

**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 **March 31, 2024**

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: **001-41989**

BOUNDLESS BIO, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

9880 Campus Point Drive, Suite 120

San Diego, CA 92121

(Address of principal executive offices)

83-0751369

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

92121

(Zip Code)

Registrant's telephone number, including area code: (858) 766-9912

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	BOLD	Nasdaq Global Select Market

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 May 6, 2024, the registrant had 22,254,537 shares of common stock, \$0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Boundless Bio, Inc.
Condensed Balance Sheets
(in thousands, except share and par value data)

	March 31, 2024 <i>(unaudited)</i>	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	\$ 25,143	\$ 23,706
Short-term investments	79,737	97,046
Prepaid expenses and other current assets	7,281	3,452
Total current assets	112,161	124,204
Property and equipment, net	2,418	2,573
Right-of-use asset, net	1,385	2,002
Restricted cash	560	560
Other assets	553	555
Total assets	<u>\$ 117,077</u>	<u>\$ 129,894</u>
Liabilities, convertible preferred stock, and stockholders' deficit		
Current liabilities		
Accounts payable and accrued liabilities	\$ 8,182	\$ 4,266
Accrued compensation	939	2,898
Lease liabilities, current portion	1,523	2,195
Total current liabilities	10,644	9,359
Commitments and contingencies (Note 8)		
Convertible preferred stock, \$0.0001 par value; 287,446,844 shares authorized, issued, and outstanding as of each of March 31, 2024 and December 31, 2023; liquidation preference of \$252.1 million as of each of March 31, 2024 and December 31, 2023	247,617	247,617
Stockholders' equity:		
Common stock, \$0.0001 par value; 402,600,000 shares authorized, 1,263,597 shares issued, and 1,262,638 shares outstanding as of March 31, 2024; 402,600,000 shares authorized, 1,248,493 shares issued, and 1,247,012 shares outstanding as of December 31, 2023	—	—
Additional paid-in-capital	10,376	8,987
Accumulated other comprehensive income / (loss)	(21)	40
Accumulated deficit	(151,539)	(136,109)
Total stockholders' deficit	(141,184)	(127,082)
Total liabilities, convertible preferred stock, and stockholders' deficit	<u>\$ 117,077</u>	<u>\$ 129,894</u>

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

Boundless Bio, Inc.
Condensed Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except per share data)

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	\$ 13,129	\$ 9,503
General and administrative	3,754	2,584
Total operating expenses	16,883	12,087
Loss from operations	(16,883)	(12,087)
Other income (expense):		
Interest income	1,421	395
Other income (expense)	32	(27)
Total other income, net	1,453	368
Net loss	\$ (15,430)	\$ (11,719)
Net loss per share, basic and diluted	\$ (12.27)	\$ (9.91)
Shares used in calculation	1,258	1,183
Comprehensive loss:		
Net loss	\$ (15,430)	\$ (11,719)
Unrealized gain/(loss) on short-term investments	(61)	278
Comprehensive loss	\$ (15,491)	\$ (11,441)

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

Boundless Bio, Inc.
Condensed Statements of Convertible Preferred Stock and Stockholders' Deficit
(unaudited)
(in thousands, except share data)

	<u>Convertible Preferred Stock</u>		<u>Common Stock</u>			Accumulated other comprehen- sive income/ (loss)	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount	Additional paid-in- capital			
Balance at December 31, 2023	287,446,844	\$ 247,617	1,247,012	\$ -	\$ 8,987	\$ 40	\$ (136,109)	\$ (127,082)
Vesting of early exercised stock options	—	—	522	—	2	—	—	2
Exercise of stock options	—	—	15,104	—	59	—	—	59
Stock-based compensation	—	—	—	—	1,328	—	—	1,328
Unrealized loss on short-term investments	—	—	—	—	—	(61)	—	(61)
Net loss	—	—	—	—	—	—	(15,430)	(15,430)
Balance at March 31, 2024	<u>287,446,844</u>	<u>\$ 247,617</u>	<u>1,262,638</u>	<u>\$ -</u>	<u>\$ 10,376</u>	<u>\$ (21)</u>	<u>\$ (151,539)</u>	<u>\$ (141,184)</u>
Balance at December 31, 2022	144,589,706	\$ 147,946	1,167,240	\$ -	\$ 5,377	\$ (398)	\$ (86,675)	(81,696)
Vesting of early exercised stock options	—	—	17,505	—	52	—	—	52
Exercise of stock options	—	—	9,195	—	31	—	—	31
Stock-based compensation	—	—	—	—	615	—	—	615
Unrealized gain on short-term investments	—	—	—	—	—	278	—	278
Net loss	—	—	—	—	—	—	(11,719)	(11,719)
Balance at March 31, 2023	<u>144,589,706</u>	<u>\$ 147,946</u>	<u>1,193,940</u>	<u>\$ -</u>	<u>\$ 6,075</u>	<u>\$ (120)</u>	<u>\$ (98,394)</u>	<u>\$ (92,439)</u>

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

Boundless Bio, Inc.
Condensed Statements of Cash Flows
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities		
Net loss	\$ (15,430)	\$ (11,719)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,328	615
Depreciation	263	237
Accretion of investments, net	(972)	(117)
Non-cash lease expense	618	533
Other	—	25
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(701)	(225)
Accounts payable and accrued liabilities	(210)	(904)
Operating lease liabilities	(672)	(535)
Net cash used in operating activities	<u>(15,776)</u>	<u>(12,090)</u>
Cash flows from investing activities		
Purchases of investments	(21,025)	(9,994)
Maturities of investments	39,245	32,246
Purchases of property and equipment	(83)	(86)
Net cash provided by investing activities	<u>18,137</u>	<u>22,166</u>
Cash flows from financing activities		
Proceeds from the exercise of stock options	59	31
Payment of deferred offering costs	(983)	—
Net cash provided by / (used in) financing activities	<u>(924)</u>	<u>31</u>
Net increase in cash and cash equivalents	1,437	10,107
Cash, cash equivalents, and restricted cash at beginning of period	24,266	11,484
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 25,703</u>	<u>\$ 21,591</u>
Components of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	\$ 25,143	\$ 21,058
Restricted cash	560	533
Cash, cash equivalents, and restricted cash at end of year	<u>\$ 25,703</u>	<u>\$ 21,591</u>
Non-cash investing and financing activities		
Deferred offering costs in accounts payable and accrued liabilities	\$ 2,144	\$ —
Addition to ROU assets	\$ —	\$ 282
Increase to ROU assets due to remeasurement of lease obligation	\$ —	\$ 646
Vesting of early exercised stock options	\$ 2	\$ 52
Unpaid property and equipment purchases	\$ 24	\$ 26

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

Boundless Bio, Inc.
Notes to Condensed Financial Statements

1. Organization and Basis of Presentation

Description of Business

Boundless Bio, Inc. (the Company) is a clinical-stage precision oncology company dedicated to unlocking a new paradigm in cancer therapeutics to address the significant unmet need in patients with oncogene amplified tumors by targeting extrachromosomal DNA (ecDNA). The Company is focused on designing and developing small molecule drugs called ecDNA directed therapeutic candidates (ecDTx). The Company was incorporated in the state of Delaware on April 10, 2018 and is headquartered in San Diego, California.

Reverse Stock Split

On March 19, 2024, the Company effected a one-for-19.5 reverse stock split of its issued and outstanding shares of common stock. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the conversion ratios for each series of the Company's convertible preferred stock. The par value and the number of authorized shares of the convertible preferred stock and common stock were not adjusted in connection with the reverse stock split.

Liquidity

Since the Company commenced operations in 2018, it has devoted substantially all of its efforts and resources to organizing and staffing the Company, business planning, raising capital, building its proprietary Spyglass platform, discovering its ecDTx, developing its ecDNA diagnostic candidate, establishing its intellectual property portfolio, conducting research, preclinical studies and clinical trials, establishing arrangements with third parties for the manufacture of its ecDTx and related raw materials, and providing other general and administrative support for these operations.

Since inception, the Company has incurred significant operating losses and negative cash flows from its operations and expects that it will continue to do so into the foreseeable future as it continues its development of, seeks regulatory approval for, and potentially commercializes any of its ecDTx and seeks to discover and develop additional ecDTx, utilizes third parties to manufacture its ecDTx and related raw materials, seeks to develop its ecDNA diagnostic candidate, hires additional personnel, and expands and protects its intellectual property. If the Company obtains regulatory approval for any of its ecDTx, it expects to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. As of March 31, 2024, the Company had an accumulated deficit of \$151.5 million and cash, cash equivalents, and short-term investments of \$104.9 million. The Company believes that its existing cash, cash equivalents, and short-term investments, as well as the net proceeds from the April 2, 2024 closing of the Company's initial public offering (IPO) discussed in footnote 13, will be sufficient to fund its operations for at least 12 months from the issuance date of these condensed financial statements.

Boundless Bio, Inc.
Notes to Condensed Financial Statements

Basis of Presentation

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. The financial statements are presented in U.S. dollars. Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) promulgated by the Financial Accounting Standards Board (FASB).

2. Summary of Significant Accounting Policies

Unaudited Condensed Interim Financial Information

The condensed balance sheet as of March 31, 2024, the condensed statements of operations and comprehensive loss for the three months ended March 31, 2024 and 2023, the condensed statements of convertible preferred stock and stockholders' deficit for the three months ended March 31, 2024 and 2023, and the condensed statements of cash flows for the three months ended March 31, 2024 and 2023 are unaudited. These unaudited condensed financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's financial position, results of operations, and cash flows for the interim period presented. The financial data and the other financial information contained in these notes to the condensed financial statements related to the three months ended March 31, 2024 and 2023 are also unaudited. The results of operations for the three months ended March 31, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024 or for any other future annual or interim period.

The condensed balance sheet as of December 31, 2023 included herein was derived from the audited financial statements as of that date. These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements included in the Company's prospectus dated March 27, 2024 related to its IPO filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, with the SEC on March 28, 2024.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenue and expenses, and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

On an ongoing basis, management evaluates its estimates, primarily related to stock-based compensation, the fair value of its investments and common stock, and accrued research and development costs. These estimates are based on historical data and experience, as well as various other factors that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The Company's estimates relating to the valuation of stock options require the selection of appropriate valuation methodologies and models, and significant judgment in evaluating ranges of assumptions and financial inputs.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents include cash in readily available checking and money market accounts.

The balance reflected in these financial statements as restricted cash represents a deposit account pledged as collateral to secure a standby letter of credit required as a security deposit on one of the Company's leased facilities. The Company has classified the restricted cash as a noncurrent asset on its balance sheets as of March 31, 2024 and December 31, 2023.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to the concentration of credit risk, consist primarily of cash, cash equivalents, and investments. The Company maintains deposits in federally insured financial institutions which exceeded federally insured limits by \$2.3 million. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company's investment policy includes guidelines for the quality of the related institutions and financial instruments and defines allowable investments that the Company may invest in, which the Company believes minimizes its exposure to concentration of credit risk.

Boundless Bio, Inc.
Notes to Condensed Financial Statements

Fair Value Measurements

Certain assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement determined based on assumptions that market participants would use in pricing an asset or liability. Financial assets and liabilities carried at fair value are classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

Cash, cash equivalents, and short-term investments are carried at fair value, determined according to the fair value hierarchy described above. The carrying values of the Company's prepaid expenses, accounts payable, and accrued expenses approximate their fair value due to the short-term nature of these assets and liabilities. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting, and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss. As of March 31, 2024 and December 31, 2023, there were \$5.3 million and \$2.2 million of deferred offering costs, respectively.

Segments

Operating segments are identified as components of an enterprise about which discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one operating segment.

Convertible Preferred Stock

The Company's convertible preferred stock is classified as temporary equity in the accompanying balance sheets and excluded from stockholders' deficit as the potential redemption of such stock is outside the Company's control and would require the redemption of the then-outstanding convertible preferred stock. The convertible preferred stock is not redeemable except for in the event of a liquidation, dissolution, or winding up of the Company. Costs incurred in connection with the issuance of convertible preferred stock are recorded as a reduction of gross proceeds from issuance. The Company does not accrete the carrying values of the preferred stock to the redemption values since the occurrence of these events was not considered probable as of March 31, 2024 and December 31, 2023. Subsequent adjustments of the carrying values to the ultimate redemption values will be made only when it becomes probable that these events will occur.

Net Loss Per Share

Basic net loss per common share attributable to common stockholders is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. The Company's potentially dilutive securities, which include its convertible preferred stock, options to purchase common stock, and common stock subject to repurchase related to unvested restricted stock and options early exercised, have been excluded from the computation of diluted net loss per share as the effect would reduce the net loss per share. Therefore, the weighted-average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same.

Boundless Bio, Inc.
Notes to Condensed Financial Statements

Recently Adopted Accounting Pronouncements

As of March 31, 2024, several new accounting pronouncements had been issued by the Financial Accounting Standards Board with future adoption dates. All applicable accounting pronouncements will be adopted by the Company by the date required. Management is reviewing the impact of adoption of all pending accounting pronouncements but is not yet in a position to determine the impact on the Company's financial statements and the notes thereto.

3. Fair Value Measurements

The following tables summarize the Company's financial assets measured at fair value on a recurring basis and their respective input levels based on the fair value hierarchy (in thousands):

As of March 31, 2024 (in thousands)	Amount	Fair Value Measurements Using		
		Level 1	Level 2	Level 3
Assets				
Money market funds (1)	\$ 22,546	\$ 22,546	\$ —	\$ —
U.S. government obligations (2)	75,082	—	75,082	—
Corporate debt securities (2)	4,655	—	4,655	—
Total fair value of assets	\$ 102,283	\$ 22,546	\$ 79,737	\$ —

(1) Included in cash and cash equivalents on the balance sheets.

(2) Included in short-term investments on the balance sheets.

As of December 31, 2023 (in thousands)	Amount	Fair Value Measurements Using		
		Level 1	Level 2	Level 3
Assets				
Money market funds (1)	\$ 21,737	\$ 21,737	\$ —	\$ —
U.S. government obligations (2)	92,143	—	92,143	—
Corporate debt securities (2)	4,903	—	4,903	—
Total fair value of assets	\$ 118,783	\$ 21,737	\$ 97,046	\$ —

(1) Included in cash and cash equivalents on the balance sheets.

(2) Included in short-term investments on the balance sheets.

