by a comparison of the carrying amounts to the sum of the future un-discounted cash flows the assets are expected to generate over the remaining useful lives of the assets. If a long-lived asset fails a recoverability test, we measure the amount by which the carrying value of the asset exceeds its fair value. There were no events or changes in business circumstances during the nine months ended September 30, 2023 that indicated the carrying amounts of any long-lived assets were not fully recoverable.

### ***Equity-Based Compensation***

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

We account for equity-based compensation arrangements issued to non-employees using the fair value approach prescribed by Accounting Standards Update ("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 — We determine the fair value of common stock based on the closing price of our common stock on the date of the grant.
- Expected term — The expected term represents the period that the equity-based awards are expected to be outstanding. We determine the expected term using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the options. For stock options granted to non-employees, the expected term equals the remaining contractual term of the option from the vesting date.

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

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 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 of 2002 (the "Sarbanes-Oxley Act"), (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.235 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.

### Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a "smaller reporting company", as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required by this Item 3.

### Item 4. Controls and Procedures.

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

Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined in Rules 13a-115(e) and 15d-15(e) under the Exchange Act, as of the end of the fiscal quarter ended September 30, 2023. Based on this evaluation, our principal executive officer and principal financial and accounting officer have concluded that during the period covered by this report, our disclosure controls and procedures were effective at a reasonable assurance level and, accordingly, provided reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended September 30, 2023 that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

None.

### Item 1A. Risk Factors.

*Our business is subject to numerous material and other risks. Careful consideration should be given to the following risks and uncertainties, those risks and uncertainties discussed in “Part I, Item 1A, Risk Factors” in our 2022 Annual Report together with all of the other information contained in this Quarterly Report, including our unaudited condensed financial statements and the related notes appearing elsewhere in this Quarterly Report. If any of the risks described below actually occur, our business, prospects, operating results and financial condition could suffer materially. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.*

#### Summary of Risk Factors

##### ***Risks Related to Our Business***

- We are a newly commercial 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 likely need 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 AspyreRx (formerly BT-001). If we are unable to successfully commercialize AspyreRx, our business will be materially harmed.
- If physicians are not willing to change current practices to adopt AspyreRx or our other product candidates, if authorized for marketing, or if our products otherwise fail to achieve and maintain market acceptance, our business, financial condition and results of operation would be materially and adversely affected.
- Competitive products may reduce or eliminate the commercial opportunity for AspyreRx or our other 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 AspyreRx and our other 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 AspyreRx and our other product candidates, if authorized for marketing.
- Any failure to offer high-quality patient support or support to health care providers 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.
- Our Loan Agreement with Hercules Capital contains restrictions that limit our flexibility in operating our business.\*
- 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 *de novo* classification or clearance to market and sell 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.
- We are substantially dependent on market acceptance in the United States of AspyreRx, and our failure to gain such market acceptance for it would negatively impact our business.
- The clinical trial process required to obtain marketing authorizations for potential additional 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 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.
- 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.
- We may not receive Breakthrough Device Designation by the FDA for our investigational CBT-based treatment platform, and even if we do, such designation may not lead to a faster development, regulatory review or clearance process, and it may not increase the likelihood that our study will receive marketing authorization from the FDA.\*

### ***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 our other product candidates, 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 AspyreRx or any of our other 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.
- There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.\*

\* Denotes a risk factor that has been added to, or materially updated in, this Quarterly Report.

## Risks Related to Our Business

***We are a newly commercial 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 newly commercial 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 only recently received marketing authorization from the FDA for our lead product, AspyreRx, and have not yet demonstrated an ability to generate revenues, 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 one product authorized for commercial sale and have not generated any revenue from product sales to date, nor do we expect to generate any revenue until the fourth quarter of 2023 following the commercial launch of AspyreRx in October 2023. We will continue to incur significant research and development and other expenses related to our preclinical and clinical development, 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 \$22.8 million and \$31.0 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of \$134.3 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory authorizations for, our product candidates.