The Company's money market funds are classified as Level 1 because they are valued using quoted market prices. The Company's investments consist of available-for-sale securities and are classified as Level 2 because their value is based on valuations using significant inputs derived from or corroborated by observable market data.

There were no transfers of assets between fair value levels for all periods presented.

4. Investments

The following tables summarize investments accounted for as available-for-sale securities (in thousands):

	As of March 31, 2024			
	Acquisition Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	\$ 22,546	\$ —	\$ —	\$ 22,546
U.S. government obligations	75,103	6	(27)	75,082
Corporate debt securities	4,655	1	(1)	4,655
Total cash equivalents and investments	\$ 102,304	\$ 7	\$ (28)	\$ 102,283
Classified as:				
Cash equivalents				\$ 22,546
Short-term investments				79,737
Total cash equivalents and investments				\$ 102,283

Boundless Bio, Inc.
Notes to Condensed Financial Statements

As of December 31, 2023

	Acquisition Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	\$ 21,737	\$ —	\$ —	\$ 21,737
U.S. government obligations	92,106	58	(21)	92,143
Corporate debt securities	4,900	5	(2)	4,903
Total cash equivalents and investments	<u>\$ 118,743</u>	<u>\$ 63</u>	<u>\$ (23)</u>	<u>\$ 118,783</u>
Classified as:				
Cash equivalents				\$ 21,737
Short-term investments				97,046
Total cash equivalents and investments				<u>\$ 118,783</u>

On March 31, 2024 and December 31, 2023, the remaining contractual maturities of all the Company's available-for-sale investments were less than 12 months. As of March 31, 2024 and December 31, 2023, the Company has not established an allowance for credit losses for any of its available-for-sale securities.

As of March 31, 2024, there were 33 available-for-sale securities, with an estimated fair value of \$56.9 million in gross unrealized loss positions. As of December 31, 2023, there were 24 available-for-sale securities, with an estimated fair value of \$40.3 million in gross unrealized loss positions. Based on its review of these investments, the Company believes that the unrealized losses reflect the impact of the rising interest rate environment and were not other-than-temporary in nature.

5. Property and Equipment

Property and equipment, net consisted of the following (in thousands):

	March 31, 2024 (unaudited)	December 31, 2023
Lab equipment	\$ 4,368	\$ 4,264
Computers and software	836	833
Leasehold improvements	46	46
Furniture and fixtures	157	157
	<u>5,407</u>	<u>5,300</u>
Less accumulated depreciation and amortization	2,989	2,727
	<u>\$ 2,418</u>	<u>\$ 2,573</u>

Depreciation and amortization expense related to property and equipment was \$0.3 million and \$0.2 million for the three months ended March 31, 2024 and 2023, respectively.

6. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following (in thousands):

	March 31, 2024 (unaudited)	December 31, 2023
Accounts payable	\$ 2,937	\$ 2,222
Accrued research and development costs	2,759	1,575
Other accrued liabilities	2,486	469
Total accounts payable and accrued liabilities	<u>\$ 8,182</u>	<u>\$ 4,266</u>

Boundless Bio, Inc.
Notes to Condensed Financial Statements

7. Lease Agreements

2022 Lease

In March 2021, as amended in November 2021, the Company entered into a non-cancelable operating lease for a facility in San Diego, California (the 2022 Lease). The 2022 Lease had an initial term that ended in May 2024, although this was subsequently amended such that this lease now ends on that date occurring 14 days after the lease commencement date for the 2024 Lease (see below). The 2022 Lease provides for the rental of lab and office space, contains rent escalation provisions, and obligates the Company to pay a portion of the operating costs related to the underlying multitenant facility. Rental payments under the 2022 Lease commenced in mid-January 2022. Based on information obtained from its landlord, the Company has recorded a right-of-use (ROU) asset and an associated lease obligation for the lab and office space leased under the 2022 Lease. The net ROU asset of \$1.4 million and associated lease obligation of \$1.5 million are reflected in the Company's balance sheet as of March 31, 2024 and are estimates that will change should there be a change in the anticipated occupancy date of the property and associated campus underlying the 2024 Lease. The Company's estimated incremental borrowing rate of approximately 8.0% was used in its present value calculation as the 2022 Lease does not have a stated rate and the implicit rate was not readily determinable.

As of March 31, 2024, future minimum lease payments under the 2022 Lease are expected to total \$1.6 million, including imputed interest of approximately \$28,000. All future payments under the 2022 Lease are expected to occur in 2024.

2024 Lease

In December 2021, the Company entered into a non-cancelable facility lease for approximately 80,000 square feet of lab and office space in La Jolla, California (the 2024 Lease). The facility to be occupied by the Company under the 2024 Lease will be built to the Company's specifications; the 2024 Lease agreement includes tenant improvement allowances totaling \$22.0 million, repayment of which is included in the future minimum lease payments called for under the agreement.

As of March 31, 2024, although construction of the property underlying the 2024 Lease is underway, the commencement date of the 2024 Lease has not yet been determined. At completion of construction, the Company will occupy the facility for a 120-month term, with payments under the lease commencing after a six-month rent abatement period and continuing through the conclusion of the term. As of March 31, 2024, the landlord has advised the Company that this property will be available for occupancy in October 2024. This date is an estimate, which is subject to change based on the delivery of the property and its associated campus. The 2024 Lease includes base lease payments aggregating \$71.9 million, as well as additional charges for common area maintenance and property taxes. The Company has the right to extend the term of the 2024 Lease for an additional 60 months.

Additionally, as a security deposit under this agreement, the Company is required to maintain a standby letter-of-credit in the amount of \$0.5 million, which must remain in place until November 2034.

Operating Leases

The Company has made upfront payments under its lease agreements totaling \$0.8 million, \$0.5 million of which is included in other long-term assets on the balance sheet as of March 31, 2024 and December 31, 2023.

Cash paid for operating lease liabilities during the three months ended March 31, 2024 and 2023 totaled \$0.7 million and \$0.7 million, respectively.

8. Commitments and Contingencies

Contracts

The Company enters into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing, manufacturing, and other services. These contracts generally provide for termination upon notice and are cancellable without significant penalty or payment and do not contain any minimum purchase commitments.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into

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Notes to Condensed Financial Statements

indemnification agreements with officers and members of its Board of Directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs because of these indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its financial statements as of March 31, 2024 and December 31, 2023.

Litigation

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. There are no matters currently outstanding for which any liabilities have been accrued. The Company was not a defendant in any lawsuit for the three months ended March 31, 2024 and the year ended December 31, 2023.

9. Convertible Preferred Stock

Series A, B, and C Convertible Preferred Stock

The Company issued its convertible preferred stock in a series of transactions as follows:

- In August 2018, 7,142,857 shares of Series A convertible preferred stock were issued for cash at a price of \$0.70 per share, resulting in aggregate net proceeds of \$4.9 million;
- In June 2019, an additional 26,046,438 shares of Series A convertible preferred stock were issued for cash at a price of \$0.70 per share, resulting in aggregate net proceeds of \$18.1 million;
- In July 2020, an additional 33,189,295 shares of Series A convertible preferred stock were issued for cash at a price of \$0.70 per share, resulting in aggregate net proceeds of \$23.2 million;
- In April 2021, the Company entered into a Series B convertible preferred stock purchase agreement under which it issued 78,211,116 shares of its Series B convertible preferred stock for cash, at a price of \$1.35 per share, resulting in aggregate net proceeds of \$105.3 million;
- In April and May 2023, the Company entered into a Series C convertible preferred stock purchase agreement under which it issued 142,857,138 shares of Series C convertible preferred stock for cash, at a price of \$0.70 per share, resulting in aggregate net proceeds of \$99.7 million.

Rights, Preferences, and Privileges of Convertible Preferred Stock

The holders of the Company's Series A, B, and C convertible preferred stock (collectively, the Preferred Stock) have the following rights, preferences, and privileges:

Voting Rights

The holders of Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to the stockholders for a vote and are entitled to the number of votes equal to the number of whole shares of common stock into which such holders of Preferred Stock could convert on the record date for determination of stockholders entitled to vote.

Dividends

The Company cannot declare and pay any common stock dividends without first declaring and paying dividends, as defined in the terms of the Company's amended and restated certificate of incorporation, to the convertible preferred stockholders. The holders of Preferred Stock are entitled to receive, when, as and if, declared by the Company's Board of Directors, noncumulative dividends at the rate of 6.0% of the applicable original issue price of such Preferred Stock (Original Issue Price), subject to appropriate adjustment in

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the event of any stock dividend, stock split, combination, or other similar recapitalization with respect to the Preferred Stock. No dividends have been declared as of March 31, 2024 or December 31, 2023, respectively.

Liquidation Rights

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or Deemed Liquidation Event (as defined in the Company's amended and restated certificate of incorporation), each holder of Preferred Stock is entitled to receive, prior and in preference to any distributions to the common stockholders, an amount equal to the greater of (i) the Original Issue Price per share, plus any declared but unpaid dividends thereon or (ii) the amount such holder would have received if such holder had converted its shares into common stock immediately prior to such liquidation event. If the assets available for distribution to the holders of Preferred Stock are insufficient to pay such holders the full amounts to which they are entitled, the assets available for distribution will be distributed on a pro rata basis among the holders of the Preferred Stock in proportion to the respective amounts that would otherwise be payable in respect of such stock. After payments have been made in full to the holders of Preferred Stock, then, to the extent available, the remaining amounts would be distributed among the holders of the common stock, pro rata based on the number of shares held by each holder.

Conversion Rights

The shares of Preferred Stock are convertible into an equal number of shares of common stock, at the option of the holder, subject to certain anti-dilution adjustments. Each share of Preferred Stock will be automatically converted into common stock, (A) immediately upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, covering the offer and sale of common stock for the account of the Company in which the aggregate gross proceeds is at least \$50.0 million and the public offering price of at least \$1.6875 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization (Qualified IPO Price), (B) at any time upon the affirmative election of the holders of at least 60% of the outstanding shares of the Preferred Stock, including at least one of the holders holding, together with its affiliates, the most, the second most, or the third most shares of Series B Preferred Stock, or (C) the closing of a transaction pursuant to which (i) the Company is merged into, or otherwise combines with, a special purpose acquisition company, or subsidiary thereof, listed on a national securities exchange (SPAC Entity) at a value per share of at least the Qualified IPO Price and (ii) the shares of capital stock of the Company immediately outstanding prior to such transaction are converted to or exchanged for shares of capital stock that represent a majority, by voting power, of the capital stock of the SPAC Entity.

Redemption

The Preferred Stock does not have redemption rights, except for the contingent redemption upon the occurrence of a Deemed Liquidation Event (as defined in the Company's amended and restated certificate of incorporation).

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Notes to Condensed Financial Statements

10. Common Stock

Common Stock Rights

The holder of each outstanding share of common stock is entitled to one vote on all matters submitted to a vote of the holders of common stock. Subject to the rights of the holders of any class of the Company's capital stock having any preference or priority over common stock, the holders of common stock are entitled to receive dividends that are declared by the Company's Board of Directors out of legally available funds. In the event of a liquidation, dissolution or winding-up, the holders of common stock are entitled to share ratably in the net assets remaining after payment of liabilities and the liquidation value of the Preferred Stock then outstanding. The common stock has no preemptive rights, conversion rights, redemption rights or sinking fund provisions, and there are no dividends in arrears or default. All shares of common stock have equal distribution, liquidation and voting rights, and have no preferences or exchange rights.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consisted of the following:

	<u>As of March 31,</u> <u>2024</u>	<u>As of December 31,</u> <u>2023</u>
Conversion of outstanding convertible preferred stock	14,740,840	14,740,840
Common stock options issued and outstanding	4,169,881	2,813,937
Equity awards available for future issuance	2,298,086	861,155
Total	<u>21,208,807</u>	<u>18,415,932</u>

11. Stock Options and Stock-Based Compensation

Equity Incentive Plan

In March 2024, the Company adopted the 2024 Incentive Plan (as amended, the Plan), which expires 10 years from its effective date. The Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, and other stock awards to its employees, consultants, and directors. Options granted under the Plan are exercisable at various dates as determined upon grant and will expire no more than 10 years from their date of grant. Stock options generally vest over terms of either 36 or 48 months. The exercise price of awards under the Plan shall not be less than 100% of the estimated fair market value of the Company's stock on the date of grant. As of March 31, 2024, a total of 2,832,882 shares of common stock were authorized for issuance under the Plan. On March 31, 2024, 2,298,086 of these shares remain available for grant under the Plan.

Prior to the adoption of the Plan, the Company had awarded common stock options under the 2018 Equity Incentive Plan (as amended, the Predecessor Plan). Under the provisions of the Plan, awards issued under the Predecessor Plan that were outstanding as of March 27, 2024, and that are subsequently cancelled or forfeit, will serve to increase the number of shares that may be issued under the Plan.

Stock Options

Stock option activity under the Plan and certain other related information is as follows:

	<u>Number</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Remaining Term</u>	<u>Aggregate-Intrinsic Value (in 000's)</u>
Balance as of December 31, 2023	2,813,937	\$ 4.10	7.8 years	\$ 562
Granted	1,375,088	\$ 11.23		
Exercised	(15,104)	\$ 3.90		
Forfeited and expired	(4,040)	\$ 4.05		
Balance as of March 31, 2024	<u>4,169,881</u>	\$ 6.47	8.9 years	\$ 33,378
Vested and expected to vest at March 31, 2024	<u>1,096,002</u>	\$ 4.13	7.6 years	\$ 11,086
Exercisable as of March 31, 2024	<u>1,161,181</u>	\$ 4.20	7.7 years	\$ 11,666

Aggregate intrinsic value in the above table is the difference between the estimated fair value of the Company's common stock as of either March 31, 2024 or December 31, 2023, and the exercise price of stock options that had exercise prices below that value.

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Notes to Condensed Financial Statements

The options exercised during the three months ended March 31, 2024 and 2023 had an intrinsic value at exercise of \$31,000 and approximately \$7,000, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense was as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Research and development expenses	\$ 524	\$ 272
General and administrative expenses	804	343
Total stock-based compensation	\$ 1,328	\$ 615

As of March 31, 2024, unrecognized compensation cost related to outstanding time-based options was \$23.0 million, which is expected to be recognized over a weighted-average period of 2.7 years.

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the stock options granted during the following periods were as follows:

	Three Months Ended March 31,	
	2024	2023
Expected option life (in years)	6.0	6.0
Assumed volatility	95 %	92 %
Assumed risk-free interest rate	4.2 %	3.6 %
Expected dividend yield	—	—

The weighted-average grant date per share fair value of options granted during the three months ended March 31, 2024 and 2023 was \$11.69 and \$7.62, respectively.

12. Net Loss Per Common Share

The following table summarizes the computation of basic and diluted net loss per common share of the Company (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2024	2023
Net loss	\$ (15,430)	\$ (11,719)
Weighted-average shares of common stock used in computing net loss per share, basic and diluted	1,258	1,183
Net loss per share, basic and diluted	\$ (12.27)	\$ (9.91)

The Company excluded the following potential shares of its common stock, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2024	2023
Conversion of outstanding convertible preferred stock	14,740,840	14,740,840
Options to purchase common stock	4,169,881	2,813,937
Options early exercised subject to future vesting	959	1,481
Total	18,911,680	17,556,258

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13. Subsequent Events

Initial Public Offering

On April 2, 2024, the Company completed its IPO, pursuant to which it sold 6,250,000 shares of its common stock at a public offering price of \$16.00 per share, resulting in net proceeds of approximately \$87.7 million, after deducting underwriting discounts, commissions, and other offering expenses. Immediately prior to the closing of the IPO, the Company's outstanding convertible preferred stock automatically converted into 14,740,840 shares of common stock. Following the closing of the IPO, no shares of convertible preferred stock were authorized or outstanding.

In connection with the closing of its IPO, on April 2, 2024, the Company's certificate of incorporation was amended and restated to authorize 700,000,000 shares of common stock, par value \$0.0001 per share and 70,000,000 shares of undesignated preferred stock, par value of \$0.0001 per share.

The condensed financial statements as of March 31, 2024, including share and per share amounts, do not give effect to the IPO as it closed subsequent to March 31, 2024.

The table below shows, on a pro forma basis, the impact of the Company's IPO on certain condensed balance sheet items as if all the transactions occurred on March 31, 2024:

(in thousands)	March 31, 2024	Pro Forma March 31, 2024
Cash, cash equivalents, and short-term investments	\$ 104,880	\$ 197,880
Deferred offering costs	\$ 5,281	\$ -
Convertible preferred stock	\$ 247,617	\$ -
Common stock	\$ -	\$ 2
Additional paid-in capital	\$ 10,376	\$ 345,710
Total stockholders' (deficit) equity	\$ (141,184)	\$ 194,153

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

The following discussion and analysis and the unaudited interim financial statements included in this Quarterly Report on Form 10-Q should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2023 and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Prospectus dated March 27, 2024 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended (Securities Act) with the Securities and Exchange Commission (SEC) on March 28, 2024 (the Prospectus).

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of 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, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design, and conduct of our ongoing and planned clinical trials and preclinical studies for our extrachromosomal DNA (ecDNA) directed therapeutic candidates (ecDTx), ecDNA diagnostic candidate, and other development programs, the potential therapeutic benefits of our ecDTx, the timing and likelihood of regulatory filings and approvals for our ecDTx, our ability to commercialize our ecDTx, if approved, the pricing and reimbursement of our ecDTx, if approved, the potential to develop future ecDTx, the potential benefits of strategic collaborations and our intent to enter into any strategic arrangements, the timing and likelihood of success, plans, and objectives of management for future operations, future results of anticipated ecDTx development efforts, and the sufficiency of our cash position to fund operations and milestones, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “contemplate,” “continue” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” or “will” or the negative of these terms or other similar expressions. These forward-looking statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial and other trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties, and assumptions, including, without limitation, the risk factors described in Part II, Item 1A, “Risk Factors” of this Quarterly Report. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances, or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Overview

We are a clinical-stage oncology company dedicated to unlocking a new paradigm in cancer therapeutics that addresses the significant unmet need in patients with oncogene amplified tumors by targeting ecDNA, a root cause of oncogene amplification observed in more than 14% of cancer patients. Using our proprietary Spyglass platform, we identify targets essential for ecDNA functionality in cancer cells, then design and develop ecDTx to inhibit those targets with the aim to prevent cancer cells from using ecDNA to grow, adapt, and become resistant to existing therapies. Instead of directly targeting the proteins produced by amplified oncogenes, like the approach of traditional targeted therapies, our ecDTx are intended to be synthetic lethal in tumor cells reliant on ecDNA. They are designed to disrupt the underlying cellular machinery that enables ecDNA to function properly, such as proteins essential for ecDNA replication, transcription, assembly, repair, and segregation.

Our lead ecDTx, BBI-355, is a novel, oral, selective small molecule inhibitor of checkpoint kinase 1 (CHK1) being studied in the ongoing first-in-human, Phase 1/2 POTENTIATE clinical trial in patients with oncogene amplified cancers (clinicaltrials.gov identifier NCT05827614). We expect to have preliminary clinical proof of concept safety and antitumor activity data of BBI-355 as a single agent and in combination with targeted therapies in the second half of 2024 from approximately 50 to 90 total enrolled patients (single agent cohorts N=30 to 40, combination cohorts N=20 to 50).

Our second ecDTx, BBI-825, is a novel, oral, selective small molecule inhibitor of ribonucleotide reductase (RNR) being studied in the ongoing first-in-human, Phase 1/2 STARMAP clinical trial in patients with resistance gene amplifications (clinicaltrials.gov identifier NCT06299761). We expect to have preliminary clinical proof of concept safety and antitumor data of BBI-825 in combination with targeted therapies in the second half of 2025.

Our third ecDTx program, in the drug discovery stage, is directed at a previously undrugged kinesin target essential for ecDNA segregation and inheritance during cell division. We are advancing this program through drug discovery to candidate identification and expect to submit an Investigational New Drug application (IND) in the first half of 2026.

We continue to leverage Spyglass to identify and preclinically validate additional ecDNA-essential targets. In addition to our three ecDTx programs described above, we have preclinically validated multiple additional ecDNA targets and have initiated ecDTx drug discovery efforts to identify candidates against such targets. We expect to continue to identify and preclinically validate additional ecDNA targets using our Spyglass platform in the future. To date, all of our ecDTx have been discovered internally, and we retain global rights for all of our programs.

To assist in identifying patients that may benefit from our ecDTx, we have developed an ecDNA diagnostic test, internally called ECHO (ecDNA Harboring Oncogenes), to detect ecDNA in patient tumor samples via routine next generation sequencing (NGS) assays. We are working with an *in vitro* diagnostic company to develop the ecDNA diagnostic into a clinical trial assay, which we intend to use in our ongoing Phase 1/2 POTENTIATE clinical trial. The U.S. Food and Drug Administration (FDA) has determined that the ecDNA diagnostic is a non-significant risk device when used in patient selection for the POTENTIATE trial, meaning that we will not be required to obtain FDA approval of an investigational device exemption for the use of the ecDNA diagnostic in this trial.

Since we commenced operations in 2018, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, building our proprietary Spyglass platform, discovering our ecDTx, developing our ecDNA diagnostic, establishing our intellectual property portfolio, conducting research, preclinical studies, and clinical trials, establishing arrangements with third parties for the manufacture of our ecDTx and related raw materials, and providing general and administrative support for these operations.

We have incurred significant operating losses since our inception and, as of March 31, 2024, we had an accumulated deficit of \$151.5 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for, and potentially commercialize any of our ecDTx and seek to discover and develop additional ecDTx, develop our ecDNA diagnostic, conduct our ongoing and planned clinical trials and preclinical studies, continue our research and development activities, utilize third parties to manufacture our ecDTx and related raw materials, hire additional personnel, expand and protect our intellectual property, as well as incur additional costs associated with being a public company. If we obtain regulatory approval for any of our ecDTx, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials, preclinical studies, and our other research and development activities and capital expenditures.

Through March 31, 2024, we have raised a total of \$253.6 million to fund our operations primarily from the gross proceeds from the sale and issuance of our convertible preferred stock. As of March 31, 2024, we had cash, cash equivalents, and short-term investments of \$104.9 million. In April 2024, we completed our IPO pursuant to which we sold 6,250,000 shares of our common stock for gross proceeds of \$100.0 million. Based upon our current operating plans, we believe that our existing cash, cash equivalents, and short-term investments, together with the net proceeds from our IPO, will be sufficient to fund our operations into the second half of 2026.

We do not have any products approved for sale and have not generated any revenue to date. We do not expect to generate any revenue from product sales until we successfully complete development and obtain regulatory approval for one or more of our ecDTx, which we expect will take a number of years and may never occur. We will need substantial additional funding in addition to the net proceeds of our IPO to support our continuing operations and pursue our long-term business plan, including to complete the development and commercialization of our ecDTx, if approved. Accordingly, until such time as we can generate significant revenue from sales of our ecDTx, if ever, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce, or terminate our research and development programs or other operations, or grant rights to develop and market ecDTx that we would otherwise prefer to develop and market ourselves.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our ecDTx for preclinical and clinical testing, as well as for commercial manufacture if any of our ecDTx obtain marketing approval. We are working with our current manufacturers to ensure that we will be able to scale up our manufacturing capabilities to support our clinical plans. In addition, we rely on third parties to package, label, store, and distribute our ecDTx, and we intend to rely on third parties for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the discovery and development of our ecDTx.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from the sale of products. We do not expect to generate any such revenue unless and until such time that our ecDTx have advanced through clinical development and regulatory approval, if ever. If we fail to complete

preclinical and clinical development of ecDTx or obtain regulatory approval for them, our ability to generate future revenues, and our results of operations and financial position would be adversely affected.

Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses.

Research and Development

Our research and development (R&D) expenses have related primarily to the building of our Spyglass platform, our ecDTx discovery efforts, our preclinical and clinical development activities, and the development of an ecDNA diagnostic test. Our R&D expenses consist of:

- direct program costs, including:
 - costs incurred under agreements with our contract research organizations (CROs), investigative sites, and consultants to conduct our clinical trials and preclinical studies, as well as third party costs related to the development of an ecDNA diagnostic test,
 - expenses related to manufacturing our ecDTx for clinical trials and preclinical studies, including fees paid to third-party manufacturers; and
- indirect costs, including:
 - personnel-related costs, including salaries, bonuses, benefits, travel, and stock-based compensation expenses for employees engaged in research and development functions,
 - the costs of outside services from third parties, including consultants,
 - the costs of lab and pharmacology supplies,
 - facilities-related costs, including rent and maintenance costs, and other costs including insurance, depreciation, supplies, and miscellaneous expenses, and
 - other costs, including costs related to travel, repairs and maintenance, service contracts, computer supplies, software, and publications and subscription services.

R&D expenses are recognized as incurred, and payments made prior to the receipt of goods or services to be used in R&D are capitalized until the goods or services are received. We use internal resources primarily to conduct our research and discovery activities as well as for managing our preclinical development, process development, manufacturing, and clinical development activities. We track direct costs on a development program specific basis. Indirect costs are not included in program costs, as these costs are general in nature and benefit all of our discovery efforts and development programs.

Although R&D activities are central to our business model, the successful development of our ecDTx is highly uncertain. There are numerous factors associated with the successful development of any ecDTx, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our clinical development programs. Product candidates in later stages of development generally have higher development costs than those in earlier stages of development. As a result, we expect that our R&D expenses will increase substantially for the foreseeable future as we continue to conduct our ongoing R&D activities, advance preclinical research programs toward clinical development, conduct clinical trials, hire additional personnel, and maintain, expand, protect, and enforce our intellectual property portfolio.

Our future R&D expenses may vary significantly based on a wide variety of factors such as:

- the number, scope, rate of progress, expense, and results of our discovery and preclinical activities and clinical trials;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the cost of developing an ecDNA diagnostic test;
- the number of patients that participate in the trials;

- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our ecDTx;
- the phase of development of our ecDTx;
- the extent of changes in government regulation and regulatory guidance;
- the efficacy and safety profile of our ecDTx;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities; and
- the extent to which we establish collaboration, license, or other arrangements.

A change in the outcome of any of these variables with respect to development of any of our ecDTx could significantly change the costs and timing associated with the development of that ecDTx.

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our current ecDTx or any future ecDTx may be affected by a variety of factors. We may never succeed in achieving regulatory approval for any of our ecDTx. Preclinical and clinical development timelines, the probability of success, and total development costs can differ materially from expectations. We anticipate that we will make determinations as to which ecDTx to pursue and how much funding to direct to each ecDTx on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments, and our ongoing assessments as to each ecDTx's commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which ecDTx may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

General and Administrative

General and administrative (G&A) expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits, travel, and stock-based compensation expenses for employees in executive, accounting and finance, business development, legal, and other administrative functions. Other significant costs include allocated facility-related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services, insurance costs, and business development expenses.

We expect that our G&A expenses will increase substantially for the foreseeable future as we continue to increase our general and administrative headcount to support our continued R&D activities and, if any ecDTx receive marketing approval, commercialization activities, as well as to support our operations generally. We also expect to incur increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on our cash, cash equivalents, and investments.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

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

	Three months ended March 31,		Change
	2024	2023	
Operating expenses:			
Research and development	\$ 13,129	\$ 9,503	\$ 3,626
General and administrative	3,754	2,584	1,170
Total operating expenses	16,883	12,087	4,796
Loss from operations	(16,883)	(12,087)	(4,796)
Other income (expense), net:			
Interest income	1,421	395	1,026
Other income (expense)	32	(27)	59
Total other income (expense), net	1,453	368	1,085
Net loss	\$ (15,430)	\$ (11,719)	\$ (3,711)

Research and Development Expenses

The following table summarizes our R&D expenses for each of the periods indicated (in thousands):

	Three months ended March 31,		Change
	2024	2023	
Direct program costs:			
BBI-355	\$ 2,231	\$ 1,798	\$ 433
BBI-825	2,136	1,019	1,117
Other development programs	1,220	1,011	209
Total direct program costs:	5,587	3,828	1,759
Indirect program costs			
Personnel-related (including stock compensation)	4,013	3,244	769
Outside services and consulting	1,786	758	1,028
Lab and pharmacology supplies	607	706	(99)
Facilities-related (including depreciation)	707	709	(2)
Other indirect program costs	429	258	171
Total indirect program costs:	7,542	5,675	1,867
Total R&D expenses	\$ 13,129	\$ 9,503	\$ 3,626

R&D expenses were \$13.1 million for the first quarter of 2024, compared to \$9.5 million for the same period in 2023. Growth in our R&D expenses was primarily due to a \$1.8 million increase in the direct program costs for our BBI-355, BBI-825, and other development programs, a \$0.5 million increase in personnel-related costs resulting from an increase in headcount and salary increases, \$0.3 million of additional stock-based compensation, and a \$1.0 million increase in third-party services and other miscellaneous R&D costs.