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

- advance our lead product, AspyreRx, through commercialization,;
- 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 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 \$22.8 million and \$31.0 million for the nine months ended September 30, 2023 and 2022, respectively, and we had an accumulated deficit of \$134.3 million as of September 30, 2023. Moreover, we anticipate that we will continue to incur significant financial losses for the foreseeable future. Our existing cash and cash equivalents of \$6.6 million as of September 30, 2023 is expected to fund our operations into the first quarter of 2024. Accordingly, there is substantial doubt about our ability to continue as a going concern. Our financial statements included elsewhere in this report do not include any adjustments that might result from the outcome of this uncertainty.

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 likely need 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. While we have reduced our operating expenses through a reduction-in-force in March 2023, we will likely need to raise additional capital to fund the commercialization activities for AspyreRx and to complete our ongoing real-world evidence program. Other unanticipated costs may arise in the course of our development efforts. If we are able to gain marketing authorization for additional product candidates that we develop, we would require 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 additional product candidates we may develop and pursue in the future;
- the timing of, and the costs involved in, obtaining marketing authorization for any 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 AspyreRx, 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 products;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

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

We believe that we will be able to fund our operating expenses and capital expenditure requirements into the first quarter of 2024. 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.

***We may not be successful in attracting, motivating and retaining highly qualified personnel in the future.***

On March 23, 2023, we announced a reduction in our workforce, or the Workforce Reduction, of approximately 35% of our employees as part of a cost reduction initiative to improve our cash runway and focus on the long-term success of the company. We estimated that we will incur approximately \$400 thousand in cash-based expenses related to severance and benefits through the third quarter of 2023 as a result of the Workforce Reduction. We may not realize, in full or in part, the anticipated benefits and savings from our Workforce Reduction, and we cannot guarantee that we will not have to undertake additional workforce reductions or restructuring activities in the future. Furthermore, the Workforce Reduction may be disruptive to our operations. For example, the Workforce Reduction could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale. If employees who were not affected by the reduction in force seek alternate employment, this could result in us seeking contract support at unplanned additional expense or harm our productivity. We may not be able to attract, motivate and retain qualified personnel who are critical to our business in the future. Recruiting and retaining qualified employees, consultants and advisors for our business is and will continue to be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. Any failure to attract or retain qualified personnel could prevent us from successfully developing our product candidates in the future.

***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 which has been authorized for marketing by 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 commercialization efforts for AspyreRx, 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, royalty financings 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 public health events, such as the effects of the 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 public health events, such as the effects of the COVID-19 pandemic;
- our ability to obtain marketing authorization or clearance for our other 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 AspyreRx or our other product candidates should they receive marketing authorization, which may vary significantly;

- the risk/benefit profile, cost and reimbursement policies with respect to AspyreRx and our other 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 AspyreRx (formerly BT-001). If we are unable to successfully commercialize AspyreRx, our business will be materially harmed.***

Our future success and ability to generate revenue from our products and product candidates is dependent on our ability to commercialize AspyreRx. We completed our pivotal clinical trial for AspyreRx in July 2022, our *de novo* classification request was accepted for substantive review by the FDA in October 2022, and we received FDA authorization for AspyreRx in July 2023. If AspyreRx encounters issues or 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 we are unable to successfully commercialize AspyreRx, including:

- 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 AspyreRx;
- 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 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 ("EMA"), 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 AspyreRx or our other product candidates, if authorized for marketing, or if our products otherwise fail to achieve and maintain market acceptance, our business, financial condition and results of operation would be materially and adversely affected.***

Our current business strategy is highly dependent on our products obtaining FDA authorization and these products being accepted and adopted in the market. Market acceptance and adoption of our products depends on educating people with cardiometabolic conditions, as well as payers, providers, 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 AspyreRx and our other product candidates, 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 AspyreRx 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, AspyreRx, we intend to focus our sales, marketing and training efforts primarily on a segment of health care providers who are early-tech adopting innovators, 74% of which are endocrinologists and diabetologists, in our initial target geographies. We believe that educating the many healthcare providers involved, from nurse practitioners to dietitians and other medical professionals in these disciplines 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 AspyreRx or our other 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 AspyreRx and our other 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 AspyreRx and our other 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 other product candidates is authorized for marketing, such products could compete with a range of therapeutic treatments that are in development.