General and Administrative Expenses

G&A expenses were \$3.8 million for the first quarter of 2024, compared to \$2.6 million for the same period in 2023. The increase in G&A expenses was primarily due to a \$0.3 million increase in personnel-related costs due to an increase in headcount and salary increases, \$0.5 million of additional stock-based compensation, an increase in professional service fees of \$0.2 million, and a \$0.2 million increase in other G&A costs.

Other Income, Net

Other income, net was \$1.5 million and \$0.4 million for the three months ended March 31, 2024 and 2023, respectively. The \$1.1 million increase resulted from the additional interest income generated by our available-for-sale investment securities portfolio due to the net proceeds from the sale of shares of our Series C convertible preferred stock in April and May 2023, as well as the increase in market yields available for such investment securities in comparison to the prior year period.

Liquidity and Capital Resources

Sources of Liquidity

Through March 31, 2024, we have raised a total of \$253.6 million to fund our operations primarily from the gross proceeds from the sale and issuance of our convertible preferred stock. In April 2024, we completed our IPO pursuant to which we sold 6,250,000 shares of our common stock for gross proceeds of \$100.0 million.

Future Funding Requirements

As of March 31, 2024, we had cash, cash equivalents, and short-term investments of \$104.9 million. Based upon our current operating plans, we believe that the net proceeds from our IPO, together with our existing cash, cash equivalents, and short-term investments, will be sufficient to fund our operations into the second half of 2026. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of conducting preclinical studies, manufacturing ecDTx, developing our ecDNA diagnostic, and testing ecDTx in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain.

We have incurred significant operating losses since our inception and, as of March 31, 2024, we had an accumulated deficit of \$151.5 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for, and potentially commercialize any of our ecDTx and seek to discover, and develop additional ecDTx, conduct our ongoing and planned clinical trials and preclinical studies, continue our research and development activities, utilize third parties to manufacture our ecDTx and related raw materials, seek to develop our ecDNA diagnostic, hire additional personnel, expand and protect our intellectual property, as well as incur additional costs associated with being a public company. If we obtain regulatory approval for any of our ecDTx, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and preclinical studies and our other research and development activities and capital expenditures.

Our future capital requirements are difficult to predict and depend on many factors, including but not limited to:

- the initiation, type, number, scope, progress, expansions, results, costs, and timing of clinical trials and preclinical studies of our ecDTx that we are pursuing or may choose to pursue in the future, including the costs of any third-party products used as combination agents in our combination clinical trials;
- the costs and timing of manufacturing for our ecDTx, including commercial manufacture at sufficient scale, if any ecDTx is approved;
- the costs and timing of developing ecDNA diagnostics, if required, and the outcome of their regulatory review;
- the costs, timing, and outcome of regulatory meetings and reviews of our ecDTx;
- the costs of obtaining, maintaining, enforcing, and protecting our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting;
- the costs associated with hiring additional personnel and consultants as our clinical and preclinical activities increase and as we operate as a public company;
- the costs and timing of establishing or securing sales and marketing capabilities if any ecDTx is approved;
- our ability to achieve sufficient market acceptance, coverage, and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses, and other similar arrangements;
- costs associated with any products or technologies that we may in-license or acquire; and

- the effects of competing technological and market developments as well as disruptions to and volatility in the credit and financial markets.

We have no other committed sources of capital. Until we can generate sufficient product revenue to finance our cash requirements, if ever, we expect to finance our future cash needs primarily through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through other collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, ecDTx, research programs, intellectual property or proprietary technology, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce, or terminate our R&D programs or other operations, or grant rights to develop and market ecDTx to third parties that we would otherwise prefer to develop and market ourselves, or on less favorable terms than we would otherwise choose.

Cash Flows

The following table summarizes our cash flows for each of the periods indicated:

	Three months ended		Change
	March 31,		
	2024	2023	
Net cash used in operating activities	\$ (15,776)	\$ (12,090)	\$ (3,686)
Net cash provided by investing activities	18,137	22,166	(4,029)
Net cash provided by / (used in) financing activities	(924)	31	(955)
Net increase in cash, cash equivalents, and restricted cash	\$ 1,437	\$ 10,107	\$ (8,670)

Operating Activities

Net cash used in operating activities was \$15.8 million and \$12.1 million for the three months ended March 31, 2024 and 2023, respectively. The net cash used in operating activities during the three months ended March 31, 2024 was primarily due to our reported net loss of \$15.4 million, net of noncash charges (including stock-based compensation expense, depreciation, and right-of-use asset amortization) totaling \$1.2 million and a \$1.6 million decrease of our net operating assets. The net cash used in operating activities during the three months ended March 31, 2023 was primarily due to our reported net loss of \$11.7 million and a \$1.7 million increase in our net operating assets, adjusted for noncash charges (including stock-based compensation expense, depreciation) totaling \$1.3 million. The increase in cash used in operations during the three months ended March 31, 2024 in comparison to the three months ended March 31, 2023 was primarily attributable to higher personnel-related costs and an increase in third-party spending associated with our discovery, development, and clinical activities.

Investing Activities

Investing activities consist primarily of the cash flows of purchases and maturities of investment securities and the cash outflow associated with purchases of property and equipment. Such activities resulted in a net inflow of funds of approximately \$18.1 million during the three months ended March 31, 2024, primarily from the net maturities of our available-for-sale securities portfolio, and a net inflow of funds of \$22.2 million during the three months ended March 31, 2023, primarily from net maturities of available-for-sale securities portfolio.

Financing Activities

Our financing activities consist of the proceeds from the exercise of common stock options by our employees and consultants. Net cash provided by / (used in) financing activities was (\$924,000) and \$31,000 during the three months ended March 31, 2024 and 2023, respectively. The change in cash used by financing activities for the first three months of 2024 was primarily due to payments made for deferred offering costs related to our IPO. The increase in cash provided by financing activities for the first three months of 2023 was the result of the exercise of common stock options by our employees and consultants.

Contractual Obligations and Other Commitments

We lease office and lab space under lease agreements with varying expiration dates through 2034. As of March 31, 2024, total future aggregate operating lease commitments was \$73.5 million. During the normal course of our business, we enter into contracts for research and professional services, and for the purchase of lab supplies used in our research activities. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not separately presented.

Off-Balance Sheet Arrangements

Since our inception, we have not had, and we do not currently have, any off-balance sheet arrangements as defined under rules and regulations of the SEC.

Critical Accounting Policies and Significant Estimates and Judgments

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and estimates from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Estimates and Judgments" included in the Prospectus, except that from the effectiveness date of our registration statement on Form S-1 (File No. 333-277696), we have a publicly traded stock price and no longer require common stock valuations.

Emerging Growth Company and Smaller Reporting Company Status

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the JOBS Act), we can take advantage of an extended transition period for complying with new or revised accounting standards. This period 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 exemption from new or revised accounting standards and, therefore, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of our IPO; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.235 billion; (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than \$1.0 billion in nonconvertible debt securities during the prior three-year period.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934, as amended (the Exchange Act) and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 4. Controls and Procedures.***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

Due to a transition period established by SEC rules applicable to newly public companies, our management is not required to evaluate the effectiveness of our internal control over financial reporting until after the filing of our Annual Report on Form 10-K for the year ending December 31, 2025. As a result, this Quarterly Report on Form 10-Q does not address whether there have been any changes in our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material proceedings. From time to time, we may become involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources, negative publicity, reputational harm, and other factors and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information included in this Quarterly Report and in the Prospectus, including our condensed financial statements and related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” before making an investment decision to purchase or sell shares of our common stock. If any of the following risks are realized, our business, financial condition, results of operations, and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment. The risks described below are not the only ones we may face, and additional risks and uncertainties not known to us or that we currently deem immaterial may also impair our business, financial condition, results of operations, and future prospects.

Summary of Risks Related to our Business

The risk factors included below are a summary of the principal risk factors associated with an investment in us. The summary below does not contain all of the risks we face. You should carefully consider this summary, together with the more detailed discussion of these risks and uncertainties set forth below in this Item 1A.

- We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- We will require substantial additional financing to finance our operations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our ecDTx development programs, commercialization efforts or other operations.
- We are early in our development efforts and have only two ecDTx in clinical development. All of our other ecDTx programs are still in the preclinical or discovery stage. If we are unable to successfully develop, obtain regulatory approval, and ultimately commercialize any of our current or future ecDTx, or experience significant delays in doing so, our business will be materially harmed.
- Our approach to treating cancer with oncogene amplifications by developing ecDTx directed against ecDNA is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing approaches will limit the commercial value of our ecDTx.
- Clinical and preclinical development involves a lengthy and expensive process with uncertain timelines and outcomes, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Our ecDTx may not achieve favorable results in clinical trials or preclinical studies or receive regulatory approval on a timely basis, if at all.
- Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials or preclinical studies could result in increased costs to us, delay or limit our ability to generate revenue, or adversely affect our commercial prospects.
- Use of our ecDTx could be associated with side effects, adverse events, or other properties or safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon an ecDTx, limit the commercial profile of an approved label, or result in other significant negative consequences that could severely harm our business, financial condition, results of operations, and prospects.
- If we are unable to successfully develop an ecDNA diagnostic to enable patient selection for our ecDTx, or if we experience significant delays in doing so, we may not realize the full commercial potential of our ecDTx.

- We face significant competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If our competitors develop and commercialize their product candidates more rapidly than we do, or their technologies or their product candidates are more effective, safer, or less expensive than our ecDTx, our business and our ability to develop and successfully commercialize ecDTx may be adversely affected.
- We rely on third parties to conduct our clinical trials and preclinical studies, to develop an ecDNA diagnostic, and to manufacture our ecDTx, and these third parties may not perform satisfactorily, which could delay, prevent, or impair our development or commercialization efforts
- If we are unable to obtain, maintain, defend, and enforce patent or other intellectual property protection for our ecDTx, ecDNA diagnostic, or technology, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our ecDTx may be adversely affected.
- The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history, have incurred significant operating losses since our inception, and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage oncology company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2018, have no products approved for commercial sale, and have not generated any revenue from the sale of our products. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital, building our proprietary Spyglass platform, discovering our ecDTx, developing our ecDNA diagnostic, establishing our intellectual property portfolio, conducting research, preclinical studies and clinical trials, establishing arrangements with third parties for the manufacture of our ecDTx and supply of related raw materials, and providing general and administrative support for these operations. Our scientific approach to the discovery and development of ecDTx, including our use of the Spyglass platform, is unproven, and we do not know whether we will be able to develop or obtain regulatory approval for any products of commercial value. In addition, we have only two ecDTx, BBI-355 and BBI-825, in early clinical development, and our other ecDTx programs remain in the preclinical or discovery stage. We have not yet completed any clinical trials, successfully developed and validated a diagnostic test, obtained regulatory approvals, manufactured products at commercial scale, or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We do not have any products approved for sale and have not generated any revenue since our inception. If we are unable to successfully develop, obtain requisite approval for and commercialize our ecDTx, we may never generate revenue. Our net losses were \$15.4 million and \$11.7 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of \$151.5 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our ecDTx will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for, and potentially commercialize any of our ecDTx and seek to discover and develop additional ecDTx, as well as operate as a public company.

To become and remain profitable, we must succeed in discovering, developing, obtaining regulatory approvals for, and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials and preclinical studies of our ecDTx, discovering additional ecDTx, obtaining regulatory approval for these ecDTx and, if required, our ecDNA diagnostic, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We are in only the preliminary stages of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able 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 have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our ecDTx pipeline, achieve our strategic objectives, or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce, or terminate our ecDTx development programs, commercialization efforts or other operations.

The development of our ecDTx, including conducting preclinical studies and clinical trials, is a very time-consuming, capital-intensive, and uncertain process. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to substantially increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials and preclinical studies and potentially seek regulatory approval for our current ecDTx and any future ecDTx we may develop. If we obtain regulatory approval for any of our ecDTx, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reasonably estimate the actual amount of capital necessary to successfully complete the development and commercialization of our ecDTx. Furthermore, we expect to incur additional costs associated with operating as a public company.

Based on our current operating plan, we believe that our existing cash, cash equivalents, and short-term investments, will be sufficient to fund our operations into the second half of 2026. In particular, we expect that our existing cash, cash equivalents and short-term investments will allow us to fund development of BBI-355 through preliminary clinical proof of concept safety and antitumor activity data from the POTENTIATE trial and BBI-825 through preliminary proof of concept safety and antitumor activity data from the STARMAP trial, as well as submit an IND for our third ecDTx program. We have based these estimates on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our existing capital may not be sufficient to complete development of our ecDTx, or any future ecDTx, and we will require substantial capital in order to advance our ecDTx and any future ecDTx through clinical trials, regulatory approval, and commercialization. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Our ability to raise additional funds may be adversely impacted by global economic conditions, disruptions to, and volatility in, the credit and financial markets in the United States and worldwide, and diminished liquidity and credit availability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce, or eliminate our research and development programs or any future commercialization efforts, or even cease operations. We expect to finance our cash needs through public or private equity or debt financings or other capital sources, including potential collaborations, licenses, and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our ecDTx.

Our future capital requirements will depend on many factors, including, but not limited to:

- the initiation, type, number, scope, progress, expansions, results, costs, and timing of clinical trials and preclinical studies of our ecDTx that we are pursuing or may choose to pursue in the future, including the costs of any third-party products used as combination agents in our clinical trials;
- the costs and timing of manufacturing for our ecDTx, including commercial manufacturing at sufficient scale, if any ecDTx is approved;
- the costs and timing of developing ecDNA diagnostics, if required, and the outcome of their regulatory review;
- the costs, timing, and outcome of regulatory meetings and reviews of our ecDTx;

- the costs of obtaining, maintaining, enforcing, and protecting our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting;
- the costs associated with hiring additional personnel and consultants as our clinical and preclinical activities increase and as we operate as a public company;
- the costs and timing of establishing or securing sales and marketing capabilities if any ecDTx is approved;
- our ability to achieve sufficient market acceptance, coverage, and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses, and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Conducting clinical trials and preclinical studies and discovering potential ecDTx is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and commercialize our ecDTx. In addition, our ecDTx, if approved, may not achieve commercial success. Our commercial revenue, if any, will initially be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, including as a result of financial and credit market deterioration or instability, market-wide liquidity shortages, geopolitical events, or otherwise.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, licenses, and other similar arrangements, we may be required to relinquish valuable rights to our future revenue streams, ecDTx, research programs, ecDNA diagnostic, intellectual property, or proprietary technology, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or future commercialization efforts, or grant rights to develop and market ecDTx that we might otherwise prefer to develop and market ourselves, or on less favorable terms than we would otherwise choose.

Risks Related to the Discovery, Development, and Regulatory Approval of Our ecDTx

We are early in our development efforts and have only two ecDTx in clinical development. All of our other ecDTx programs are still in the preclinical or discovery stage. If we are unable to successfully develop, obtain regulatory approval, and ultimately commercialize any of our current or future ecDTx, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts and have only two ecDTx, BBI-355 and BBI-825, in early clinical development. All of our other ecDTx programs are still in the preclinical or discovery stage. We have invested substantially all of our efforts to date in developing our ecDTx, developing our ecDNA diagnostic as a potential patient selection tool, identifying other targets for therapeutic pursuit, and continuing to develop our proprietary Spyglass platform. We will need to progress BBI-355 and BBI-825 through first-in-human clinical trials and progress our other ecDTx programs through additional preclinical studies to enable us to submit INDs to the FDA and receive allowance from the FDA to proceed with initiating their clinical development. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our ecDTx. The success of our ecDTx will depend on several factors, including the following:

- successful initiation and enrollment of clinical trials, and timely completion of clinical trials and preclinical studies with favorable results;
- allowance to proceed with clinical trials for our ecDTx under INDs by the FDA, or under similar regulatory submissions by comparable foreign regulatory authorities;
- the frequency and severity of adverse events observed in clinical trials and preclinical studies;
- maintaining and establishing relationships with CROs and clinical sites for the clinical development of our ecDTx, and ability of such CROs and clinical sites to comply with clinical trial protocols, Good Clinical Practice requirements (GCPs) and other applicable requirements;
- demonstrating the safety and efficacy of our ecDTx to the satisfaction of applicable regulatory authorities, including by establishing a safety database of a size satisfactory to regulatory authorities;
- successful development, validation, and regulatory approval of companion diagnostic tests for use in patient selection with our ecDTx, if required;
- receipt of regulatory approvals from applicable regulatory authorities, including approvals of new drug applications (NDAs), from the FDA and maintaining such approvals;
- maintaining relationships with our third-party manufacturers and their ability to comply with current Good Manufacturing Practice requirements (cGMPs) as well as making arrangements with our third-party manufacturers for, or establishing our own, commercial manufacturing capabilities at a cost and scale sufficient to support commercialization;
- establishing sales, marketing, and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtaining, maintaining, protecting, and enforcing any patent and trade secret protection, patent term extensions (if applicable) and/or regulatory exclusivity for our ecDTx;
- maintaining an acceptable safety profile of our products following regulatory approval, if any;
- maintaining and growing an organization of people who can develop and commercialize our products; and
- acceptance of our products, if approved, by patients, the medical community, and third-party payors.

If we are unable to develop, obtain regulatory approval for, or, if approved, successfully commercialize our ecDTx, or if we experience delays as a result of any of the above factors or otherwise, our business would be materially harmed.

Our approach to treating cancer with oncogene amplifications by developing ecDTx directed against ecDNA is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing approaches will limit the commercial value of our ecDTx.

The success of our business depends primarily upon our ability to discover, develop, and commercialize products based on our scientific approach, which is focused on developing therapies that are directed against ecDNA in oncogene amplified cancers, a novel and unproven approach. While we have had favorable preclinical study results for certain of our ecDTx programs, we have not yet succeeded and may not succeed in demonstrating efficacy and safety for any of our ecDTx in clinical trials or in obtaining regulatory approvals from the FDA or other regulatory authorities or in commercializing such ecDTx. BBI-355 and BBI-825 are in early clinical

development, and, as an organization, we have not completed any clinical trials for any of our ecDTx. Our research methodology and scientific approach in using our Spyglass platform may be unsuccessful in identifying and discovering additional ecDTx, and, even if successful, we may not be able to submit INDs and have such INDs allowed to proceed to enable us to commence clinical trials on the timelines we expect, if at all. Any ecDTx we do discover may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing or make the ecDTx unmarketable or unlikely to receive regulatory approval. In particular, developing therapies that are directed against ecDNA in oncogene amplified cancers is a novel approach that may have unexpected consequences, including adverse events that preclude successful development and approval of our ecDTx. Further, because our current ecDTx and all of our discovery programs are ecDNA based, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs.

In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our scientific approach. If we fail to stay at the forefront of technological change in utilizing our approach to create and develop ecDTx and, if required, diagnostic tests, we may be unable to compete effectively. Our competitors may render our approach obsolete or limit the commercial value of our products or ecDTx by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our approach. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value and potential of our ecDTx.

If any of these events occur, we may be forced to delay, modify, or abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Clinical and preclinical development involves a lengthy and expensive process with uncertain timelines and outcomes, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Our ecDTx may not achieve favorable results in clinical trials or preclinical studies or receive regulatory approval on a timely basis, if at all.

Clinical and preclinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials or preclinical studies will be conducted as planned, including whether we are able to meet expected timeframes for data readouts, or completed on schedule, if at all, and failure can occur at any time during the trial or study process. Despite promising preclinical or clinical results, any ecDTx can unexpectedly fail at any stage of clinical or preclinical development. The historical failure rate for product candidates in our industry is high, particularly in the earlier stages of development.

The results from preclinical studies or clinical trials of an ecDTx or of a competitor's product candidates in the same class may not predict the results of later clinical trials of our ecDTx, and interim, topline, or preliminary results of a clinical trial are not necessarily indicative of final results. ecDTx in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. If unexpected observations or toxicities are observed in these studies, or in future IND-enabling studies for any of our other ecDTx development programs, such results may delay or prevent the initiation of clinical trials for such ecDTx programs.

Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Such setbacks have occurred and may occur for many reasons, including, but not limited to: clinical sites and investigators may deviate from clinical trial protocols, whether due to lack of training or otherwise, and we may fail to detect any such deviations in a timely manner; patients may fail to adhere to any required clinical trial procedures, including any requirements for post-treatment follow-up; our ecDTx may fail to demonstrate effectiveness or safety in certain patient subpopulations, which has not been observed in earlier trials due to limited sample size, lack of analysis, or otherwise; or our clinical trials may not adequately represent the patient populations we intend to treat, whether due to limitations in our trial designs or otherwise, such as where one patient subgroup is overrepresented in the clinical trial. There can be no assurance that we will not suffer similar setbacks despite the data we observed in earlier or ongoing studies. Based upon negative or inconclusive results, we or any future collaborator may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, which would cause us to incur additional operating expenses and delays and may not be sufficient to support regulatory approval on a timely basis or at all.

As a result, we cannot be certain that our ongoing and planned clinical trials and preclinical studies will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our ecDTx in those and other indications, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials or preclinical studies could result in increased costs to us, delay or limit our ability to generate revenue, or adversely affect our commercial prospects.

Before obtaining approval from regulatory authorities for the sale of our ecDTx, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the ecDTx in humans. Before we can initiate clinical trials for our preclinical ecDTx, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about ecDTx chemistry, manufacturing, and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any ecDTx before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical ecDTx programs. Moreover, even if we commence clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion, or the termination or suspension, of our ongoing and planned clinical trials or preclinical studies for our current and any future ecDTx could significantly affect our product development timelines and product development costs.

We do not know whether our planned clinical trials and preclinical studies will begin on time or if our ongoing or future trials or studies will be completed on schedule, if at all. The commencement, data readouts, and completion of clinical trials and preclinical studies can be delayed for a number of reasons, including delays related to:

- inability to obtain animals or materials to initiate and generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtaining allowance from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- any failure or delay in reaching an agreement with 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;
- delays in identifying, recruiting, and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards (IRBs) or ethics committees (ECs) at clinical trial sites;
- IRBs/ECs refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional patients, or withdrawing their approval of the trial;
- changes to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with GCP requirements or applicable regulatory requirements or guidelines in other countries;
- obtaining raw materials for manufacturing sufficient quantities of our ecDTx or obtaining sufficient quantities of combination therapies or other materials needed for use in clinical trials and preclinical studies;
- patients failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including patients failing to remain in our trials due to movement restrictions, health reasons, or otherwise resulting from any future public health concerns;
- patients choosing alternative treatments for the indications for which we are developing our ecDTx, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trials or preclinical studies or costs being greater than we anticipate;
- patients experiencing severe or serious unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to our ecDTx;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization (CMO), delays or failure by our CMOs or us to make any necessary changes to such manufacturing process, or failure of our CMOs to produce clinical trial materials in accordance with cGMP regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations, or guidelines, and are subject to oversight by these governmental agencies and ECs or IRBs at the medical institutions where the clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a data safety monitoring board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with GCP and other regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations, or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing, or successful completion of a clinical trial.

Further, in the future we may conduct clinical trials in foreign countries, and this will present additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our ecDTx.

In addition, many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of an ecDTx. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our ecDTx. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our ecDTx could be significantly reduced. Any of these occurrences may harm our business, financial condition, results of operations, and prospects.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Successful and timely completion of clinical trials will require that we identify and enroll a specified number of patients for each of our clinical trials. We may not be able to initiate or continue clinical trials for our ecDTx if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and characteristics of the patient population, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the ecDTx being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development. We will be required to identify and enroll a sufficient number of patients for each of our clinical trials and monitor such patients adequately during and after treatment. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting, which could adversely impact the outcomes of our trials and could have safety concerns for the potential patients. Potential patients for any planned clinical trials may also not meet the entry criteria for such trials.

In particular, because our ecDTx are focused on patients with tumors harboring oncogene amplifications on ecDNA, our ability to enroll eligible patients may be limited or take more time than we anticipate, due to the frequency of the biomarker we are seeking to target, or our ability to effectively identify such biomarker. We also may encounter difficulties in identifying and enrolling patients with the proper tumor characteristics or stage of disease appropriate for our planned clinical trials and monitoring such patients adequately during and after treatment. Additionally, other pharmaceutical companies targeting these same types of cancer are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If patients are unwilling or unable to participate in our trials for any reason, including the existence of concurrent clinical trials for similar

target populations, the availability of approved therapies, or the fact that enrolling in our trials may prevent patients from taking a different product, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting trials, and obtaining regulatory approval of our ecDTx may be delayed. Additionally, because our clinical trials are in patients with relapsed/refractory cancer, the patients are typically in the late stages of their disease and may experience disease progression independent from our ecDTx, making them unevaluable for purposes of the clinical trial and requiring additional patient enrollment. Our inability to enroll a sufficient number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

In addition, we rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely enrollment of our clinical trials. Though we have entered into agreements governing their services, we have limited influence over their actual performance. We cannot be certain that our assumptions used in determining expected clinical trial timelines are correct, or that we will not experience delays or difficulties in enrollment, or be required by the FDA or other regulatory authority to increase our enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Use of our ecDTx could be associated with side effects, adverse events, or other properties or safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon an ecDTx, limit the commercial profile of an approved label, or result in other significant negative consequences that could severely harm our business, financial condition, results of operations, and prospects.

As is the case with oncology drugs generally, it is likely that there may be side effects and adverse events associated with use of our ecDTx. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of expected or unexpected side effects or unexpected characteristics. Undesirable side effects caused by our ecDTx when used alone or in combination with approved or investigational drugs could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label, or lead to the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations, and prospects significantly.

Moreover, if our ecDTx are associated with undesirable side effects in clinical trials or demonstrate characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the ecDTx if approved. Unacceptable enhancement of certain toxicities may be seen when our ecDTx are combined with standard of care therapies, or when they are used as single agents. We may also be required to modify our development and clinical trial plans based on findings in our ongoing clinical trials. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compounds.

It is possible that as we test our ecDTx in larger, longer, and more extensive clinical trials, including with different dosing regimens, or as the use of these ecDTx becomes more widespread following any regulatory approval, more illnesses, injuries, discomforts, and other adverse events than were observed in earlier trials, as well as new conditions that did not occur or went undetected in previous trials, may be discovered. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, and prospects significantly.

In addition, we plan to study our ecDTx in combination with other therapies, which may exacerbate adverse events associated with such ecDTx. Patients treated with our ecDTx may also be undergoing surgical, radiation, and/or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our ecDTx but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, we expect that some of the patients enrolled in our clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such trials.

In addition, if one or more of our ecDTx receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend, or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- we may be required to recall a product or change the way such product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or a contraindication;

- we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS) or create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials, or change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to patients;
- sales of the product may decrease significantly or the product could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular ecDTx, if approved, and could significantly harm our business, results of operations, and prospects.

As an organization, we have never completed any clinical trials and may be unable to do so for any of our ecDTx.

We are early in our development efforts for our ecDTx, have never completed any clinical trials, and we will need to successfully complete our ongoing and later-stage and pivotal clinical trials in order to obtain FDA or comparable foreign regulatory approval to market our ecDTx. Carrying out later-stage clinical trials and the submission of a successful NDA is a complicated process. We are currently conducting our first Phase 1/2 clinical trial for BBI-355 and our first Phase 1/2 clinical trial for BBI-825. We have not yet conducted any clinical trials for our other ecDTx or development programs. We have limited experience as a company in preparing and submitting marketing applications and have not previously submitted an NDA or other comparable foreign regulatory submission for any ecDTx. In addition, as a company, we have had limited interactions with the FDA and no interaction with other comparable foreign regulatory authorities and cannot be certain how many additional clinical trials of our ecDTx will be required or how such trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission and regulatory approval of any of our ecDTx. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of ecDTx that we develop. Failure to commence or complete, or delays in, our planned clinical trials could prevent us from or delay us in submitting marketing applications, including NDAs, for and commercializing our ecDTx.

If we are unable to successfully develop an ecDNA diagnostic to enable patient selection for our ecDTx, or if we experience significant delays in doing so, we may not realize the full commercial potential of our ecDTx.