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 products and other 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 products and other product candidates that receive regulatory marketing authorization or clearance. 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 products or other 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 AspyreRx and our other product candidates, if authorized for marketing.***

We are currently commencing 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 products and other product candidates, if authorized for marketing. Any failure or delay in the development of our sales, marketing and distribution capabilities would adversely impact the commercialization of AspyreRx and our other product candidates, if authorized for marketing.

Factors that may inhibit our efforts to commercialize AspyreRx and our other 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 AspyreRx or our other product candidates, 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 AspyreRx and our other 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 AspyreRx and our other product candidates, 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 AspyreRx and our other product candidates, 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 health care providers 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 effects of the COVID-19 pandemic, and similar events, which could result in lengthy interruptions in access to our platform. In addition, acts of terrorism, including malicious internet-based activity, could cause disruptions to the internet or the economy as a whole. Even with our disaster recovery arrangements, access to our platform could be interrupted. If our systems were to fail or be negatively impacted as a result of a natural disaster or other event, our ability to deliver our platform and products to our patients would be impaired or we could lose critical data. If we are unable to develop adequate plans to ensure that our business functions continue to operate during and after a disaster, and successfully execute on those plans in the event of a disaster or emergency, our business, financial condition, and results of operations would be harmed.

We have implemented a disaster recovery program that allows us to move 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, or of the conflict in the Israel-Gaza region and any potential increase in hostilities in the Middle East, 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 the Loan Agreement, as amended by the Amendment, with Hercules Capital as agent and lender. The Loan Agreement provides for an up to \$50.0 million 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, the current and future intellectual property of the Company and our subsidiaries, 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, we are required to maintain a minimum aggregate balance of \$2.5 million in cash in one or more controlled accounts. 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 us. Additionally, we did not receive net cash proceeds of at least \$40 million prior to March 15, 2023 and as a result the associated borrowing is no longer available to us.

Amortization payments under the Term Loan Facility begin November 1, 2023.

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 September 30, 2023 and December 31, 2022, we had NOLs for U.S. federal and state income tax purposes of approximately \$77.6 million and \$59.8 million, respectively. NOLs generated between January 1, 2020 and September 30, 2023 for U.S. federal tax reporting purposes of approximately \$73.3 million have an indefinite life. NOLs generated between January 1, 2020 and September 30, 2023 for state tax reporting purposes of approximately \$4.4 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 our 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 September 30, 2023 and December 31, 2022. 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 de novo classification or clearance to market and sell 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 AspyreRx was accepted for substantive review. In July 2023, the FDA notified us that AspyreRx was authorized for marketing. If we are not successful in obtaining timely marketing authorization for our other product candidates from the FDA, we may never be able to pursue authorization by foreign regulatory authorities or to generate significant revenue and may be forced to cease operations. 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 other 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 2023. During the meeting the FDA provided helpful context, clarifications and guidance, and we submitted our response to the FDA's comments on April 17, 2023. In July 2023, we received authorization from the FDA for AspyreRx.

In addition, 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.

***We are substantially dependent on market acceptance in the United States of AspyreRx, and our failure to gain such market acceptance would negatively impact our business.***

Since our inception, we have devoted substantially all of our efforts to the development of AspyreRx. If we are unable 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 AspyreRx. Further, because we have incurred costs prospectively in advance of FDA *de novo* classification, we would be unable to recoup these costs if AspyreRx fails to obtain market acceptance. 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 potential additional 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 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.***

Conducting clinical trials is a complex and expensive process, can take many years, and outcomes are inherently uncertain. 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, Institutional Review Boards ("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. The data we collect from our pilot studies and clinical trials may not be sufficient to support future FDA 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 other product candidates; the enrollment of patients in clinical trials; the release of data from clinical trials; the obtainment of the right to affix the CE mark in the European Union. The actual timing of these milestones could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot assure you that we will meet our projected milestones and if we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

Clinical trials are necessary to support *de novo* classification requests and certain 510(k) premarket notifications and may be necessary to support subsequent 510(k) submissions for modified versions of any digital therapeutic devices for which we obtain marketing authorization. This requires the enrollment of large numbers of suitable subjects, which may be difficult to identify, recruit and maintain as participants in the clinical trial. Adverse outcomes in our pivotal trials or post-market studies could also result in restrictions on or withdrawal of marketing authorization or 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 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 other 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 other 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.

***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 potential future clinical trials on our targeted timelines, or at all, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Slow enrollment in our clinical trials may lead to delays in our development timelines and milestones.

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

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our other 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 marketing 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 or clearance.***

It is important to our business strategy that we continue to enhance AspyreRx 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 authorizations or identify alternate regulatory pathways to market for such product candidate.***

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

For example, in the United States, other than AspyreRx for T2D, 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.

***We may not receive Breakthrough Device Designation by the FDA for our investigational CBT-based treatment platform, and even if we do, such designation may not lead to a faster development, regulatory review or clearance process, and it may not increase the likelihood that our study will receive marketing authorization from the FDA.***

We intend to seek Breakthrough Device Designation from the FDA by the end of 2023 for our investigational CBT based treatment platform. The FDA's breakthrough devices program is a voluntary program for certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and healthcare providers with timely access to these medical devices by speeding up their development, assessment and review, while preserving the statutory standards for premarket approval, 510(k) clearance and de novo marketing authorization, consistent with the FDA's mission to protect and promote public health.

Even if received, Breakthrough Device Designation may not result in a faster development process, review or clearance compared to conventional FDA procedures and does not assure ultimate marketing authorization by the FDA. In addition, even if a product qualifies as a breakthrough device, the FDA may later decide that the product no longer meets the conditions for qualification and revoke such designation.

## **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 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; premarket clearance and approval; establishment registration and device listing; marketing, sales and distribution; complaint handling; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export.

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

***We may not receive the necessary *de novo* classification grant for our other product candidates and failure to timely obtain these regulatory authorizations would adversely affect our ability to grow our business.***

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing products, we must first receive either clearance under Section 510(k) of the FD&C Act, or authorization under the *de novo* classification process added under the FDAMA, or premarket approval (“PMA”) from the FDA, unless an exemption applies.

The *de novo* classification process, which is how the FDA authorized AspyreRx, provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. A *de novo* classification is a risk-based classification process where devices that are classified into Class I or Class II through a *de novo* classification request may be marketed and used as predicates for future premarket notification 510(k) submissions.

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

Where the *de novo* classification or 510(k) clearance pathways are not available for medical devices, and where no policy of enforcement discretion exists enabling a manufacturer to market a medical device without obtaining premarket authorization, the process of obtaining PMA approval may apply, which is the most rigorous product development pathway for seeking marketing approval for a medical device. In review of a PMA application, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to 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. Each of the PMA approval, *de novo* classification, and the 510(k) clearance processes can be expensive, lengthy and uncertain. The FDA’s 510(k) clearance process usually takes from three to 12 months, but can last longer, while the *de novo* classification request process is usually longer and requires a clinical trial. The process of obtaining a PMA is much more costly and uncertain than the *de novo* or 510(k) clearance processes and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved, granted marketing authorization or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business. Furthermore, even if we are granted regulatory authorizations, clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

In the United States, we received authorization for AspyreRx through the *de novo* classification pathway. Some modifications to AspyreRx that have not been previously authorized may require us to submit a 510(k) premarket clearance application or a subsequent *de novo* classification request prior to implementing the change for marketing. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials or the interpretation of data from 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 authorized product 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 definition of a “medical device” in the United States.***

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

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

After *de novo* classification for AspyreRx, we are 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 AspyreRx and our other product candidates, 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.

Following authorization of AspyreRx, or any other product candidates we may commercialize, if 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 sizable 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 timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device authorization, seizure of our products or delay in clearance or approval of future products.