A key component of our strategy is our ability to identify patients with tumors harboring oncogene amplifications on ecDNA from genomic data obtained through NGS of patient tumor samples. Identification of these patients will require the development and use of an ecDNA diagnostic assay. We have engaged a third-party *in vitro* diagnostic company to develop our ecDNA diagnostic as a clinical trial assay for use during our Phase 1/2 POTENTIATE clinical trial of BBI-355. We may continue to work with this company on this, and/or other ecDNA diagnostic assays in the future, or we may choose to work with other third-party diagnostic developers. We may have difficulty in maintaining our relationship with our current third-party diagnostic developer or establishing or maintaining relationships with other third-party diagnostic development companies in the future, and we may face competition from other companies in establishing these relationships.

There are also several risks associated with the development of an ecDNA diagnostic assay. We may not be able to identify predictive biomarkers to identify patients whose tumors harbor oncogene amplifications on ecDNA. We may not be able to validate an ecDNA diagnostic and the related biomarkers or their functional relevance clinically. Potential biomarkers, even if validated preclinically, may not be functionally validated in human clinical trials. Any failure by us or our third-party diagnostic developer to successfully develop or obtain marketing authorization for an ecDNA diagnostic assay, or any delays in doing so, may harm the commercial prospects of our ecDTx.

We intend to develop our ecDTx in combination with other therapies, which exposes us to additional risks.

We intend to develop our current and any future ecDTx for use in combination with one or more currently approved cancer therapies. Even if any ecDTx we develop was to receive regulatory approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our ecDTx or that safety, efficacy, manufacturing, or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our ecDTx for use in combination with other drugs or biologics or for indications other than cancer. Developing combination therapies using approved therapeutics, as we plan to do for our ecDTx, also exposes us to additional clinical risks, such as the requirement that we demonstrate the safety and efficacy of each active component of any combination regimen we may develop.

If the FDA or similar foreign regulatory authorities revoke the approval of combination agents, or if safety, efficacy, manufacturing, or supply issues arise with the drugs we choose to evaluate in combination with our ecDTx, we may be unable to obtain approval of or market our ecDTx for combination therapy regimens.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our ecDTx are unable to produce sufficient quantities for clinical trials or for commercialization of our ecDTx, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations, and prospects.

We may expend our limited resources to pursue a particular ecDTx or a particular indication for an ecDTx and fail to capitalize on ecDTx or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific ecDTx, development programs, and indications. As a result, we may forgo or delay pursuit of opportunities with other ecDTx that could have had greater commercial potential. Our resource allocation and other decisions may cause us to fail to identify and capitalize on viable potential ecDTx or additional indications for our ecDTx or other profitable market opportunities. Our spending on current and future research and development programs and ecDTx for specific indications may not yield any commercially viable ecDTx. If we do not accurately evaluate the commercial potential or target market for a particular indication or ecDTx, we may relinquish valuable rights to that ecDTx through collaborations, licenses, and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such ecDTx.

We may in the future conduct certain of our clinical trials for our ecDTx outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We may in the future conduct one or more of our clinical trials for our ecDTx outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the United States population and United States medical practice; the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the relevant study was not conducted pursuant to an IND, the FDA will not accept the data as support for a marketing application unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our ecDTx, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our development of our ecDTx.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment, and storage requirements;
- inconsistent standards for reporting and evaluating clinical data and adverse events;
- diminished protection of intellectual property in some countries; and
- public health concerns or political instability, civil unrest, war, or similar events that may jeopardize our ability to commence, conduct, or complete a clinical trial and evaluate resulting data.

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

From time to time, we may publicly disclose interim, topline, or preliminary data from our clinical trials and preclinical studies, 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 interim, topline, or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result, in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available. Interim data from clinical trials that we may complete are further subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, topline, or preliminary data and final data could significantly harm our business prospects.

In addition, others, including regulatory authorities, 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 value of the particular program, the approvability or commercialization of the particular ecDTx or product and our company in general. Moreover, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, ecDTx or our business. 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 approval for, and commercialize our ecDTx may be harmed, which could harm our business, operating results, prospects, or financial condition.

Changes in methods of ecDTx manufacturing or formulation may result in additional costs or delay.

As our ecDTx progress through clinical trials to regulatory approval and commercialization, it is common that various aspects of the ecDTx development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize safety, efficacy, yield, and manufacturing batch size, minimize costs, and achieve consistent quality and results. For example, in the future we may consider developing a higher dosage strength tablet for use in our ongoing Phase 1/2 POTENTIATE clinical trial of BBI-355. There can be no assurance that this or any other future manufacturing or formulation changes will achieve their intended objectives. These changes and any future changes we may make to our ecDTx may also cause such candidates to perform differently and affect the results of future clinical trials conducted with the altered materials. Such changes or related unfavorable clinical trial results could delay initiation or completion of additional clinical trials, require the conduct of bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay or prevent potential regulatory approval, and jeopardize our ability to commercialize our ecDTx, if approved, and generate revenue.

If we are required by the FDA or comparable foreign regulatory authority to obtain approval of a companion diagnostic test, such as our investigational ecDNA diagnostic, in connection with approval of any of our ecDTx, and we do not obtain, or face delays in obtaining, FDA or foreign approval of such companion diagnostic, we will not be able to commercialize our ecDTx, and our ability to generate revenue will be materially impaired.

We are currently working with a third party to develop an ecDNA diagnostic assay to identify patients with tumors harboring oncogene amplifications on ecDNA. We believe an ecDNA diagnostic will be helpful in identifying patients that may benefit from certain of our ecDTx, including BBI-355. If the FDA believes that the safe and effective use of any of our ecDTx depends on an *in vitro* diagnostic, such as our investigational ecDNA diagnostic, then it may require approval or clearance of that diagnostic as a companion diagnostic at the same time that the FDA approves our ecDTx, if at all. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. If an ecDNA diagnostic, or an alternative companion diagnostic is not commercially available in this situation, we may be required to complete the development of an ecDNA diagnostic or obtain an alternative companion diagnostic that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostics is time-consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities, and the FDA has generally required premarket approval of companion diagnostics for cancer therapies. As such, we expect we may need to obtain approval for any ecDNA diagnostic we may develop for use with our ecDTx. The approval or clearance of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect.

If the FDA or a comparable foreign regulatory authority requires approval or clearance of a companion diagnostic for any of our ecDTx, whether before, simultaneously with, or after the ecDTx obtains regulatory approval, we and/or third-party developers may encounter difficulties in developing and obtaining approval or clearance for these companion diagnostics. Any delay or failure by us or third-party developers to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of the relevant ecDTx. We or our third-party developers may also experience delays in developing a sustainable, reproducible, and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our ecDTx, if approved, on a timely or profitable basis, if at all.

We may attempt to secure approval from the FDA through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary regulatory approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

We may in the future seek an accelerated approval for one or more of our ecDTx. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such confirmatory studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, in December 2022, President Biden signed an omnibus appropriations bill to fund the US government through fiscal year 2023. Included in the omnibus bill is the Food and Drug Omnibus Reform Act of 2022, which among other things provided the FDA with new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval and additional oversight over confirmatory trials. Under these provisions, the FDA may, among other things, require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

Prior to seeking approval for any of our ecDTx, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or obtain any other form of expedited development, review, or approval. Furthermore, if we decide to submit an application for accelerated approval for our ecDTx, there can be no assurance that such submission or application will be accepted or that any expedited development, review, or approval will be granted on a timely basis, or at all. The FDA could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review, or approval for our ecDTx would result in a longer time period to commercialization of such ecDTx, if any, could increase the cost of development of such ecDTx, and could harm our competitive position in the marketplace.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder its ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. In addition, government funding of other government agencies 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 drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, future pandemics may lead to similar inspectional or administrative delays. If any future prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, our ecDTx development programs and our ability to seek or obtain regulatory approval for or commercialize our ecDTx may be delayed.

We are dependent on third parties to conduct our clinical trials and preclinical studies. Specifically, we rely on, and intend to continue to rely on, medical institutions, clinical investigators, CROs, and consultants to conduct our preclinical studies and clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators, and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have and will have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards and requirements, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. In addition, we and our CROs are required to comply with Good Laboratory Practice (GLP) requirements for certain preclinical studies, as well as GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for clinical trials of all of our ecDTx. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GLP or GCP or other requirements, the clinical data generated in our preclinical studies or clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications, if ever. Further, our clinical trials must be conducted with products produced in accordance with cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any of our CROs, investigators, or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols, or meet regulatory requirements, or otherwise perform in a substandard manner, our clinical trials may be extended, delayed, or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, in a timely manner or at all. Switching or adding additional CROs, investigators, and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

We rely on third parties for the manufacture of our ecDTx for clinical and preclinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our ecDTx or products or such quantities at an acceptable cost, which could delay, prevent, or impair, our development or commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to develop our own clinical or commercial-scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of our ecDTx and related raw materials for clinical and preclinical development, as well as for commercial manufacture if any of our ecDTx receive regulatory approval. The facilities used by third-party manufacturers to manufacture our ecDTx must be approved for the manufacture of our ecDTx by the FDA and any comparable foreign regulatory authority pursuant to inspections that will be conducted after we submit an NDA to the FDA or any comparable submission to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of products. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance, and qualified personnel. If the FDA or any comparable foreign regulatory authority does not approve these facilities for the manufacture of our ecDTx or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or market our ecDTx, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of ecDTx or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our ecDTx.

Our or a third party's failure to execute on our manufacturing requirements on commercially reasonable terms, in a timely manner and in compliance with cGMP or other regulatory requirements could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of our ecDTx;
- delay in submitting regulatory applications, or receiving regulatory approvals, for our ecDTx;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our ecDTx; and
- in the event of approval to market and commercialize our ecDTx, an inability to meet commercial demands for our ecDTx.

In addition, we do not have any long-term commitments or supply agreements with our third-party manufacturers. We may be unable to establish any long-term supply agreements with third-party manufacturers or to do so on acceptable terms or at all, which increases the risk of failing to timely obtain sufficient quantities of our ecDTx or such quantities at an acceptable cost. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to obtain adequate raw materials and other materials required for manufacturing;
- failure to manufacture our product according to our schedule or at all;
- failure to successfully scale up manufacturing capacity, if required;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our ecDTx and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our ecDTx. If our existing or future third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all.

In addition, our current and anticipated future dependence upon others for the manufacture of our ecDTx or products may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on third parties for the development of a diagnostic and to manufacture our ecDTx and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements, or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are intentionally or inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's or other third party's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure of such technology or information would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may seek to enter into collaborations, licenses, and other similar arrangements and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships.

We may seek to enter into collaborations, joint ventures, licenses, and other similar arrangements for the development or commercialization of our ecDTx, if approved, due to capital costs required to develop or commercialize the ecDTx or manufacturing constraints. We may not be successful in our efforts to establish or maintain such collaborations for our ecDTx because our research and development pipeline may be insufficient, our ecDTx may be deemed to be at too early of a stage of development for collaborative effort, or third parties may not view our ecDTx as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex. Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us. For example, we may need to relinquish valuable rights to our future revenue streams, research programs, intellectual property, ecDTx or ecDNA diagnostic, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. In addition, if we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our ecDTx. Our ability to generate revenue from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a collaboration, license, or strategic transaction, we will achieve an economic benefit that justifies such transaction, and such transaction may not yield additional development or ecDTx for our pipeline. Furthermore, we may not be able to maintain such collaborations if, for example, the development or approval of an ecDTx is delayed, the safety of an ecDTx is questioned, or the sales of an approved ecDTx are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our ecDTx, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our ecDTx, could delay the development and commercialization of our ecDTx, if approved, and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Commercialization of Our ecDTx

Even if we receive regulatory approval for any ecDTx, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

Any regulatory approvals that we may receive for our ecDTx will require the submission of reports to regulatory authorities, subject us to surveillance to monitor the safety and efficacy of the product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions, or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS as a condition of approval of our ecDTx, which could include requirements for a medication guide, physician communication plans, or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools.

In addition, if the FDA or a comparable foreign regulatory authority approves our ecDTx, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Manufacturers of approved products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. Failure to comply with regulatory requirements or later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- fines, restitutions, disgorgement of profits or revenue, warning letters, untitled letters, adverse publicity requirements, or holds on clinical trials;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions and the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our ecDTx and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be promulgated that could prevent, limit, or delay marketing authorization of any ecDTx. We also cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our ecDTx, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive regulatory approval for an ecDTx, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our ecDTx, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The commercial success of our ecDTx will depend upon the degree of market acceptance of such ecDTx by physicians, patients, healthcare payors, and others in the medical community.

Our ecDTx may not be commercially successful. Even if any of our ecDTx receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, or the medical community. The commercial success of any of our current or future ecDTx will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety, including as compared to any more-established products;
- the indications for which our ecDTx are approved;

- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers, and other third-party payors;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as availability, safety, and efficacy of competitive drugs;
- the effectiveness of our or any potential future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product.

If any ecDTx is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors, or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

The successful commercialization of our ecDTx, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels, and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our ecDTx could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers, and other third-party payors are essential for most patients to be able to afford prescription medications such as our ecDTx, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our ecDTx by third-party payors will have an effect on our ability to successfully commercialize those ecDTx. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved ecDTx. Even if we obtain coverage for a given ecDTx by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high.

If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our ecDTx would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such ecDTx. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions, and fines should we be found to be in violation of any applicable obligations thereunder.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our ecDTx as substitutable and offer to reimburse patients only for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our ecDTx, pricing of existing drugs may limit the amount we will be able to charge for our ecDTx. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in ecDTx development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our ecDTx and may not be able to obtain a satisfactory financial return on ecDTx that we may develop. In addition, in the event that we develop companion diagnostic tests for use with our ecDTx, once approved, such companion diagnostic tests will require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical product. Similar challenges to obtaining coverage and reimbursement applicable to pharmaceutical products will apply to companion diagnostics tests.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products.

Obtaining and maintaining reimbursement status is time-consuming, costly, and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our ecDTx to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our ecDTx, if approved in these jurisdictions. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our ecDTx. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our ecDTx. We expect to experience pricing pressures in connection with the sale of any of our ecDTx due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs, surgical procedures, and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. See the section titled “Risk Factors—Risks Related to Our Business Operations and Industry—Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize our ecDTx and may adversely affect the prices we may set” for additional related information.