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

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

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

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

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

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

***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 AspyreRx or any of our other 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 products and other product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payers, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new products are typically made by CMS, an agency within the U.S. Department of Health and Human Services (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. Currently, there is no defined benefit category under CMS for prescription digital therapeutics. 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 our products and other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our products and other product candidates will be covered and paid for by commercial health plans, pharmacy benefits managers, other healthcare management organizations, or reimbursed by government health administration authorities. 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 and other 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 products and other 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 products and other 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 products and other 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), other types of healthcare practitioners (like physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians 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 Affordable Care Act (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 most 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. In August 2023, the government selected the first 10 drugs to be put through the Medicare drug price negotiation program, which is currently subject to several constitutional challenges. The outcomes of these challenges on the IRA, and the effect of the IRA on our business and the healthcare industry in general are 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 products and other 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 other product candidates. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates we may develop may lose any regulatory marketing authorization that may have been obtained and we may not achieve or sustain profitability.

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

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

## **Risks Related to Our Legal and Regulatory Environment**

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

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

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

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

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

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

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act ("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 September 30, 2023, and taking into account shares sold in our ATM program since then, our Executive Chairman, David Perry controls approximately 36.0% 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 (the "DGCL"), 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 DGCL 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 effects of public health events, such as the COVID-19 pandemic, and economic and political developments, including the conflicts in Ukraine and Israel, 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.

***If our common stock becomes subject to the penny stock rules, it may be more difficult to sell our common stock.***

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than \$5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTC Bulletin Board does not meet such requirements and if the price of our common stock is less than \$5.00 and our common stock is no longer listed on a national securities exchange such as The Nasdaq Capital Market, our stock may be deemed a penny stock. The penny stock rules require a broker-dealer, at least two business days prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver to the customer a standardized risk disclosure document containing specified information and to obtain from the customer a signed and dated acknowledgment of receipt of that document. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive: (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

***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 public health events, such as the effects of the COVID-19 pandemic and economic and political developments, including the conflicts in Ukraine and Israel, 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 conflicts in Ukraine and Israel. 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 products and other 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 products and other 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 products and other 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.

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

On April 5, 2023, we received a deficiency letter, or the April Letter, from the Staff of Nasdaq Stock Market notifying us that we were not in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market. The April Letter further noted that as of its date, we did not have a market value of listed securities of \$35 million, or net income from continued operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years, the alternative quantitative standards for continued listing on The Nasdaq Capital Market. On April 24, 2023, we received a letter from Nasdaq notifying us that we had regained compliance with Nasdaq's continued listing standards by demonstrating compliance with Nasdaq's alternative standard of market value of listed securities in excess of \$35 million under Nasdaq Listing Rule 5550(b)(2) and that the matter was closed. However, on June 16, 2023, we received deficiency letters, or the June Letters, from the Staff notifying us that we were not in compliance with the minimum bid price requirement and the market value of listed securities requirement for continued listing on The Nasdaq Capital Market. The June Letters noted that, as of their date, the bid price of our common stock was below \$1 per share and our market value of listed securities was below \$35 million, in each case for 30 consecutive business days. In accordance with Nasdaq rules, we have been provided 180 calendar days, or until December 13, 2023, or the Compliance Deadline, to regain compliance. The June Letters are only a notification of deficiency, not of imminent delisting, and have no current effect on the listing or trading of our securities on The Nasdaq Capital Market.

If at any time before the Compliance Deadline the market value of our listed securities closes at \$35 million or more for a minimum of ten consecutive business days, Nasdaq will provide written notification that we have achieved compliance with the market value of listed securities requirement, and the matter would be resolved. If we are not able to regain compliance with the market value of listed securities requirement by the Compliance Deadline, our common stock may be subject to delisting from The Nasdaq Capital Market,

If at any time before the Compliance Deadline the closing bid price of our common stock closes at or above \$1.00 per share for 10 consecutive business days, Nasdaq will provide written notification that we have achieved compliance with the minimum bid price requirement, and the matter would be resolved. If we do not regain compliance with the minimum bid price requirement before the Compliance Deadline, then Nasdaq may grant us a second 180 calendar day period to regain compliance, provided we (i) meet the continued listing requirement for market value of listed securities and all other initial listing standards for The Nasdaq Capital Market, other than the minimum closing bid price requirement and (ii) notify Nasdaq of our intent to cure the deficiency during the second compliance period.

There can be no assurance that we will be able to regain compliance with the Nasdaq's minimum bid price requirement or market value of listed securities requirement ahead of the Compliance Deadline, or if we are granted a second compliance period to meet the minimum bid price requirement, that we would be able to regain compliance during the second compliance period. If we are unable to regain compliance with Nasdaq's continued listing requirements, our common stock may be subject to delisting from The Nasdaq Capital Market. Upon a delisting from The Nasdaq Capital Market, our stock would likely be traded in the over-the-counter inter-dealer quotation system, more commonly known as the OTC. OTC transactions involve risks in addition to those associated with transactions in securities traded on the securities exchanges, such as The Nasdaq Capital Market, or, together, Exchange-listed stocks. Many OTC stocks trade less frequently and in smaller volumes than Exchange-listed stocks. Accordingly, our stock would be less liquid than it would be otherwise. Also, the prices of OTC stocks are often more volatile than Exchange-listed stocks. Additionally, institutional investors are usually prohibited from investing in OTC stocks, and it might be more challenging to raise capital when needed.

***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 September 30, 2023, as adjusted for shares sold in our ATM program since then, we had outstanding 47,403,398 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.

In addition, 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.

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

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (“SVB”) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (“FDIC”) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership; since then, additional financial institutions have experienced similar failures and have been placed into receivership. It is possible that other banks will face similar difficulty in the future. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments financial institutions that have been placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. Although we are not a borrower or party to any such instruments with any financial institution currently in receivership, if any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, if any of the parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties’ ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to credit agreements and arrangements with banks in receivership or other financial difficulty, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure or reorganization of such financial institutions and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations or result in breaches of our financial and/or contractual obligations. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by the parties with whom we conduct business, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a party with whom we conduct business may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy. In addition, a party with whom we conduct business could be adversely affected by any of the liquidity or other risks that are described above, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any bankruptcy or insolvency of a party with whom we conduct business, or the failure of such party to make payments when due, or any breach or default by such party, could result in material losses to us and may have a material adverse impact on our business.

***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 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.

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

On July 25, 2023, the Company entered into a Securities Purchase Agreement with certain related party and non-related party investors pursuant to which the Company agreed to issue and sell an aggregate of 2,897,654 shares of the Company's common stock at a purchase price of \$0.7299 per share in a private placement. Upon the closing of the private placement on July 27, 2023, the Company received gross proceeds of approximately \$2.1 million, before the deduction of \$233 thousand in offering expenses. The Company used the net proceeds from the private placement to support the launch of AspyreRx. Based in part upon the representations of the investors in the Securities Purchase Agreement, the offering and sale of the securities was made in reliance on the exemption from registration provided for under Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder.

## **Item 3. Defaults Upon Senior Securities.**

None

## **Item 4. Mine Safety Disclosures.**

Not Applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>
3.1	<a href="#">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).</a>
3.2	<a href="#">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).</a>
10.1	<a href="#">Securities Purchase Agreement, dated July 25, 2023, by and among Better Therapeutics, Inc. and each purchaser party thereto (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on July 26, 2023).</a>
10.2	<a href="#">Securities Purchase Agreement, dated July 25, 2023, by and among Better Therapeutics, Inc. and each purchaser party thereto (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on July 26, 2023).</a>
31.1*	<a href="#">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.</a>
31.2*	<a href="#">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.</a>
32.1**	<a href="#">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.</a>
32.2**	<a href="#">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.</a>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

\* Filed herewith.

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

**SIGNATURES**

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

**BETTER THERAPEUTICS, INC.**  
(Registrant)

Date: November 9, 2023

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

Date: November 9, 2023

By: /s/ Mark Heinen  
\_\_\_\_\_  
**Mark Heinen**  
**Chief Financial Officer**  
(Principal Financial and Accounting Officer)

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

I, Frank Karbe, certify that:

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

Date: November 9, 2023

By: \_\_\_\_\_  
/s/ Frank Karbe  
**Frank Karbe**  
**Chief Executive Officer**