We face significant competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If our competitors develop and commercialize their product candidates more rapidly than we do, or their technologies or their product candidates are more effective, safer, or less expensive than our ecDTx, our business and our ability to develop and successfully commercialize ecDTx may be adversely affected.

The biopharmaceutical industry is characterized by rapid advancing technologies, intense competition, and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing, or may develop products, or product candidates competitive with our ecDTx. Any ecDTx that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of indications for which we may attempt to develop ecDTx. In particular, there is intense competition in the oncology field. Our competitors include larger and better-funded pharmaceutical, biopharmaceutical, biotechnology, and therapeutics companies. Moreover, we may also compete with universities and other research institutions that may be active in oncology research and could be in direct competition with us. We also compete with these organizations to recruit management, scientists, and clinical development personnel, and our inability to compete successfully could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling patients for clinical trials, and identifying and in-licensing intellectual property related to new ecDTx, as well as entering into collaborations, joint ventures, license agreements, and other similar arrangements. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

If any of our ecDTx are approved, they will compete with surgery, radiation, and drug therapy, including chemotherapy, hormone therapy, biologic therapy, such as monoclonal and bispecific antibodies, antibody-drug conjugates, radiopharmaceuticals, immunotherapy, cell-based therapy, and targeted therapy, or a combination of any such methods, either approved or under development, that are intended to treat the same indications that we are targeting or may target, including through approaches that may prove to be more effective, have fewer side effects, be less costly to manufacture, be more convenient to administer, or have other advantages over our ecDTx. There are numerous companies developing precision oncology medicines with which we may compete. In addition to competing with other therapies targeting similar indications, there are numerous other companies and academic institutions focused on similar targets as our ecDTx and/or different scientific approaches to treating the same indications. We face competition from such companies in seeking any future potential collaborations to partner our ecDTx, as well as potentially competing commercially for any approved products.

Specifically, for BBI-355, Acrivon Therapeutics, Esperas Pharma, and PharmaEngine have CHK1 inhibitors in clinical development. BenevolentAI, Fosun Pharma, Impact Therapeutics, and Sumitomo Pharma have publicly disclosed preclinical stage CHK1 inhibitors. For BBI-825, there are several generic approved agents that inhibit RNR as part of their broader mechanism of action, including gemcitabine and hydroxyurea. For our pipeline of ecDTx programs, potential competition includes established companies as well as emerging biotechnology companies that may launch programs against similar targets; however, we are not aware of any companies with ecDNA-directed therapeutic programs in clinical development or a patient selection strategy for ecDNA-enabled oncogene amplification. We are aware of one early-stage private company that is focused on research in ecDNA, Eonic Biosciences.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales, and supply resources or experience than we do. If we successfully obtain approval for any ecDTx, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered, and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing, and sales capabilities, price, reimbursement coverage, and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive, or marketed and sold more effectively than any products we may develop. Competitive products may make any ecDTx we develop obsolete or noncompetitive before we recover the expense of developing and commercializing it. If we are unable to compete effectively, our opportunity to generate revenue from the sale of any ecDTx we may develop, if approved, could be adversely affected.

The market opportunities for our ecDTx may be limited to patients who are ineligible for, or have failed, prior treatments and may be small or different from our estimates.

Cancer therapies are defined by lines of therapy as well as by treatment-naïve or previously-treated status. Often the initial approval for a new therapy is in later lines and subsequent approval in an earlier line may not be feasible. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, including surgery, radiation therapy, targeted therapy, immunotherapy, chemotherapy, hormone therapy, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of additional chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Third line therapies can include antibody and small molecule targeted therapies, more invasive forms of surgery, and new technologies. In markets with approved therapies, there is no guarantee that our ecDTx, even if approved, would be approved for second line or first line therapy. This could limit our potential market opportunity. In addition, we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive later stage therapy and who have the potential to benefit from treatment with our ecDTx, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, publicly available clinical molecular reports, patient foundations, or market research, and may prove to be incorrect. Further, new trials or information may change the estimated incidence or prevalence of these cancers. Further, specific to our biomarker-driven strategy, data analytics and information from databases that we rely on for identifying or validating some of our biomarker-target relationships may not accurately reflect potential patient populations or may be based on incorrect methodology. As ecDNA in oncogene amplified cancers is a new and novel approach, this heightens the risk that our estimates of the eligible patient population may not be accurate. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our ecDTx, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing, or distribution capabilities, nor have we ever commercialized a product. If any of our ecDTx ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company with the marketing, sale, or distribution of biopharmaceutical products, and there are significant risks involved in the building and managing of a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing, and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to

assist us in sales, marketing, and distribution functions on acceptable financial terms, or at all. In addition, our ecDTx revenue and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell, and distribute any ecDTx that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our ecDTx effectively. If we are not successful in commercializing our ecDTx, either on our own or through arrangements with one or more third parties, we may not be able to generate any future ecDTx revenue and we would incur significant additional losses.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our ecDTx in foreign markets. We are not permitted to market or promote any of our ecDTx before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our ecDTx. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing, and distribution of our ecDTx. Approval procedures may be more onerous than those in the United States and may require that we conduct additional preclinical studies or clinical trials. If we obtain regulatory approval of our ecDTx and ultimately commercialize our ecDTx in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- compliance with export control and import laws and regulations and unexpected changes in tariffs, trade barriers, and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing, and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, public health pandemics or epidemics, or natural disasters including earthquakes, typhoons, floods, and fires.

Risks Related to Our Business Operations and Industry

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, regulatory approval, and commercialization activities relating to our ecDTx, which may change from time to time, including the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the timing and success or failure of preclinical studies or clinical trials for our ecDTx or competing products, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;

- coverage and reimbursement policies with respect to our ecDTx, if approved, and potential future drugs that compete with our ecDTx ;
- the cost of manufacturing our ecDTx, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
- expenditures that we may incur to acquire, develop, or commercialize additional ecDTx and technologies;
- the level of demand for any approved ecDTx, which may vary significantly and be difficult to predict;
- our ability to establish and maintain collaborations, licensing, or other arrangements;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and amount of any milestone, royalty, or other payments payable by us or due to us under any collaboration, licensing, or other similar agreement.

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. Investors should not rely on our past results as an indication of our future performance.

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 revenue or operating results 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 revenue or earnings guidance we may provide.

Our success is dependent on our ability to attract and retain highly qualified management and other clinical and scientific personnel.

Our success depends in part on our continued ability to attract, recruit, retain, manage, and motivate highly qualified management, clinical, and scientific personnel, and we face significant competition for experienced personnel. We are highly dependent upon our senior management, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our clinical trials and preclinical studies, regulatory approvals, or the commercialization of our ecDTx. Although we have executed employment agreements with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

In addition, employment candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either due to the trading price of our stock or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Our ability to recruit and retain highly skilled employees may be adversely affected by any significant appreciation or depreciation in our stock price relative to the original purchase or exercise price of our stock awards.

We will need to expand and effectively manage our managerial, operational, financial, and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management, clinical, and scientific personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology, and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain, and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital, and our ability to implement our business strategy.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As of May 6, 2024, we had 72 full-time employees. As we continue development and pursue the potential commercialization of our ecDTx, as well as transition to functioning as a public company, we will need to expand our financial, development, regulatory, manufacturing, information technology, marketing, and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers, and other third parties, and we may not be successful in doing so. Our future financial performance and our ability to develop and commercialize our ecDTx and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

We are subject to various U.S. federal, state, and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers expose us to broadly applicable foreign, federal, and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute any products for which we obtain regulatory approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order 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 Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly
- presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. 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 civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items, or services. 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;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS), information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants, and certified nurse-midwives), and teaching hospitals and other healthcare providers, as well as ownership and investment interests held by such healthcare professionals and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biopharmaceutical companies to report information on the pricing of certain drug products; and some state and local laws that require the registration or pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain consulting agreements and advisory board agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil, or administrative sanctions, including exclusions from government-funded healthcare programs.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize our ecDTx and may adversely affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any ecDTx for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, the Affordable Care Act (ACA) was enacted in the United States in 2010. The ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been executive, judicial, and Congressional 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. Thus the ACA will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, beginning April 1, 2013, Medicare payments to providers were reduced under the sequestration required by the Budget Control Act of 2011, which will remain in effect through 2032, unless additional Congressional action is taken. Additionally, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory cap on the Medicaid drug rebate beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products.

Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on the pharmaceutical industry cannot yet be fully determined but is likely to be significant. Additional drug pricing proposals could appear in future legislation.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition, and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our ecDTx, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition, and prospects.

We expect that these existing laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our ecDTx, if approved.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit, delay, or cease commercialization of our ecDTx.

We face an inherent risk of product liability as a result of the clinical trials of our ecDTx and will face an even greater risk if we commercialize our ecDTx, if approved. For example, we may be sued if our ecDTx allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the ecDTx, negligence, strict liability, and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering, or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit, delay, or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our ecDTx;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of our management's time and our resources;
- substantial monetary awards to trial participants or product recipients;
- product recalls, withdrawals, or labeling, marketing, or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize our ecDTx; and
- a decline in our stock price.

We currently hold approximately \$5.0 million in product liability insurance coverage in the aggregate. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our ecDTx. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our ecDTx. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our insurance policies are expensive and protect us from only some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employee benefits liability, business automobile, workers' compensation, products/clinical trial liability, cyber liability, clinical trials, and directors' and officers', and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

We and our service providers may be subject to a variety of data protection, privacy, and security obligations, including laws, regulations, standards, and contractual provisions, which could increase compliance costs, and our actual or perceived failure to comply with such laws and obligations could subject us to potentially significant liability, fines, or penalties and otherwise harm our business.

We and our service providers maintain a large quantity of sensitive information, including confidential business and patient health information, in connection with our clinical trials, and are subject to laws and regulations governing the privacy and security of such information. The global data protection landscape is rapidly evolving, and we and our service providers may be affected by or subject to existing, amended, or new laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, thus creating potentially complex compliance issues for us and our service providers, strategic partners, and future customers. The cost of compliance with these laws, regulations, and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state, or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties, and damage to our reputation, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, numerous federal and state laws and regulations, including health information privacy laws, data breach notification laws, and consumer protection laws, that govern the collection, use, storage, transfer, disclosure, protection, and other processing of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Consequently, depending on the facts and circumstances, we could be subject to significant penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

In addition, certain state laws govern the privacy and security of health-related and other personal information, many of which may differ from each other and from HIPAA, thus, complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. By way of example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the CCPA), gives California residents a number of individual privacy rights related to how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. It also imposes additional data protection obligations on covered businesses, such as additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. The CCPA also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required. Similar laws have been passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. In the event that we are subject to or affected by HIPAA, the CCPA, or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

There are also privacy laws in other countries that may impact our operations, now or in the future. For example, in Europe, the General Data Protection Regulation (GDPR) went into effect in May 2018, and imposes stringent requirements regarding the collection, use, disclosure, storage, transfer, or other processing of personal data of individuals within the European Economic Area (EEA). Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. The GDPR also confers a private right of action in some circumstances on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease or change our data processing activities, enforcement notices, assessment notices (for a compulsory audit), and/or civil claims (including class actions).

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the European Economic Area (EEA), and the United States remains uncertain. Case law from the Court of Justice of the European Union (CJEU) states that reliance on the standard contractual clauses—a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework (DPF), rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames.

Further, following the withdrawal of the United Kingdom from the European Union and the end of the transition period, from January 1, 2021, companies could also be subject to the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the UK GDPR). The UK GDPR mirrors the fines under the GDPR and has the ability to fine up to the greater of €20 million/£17 million or 4% of global turnover. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF. As we expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, store, use, transfer, disclose, and otherwise process data, update our data privacy and security policies and procedures, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and our service providers to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose such information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity, and adversely affect our business, financial condition, results of operations, and prospects.

Our information technology systems, or those of any of our service providers, may fail or suffer security incidents and other disruptions, which could result in a material disruption of our ecDTx development programs, compromise sensitive information related to our business, or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

In the ordinary course of business, we collect, store, and transmit confidential information including but not limited to intellectual property, clinical trial data, proprietary and confidential business information, and personal information of our employees and contractors (collectively, Confidential Information). Our information technology systems and those of our third-party service providers, strategic partners, and other contractors or consultants are vulnerable to attack, damage, and interruption from computer viruses and malware (e.g. ransomware), malicious code, misconfigurations, "bugs" or other vulnerabilities, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, and sophisticated nation-state and nation-state-supported actors. In addition, attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication, and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can also be no assurance that our and our third-party service providers', strategic partners', contractors', or consultants' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. If any such event, whether actual or perceived, were to occur, it could impact our reputation and/or operations, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on a third party to manufacture our ecDTx, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any actual or perceived disruption or security incident affects our systems (or those of our third-party collaborators, service providers, contractors or consultants) or were to result in a loss of or accidental, unlawful, or unauthorized access to, use of, release of, or other processing of Confidential Information, we could incur liability, the further development and commercialization of our ecDTx could be delayed, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws.

We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our Confidential Information. If our third-party vendors fail to protect their information technology systems and our Confidential Information, we may be vulnerable to disruptions in service and unauthorized access to our Confidential Information and we could incur liability and reputational damage. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Some of the federal, state, and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular categories of personally identifiable information, which could result from incidents experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Any adverse impact to the availability, integrity or confidentiality of our or third-party systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Although we currently hold cybersecurity insurance, the costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses.

Our business is subject to risks arising from pandemic and epidemic diseases.

The COVID-19 worldwide pandemic presented substantial public health and economic challenges and affected our employees, patients, physicians and other healthcare providers, communities, and business operations, as well as the U.S. and global economies and financial markets. Any future pandemic or epidemic disease outbreaks could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our ecDTx for use in our clinical trials and research and preclinical studies and, delay, limit or prevent our employees and CROs from continuing research and development activities, impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, alter the results of the clinical trial based on participants contracting the disease or otherwise increasing the number of observed adverse events, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our preclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition, and results of operations. Any future pandemic or epidemic disease outbreak could also potentially further affect the business of the FDA, EMA, or other regulatory authorities, which could result in delays in meetings related to our planned clinical trials, as well have an adverse impact on global economic conditions, which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed.

Our business could be affected by litigation, government investigations, and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry, and we could be subject to litigation, government investigation, and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment, and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief, and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations, and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage, and modifications of our business practices, which could have a material adverse effect on our business and results of operations. Even if such a proceeding, investigation, or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

Our employees and independent contractors, including principal investigators, CROs, consultants, and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants, and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless, and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete, and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud, and abuse and other healthcare laws and regulations in the United States and abroad (iv) laws that require the true, complete, and accurate reporting of financial information or data, or (v) laws that prohibit insider trading. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. 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 be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 and financial results, including, without limitation, the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses, and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases, and out-licensing or in-licensing of intellectual property, products, or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations, and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity, and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky, and costly endeavor for which we may never realize the full benefits. Furthermore, we may experience losses related to investments in other companies, including as a result of failure to realize expected benefits or the materialization of unexpected liabilities or risks, which could have a material negative effect on our results of operations and financial condition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition, and prospects.

Our ability to use net operating loss carryforwards and other tax attributes may be limited in connection with our IPO or other ownership changes.

We have incurred substantial losses during our history, do not expect to become profitable in the near future, and may never achieve profitability. As of December 31, 2023, we had net operating loss (NOL) carryforwards of approximately \$66.4 million for federal income tax purposes and \$127.0 million for state income tax purposes, which may be available to offset our future taxable income, if any. Our federal NOL carryforwards will not expire but may generally be used to offset only 80% of taxable income, which may require us to pay federal income taxes in future years despite having additional federal NOL carryforwards to utilize. Our state NOL carryforwards begin to expire in various amounts in 2040. Our NOL carryforwards and other tax attributes are subject to review and possible adjustment by the Internal Revenue Service (IRS) and state tax authorities.

In addition, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the Code), our federal NOL carryforwards may be or become subject to an annual limitation in the event we have had or have in the future an “ownership change.” For these purposes, an “ownership change” generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company’s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We have not determined the amount of the cumulative change in our

ownership resulting from our IPO or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. However, we believe that our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including potential changes in connection with our IPO. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain, defend, and enforce patent or other intellectual property protection for our ecDTx, ecDNA diagnostic, or technology, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our ecDTx may be adversely affected.

We rely upon a combination of patent, trade secret, and trademark protection for our ecDTx, our ecDNA diagnostic, and proprietary technologies to prevent third parties from exploiting our achievements, thus eroding our competitive position in our market. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success depends in large part on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property protection in the United States and other countries with respect to our ecDTx, our ecDNA diagnostic, and other proprietary technologies we may develop. We generally seek to protect our proprietary position, in part, by filing patent applications in the United States and abroad relating to our ecDTx and diagnostics, manufacturing processes, and methods of use. We may also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending patent applications from third parties. If we are unable to obtain, maintain, expand, enforce, and defend the scope of our intellectual property protection, our business, financial condition, results of operations, and prospects could be materially harmed.

Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our intellectual property, obtain, maintain, expand, enforce, and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patent applications we currently or may in the future pursue or may in-license will issue as patents in any particular jurisdiction, whether the claims of any issued patents will provide sufficient protection against competitors or other third parties, or if these patents are challenged by our competitors, whether the patents will be found to be invalid, unenforceable, or not infringed.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, defend, or license all necessary or desirable patent applications or patents at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, third-party collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with our ecDTx or technologies. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable in light of the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to invent the inventions claimed in any of our owned patents or pending patent applications, or that we or any future licensors were the first to file for patent protection of such inventions. If a third party can establish that we were not the first to make or the first to file for patent protection of such inventions, our patents and patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our current and future patent applications may not result in patents being issued.

Any issued patents may not afford sufficient protection of our ecDTx or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies or products. Further, even if these patents are granted, they may be difficult to enforce. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. In the event we experience noncompliance events that cannot be corrected and we lose our patent

rights, competitors could enter the market, which would have a material adverse effect on our business. Further, any issued patents that we own or may license in the future covering our ecDTx could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or other countries, including the U.S. Patent and Trademark Office (USPTO). Also, patent terms, including any extensions or adjustments that may or may not be available to us, may be inadequate to protect our competitive position on our ecDTx for an adequate amount of time, and we may be subject to claims challenging the inventorship, validity, or enforceability of our patents and/or other intellectual property. Changes in United States patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our ecDTx. Further, if we encounter delays in our development and testing of our ecDTx, clinical trials, or regulatory review and approval of our ecDTx, the period of time during which we could market our ecDTx under patent protection may be reduced (i.e., patents protecting the ecDTx might expire before or shortly after such ecDTx are commercialized). Thus, our patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or afford us any meaningful competitive advantage.

Moreover, the claim coverage in a patent application can be significantly reduced before the corresponding patent is granted. Even if patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents issuing from our owned and any future in-licensed patent applications may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our ecDTx and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non-infringing manner, which could materially adversely affect our business, financial condition, results of operations, and prospects. Furthermore, our competitors or other third parties may avail themselves of safe harbors under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) to conduct research and clinical trials.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patent rights may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party post-issuance submission of prior art to the USPTO challenging the validity of one or more claims of our patents or patents we may license in the future. Third-party submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on our pending patent application or patent application we may license in the future. A third party may also claim that our patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In addition, we may become involved in opposition, derivation, revocation, reexamination, reissue, post-grant, proceedings, inter partes review, interference proceedings, or other similar proceedings in the United States and/or foreign jurisdictions challenging our patent rights. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, and may allow third parties, including generic drug companies, to commercialize our ecDTx and other proprietary technologies we may develop and compete directly with us.

Moreover, some of our patent rights may in the future be co-owned with third parties. In the United States, each co-owner has the freedom to license and exploit the technology. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patent rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of such patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, maintaining, enforcing, and defending patents on our ecDTx in all countries throughout the world is expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Prosecution of foreign patent applications is often a longer process and patents may grant at a later date, and with a shorter term, than in the United States. The requirements for patentability differ in certain jurisdictions and countries. Additionally, the patent laws of some countries do not afford intellectual property protection to the same extent as the laws of the United States. For example, other countries may impose substantial restrictions on the scope of claims, limiting patent protection to specifically disclosed embodiments. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our intellectual property in and into the United States or other jurisdictions. Competitors may use our intellectual property in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or patents we may license in the future or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property

protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan, and China, may have a higher standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and any patents we may license in the future at risk of being invalidated or interpreted narrowly, could put our patent applications and any patent applications we may license in the future at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. In addition, geopolitical actions in the United States and in foreign countries (such as the wars between Russia and Ukraine and Israel and Hamas) could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any future licensors and the maintenance, enforcement, or defense of our issued patents, which could impair our competitive intellectual property position.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. In some circumstances, we may be dependent on any future licensors to take the necessary action to comply with these requirements with respect to any licensed intellectual property. For example, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. In certain circumstances, we may rely on licensing partners to pay these fees due to the U.S. and non-U.S. patent agencies. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, China, India, and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner, and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some cases, a foreign filing license may be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We would also be dependent on any future licensors to take the necessary actions to comply with these requirements with respect to any intellectual property we may license in the future.

Public health pandemics (such as the COVID-19 pandemic), geopolitical instability (war and terrorism), natural disasters, or similar events may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for our products and eCDTx.

Changes in patent laws or their interpretations could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States or in other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the America Invents Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us or our licensors could therefore be awarded a patent covering an invention of ours or our licensors even if we or our licensors had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors are the first to either (i) file any patent application related to our ecDTx and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims or any patent claims we may license in the future that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. We cannot predict how decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. For example, the U.S. Supreme Court held in *Amgen v. Sanofi* (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. As such, our patent rights with functional claims may be vulnerable to third party challenges seeking to invalidate these claims for lacking enablement or adequate support in the specification. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have or may obtain or license in the future.

In 2012, the European Union Patent Package (EU Patent Package) regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (UPC) for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC, unless otherwise opted out. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patent, and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and ecDTx due to increased competition and, resultantly, on our business, financial condition, results of operations, and prospects. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC.

Issued patents covering our ecDTx could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Our patent rights may be subject to priority, validity, inventorship, ownership, and enforceability disputes. Legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time-consuming and likely to divert significant resources from our core business, including distracting our management and scientific personnel from their normal responsibilities and generally harm our business. If we or any future licensors are unsuccessful in any of these proceedings, such patents and patent applications may be narrowed, invalidated, or held unenforceable. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we initiate legal proceedings against a third party to enforce a patent covering our ecDTx, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, lack of sufficient written description, failure to claim patent-eligible subject matter, or obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading or inconsistent statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patent rights or any patent rights we may obtain or license in the future in such a way that they no longer cover our ecDTx or prevent third parties from competing with our ecDTx. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for our ecDTx. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect the competitive position of our ecDTx for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our ecDTx are obtained, once the patent has expired, we may be vulnerable to competition from competitive products, including generics. Given the amount of time required for the development, testing, and regulatory review of new ecDTx, patents protecting such ecDTx might expire before or shortly after such ecDTx are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not have sufficient patent life to protect our products, our business, financial condition, results of operations, and prospects will be adversely affected.

If we do not obtain patent term extension and equivalent extensions outside of the United States for our ecDTx, our business may be materially harmed.

Depending upon the timing, duration, and specifics of any FDA regulatory approval of any of our ecDTx, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate. However, we may not be granted an extension for various reasons, including failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or failing to satisfy other applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we may license from a third party in the future, we may need the cooperation of that third party. If we are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed).

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, consultants, collaborators, or other third parties have an interest in our patent rights, trade secrets, or other intellectual property as an inventor, co-inventor, or owner of trade secrets. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our ecDTx and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets, or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or the right to use intellectual property that is important to our ecDTx and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our ecDTx and proprietary technologies, we may rely on trade secret protection and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, third-party collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Trade secrets and know-how can be difficult to protect. We cannot guarantee that we have entered into applicable agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that any potential trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, others may independently discover similar trade secrets and proprietary information. If any of our trade secrets were to be disclosed or misappropriated or if any such information were to be independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants, or others who are involved in developing our ecDTx. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our ecDTx and other proprietary technologies we may develop. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Some of our employees, consultants, and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope, or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and ecDTx.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims, or the expiration of relevant patents, are or will be complete or thorough, nor can we be certain that we have identified or will identify each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future ecDTx in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our ecDTx could have been filed by others without our knowledge. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, the written disclosure in a patent, and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or ecDTx are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our ecDTx. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our ecDTx that are held to be infringing. We might, if possible, also be forced to redesign ecDTx or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Third-party claims of intellectual property infringement, misappropriation, or other violations against us or our collaborators could be expensive and time consuming and may prevent or delay the development and commercialization of our ecDTx.

Our commercial success depends in part on our ability to avoid infringing, misappropriating, and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we plan to commercialize our therapeutic and diagnostic programs and in which we are developing other proprietary technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our ecDTx and diagnostic programs and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot assure that our ecDTx and diagnostic programs and other proprietary technologies we develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued for which a third party, such as a competitor in the fields in which we are developing our ecDTx and diagnostic programs, might assert as infringed by us. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to our ecDTx. As such, we monitor third-party patents in the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe. For example, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover ecDTx or the use of our ecDTx. We are aware of certain patent applications in the United States and elsewhere that contain claims that, if issued in their present form, may cover one of our ecDTx. While we believe we would have valid defenses to claims of patent infringement, we cannot be certain that we would prevail in any dispute, and we cannot be certain how an adverse determination would affect our business.

In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable, and infringed by us. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Such licenses may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms or at all, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. In addition, we may in the future pursue patent challenges with respect to third-party patents, including as a defense against the foregoing infringement claims. The outcome of such challenges is unpredictable.

Even if resolved in our favor, the foregoing proceedings could be very expensive, particularly for a company of our size, and time-consuming. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Such proceedings may also absorb significant time of our technical and management personnel and distract them from their normal responsibilities. Uncertainties resulting from such proceedings could impair our ability to compete in the marketplace. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments and 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. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, or results of operations.

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments and 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. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent proceedings could compromise our ability to compete in the marketplace. If we do not prevail in the patent proceedings the third parties may assert a claim of patent infringement directed at our ecDTx.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming, and unsuccessful.

Third parties, such as a competitor, may infringe our patent rights. In an infringement proceeding, a court may decide that a patent we own or a patent we may license in the future is invalid or unenforceable or may refuse to stop the other party from using the invention at issue. In addition, our patent rights may become involved in inventorship, ownership, priority, enforceability, or validity disputes. To counter or defend against such claims can be expensive and time-consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and proceedings, there is a risk that some of our confidential information could be compromised by disclosure during such litigation and proceedings.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and 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. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted, circumvented, or declared generic or determined to be infringing, misappropriating, or violating other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in the markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In the event that our trademarks are successfully challenged or determined to be infringing, misappropriating, or violating other marks, 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. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we may propose to use with our ecDTx in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe, misappropriate, or otherwise violate the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to obtain, protect, or enforce our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement, misappropriation, dilution, or other claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to obtain, enforce, or protect our proprietary rights related to trademarks, trade names, domain name, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations, and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our ecDTx or utilize similar technology but that are not covered by the claims of the patents that we own or may license in the future;
- we or our licensors or collaborators might not have been the first to make the inventions covered by our current or future patent applications;
- we or our licensors or collaborators might not have been the first to file patent applications covering our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending and future patent applications that we own or may license will not lead to issued patents;
- any issued patent that we own or license in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- our competitors or other third parties might conduct research and development activities in countries where we or our licensors do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we may fail to identify potential patentable subject matter and/or may fail to file on it;

- the patents or other intellectual property rights of others may harm our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property or disclose information resulting in a loss of protection for such trade secret.

Should any of the foregoing occur, it could adversely affect our business, financial condition, results of operations, and prospects.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

The growth of our business may depend in part on our ability to acquire, in-license, or use third-party intellectual property and proprietary rights. For example, our ecDTx may require specific formulations to work effectively and efficiently, we may develop ecDTx containing our compounds and pre-existing pharmaceutical compounds, or we may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our ecDTx, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patent or other intellectual property rights we may co-own with third parties, we may require licenses to such co-owners' interest to such patents. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe, misappropriate, or otherwise violate those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we may collaborate with academic institutions to accelerate our research and development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. Even if we are able to obtain a license, it may be non-exclusive, and our competitors may also receive access to the same technologies licensed to us.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our ecDTx. More established companies may have a competitive advantage over us due to their size, cash resources, or greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional ecDTx that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations, and prospects could suffer.

Risks Related to Ownership of Our Common Stock

Prior to our IPO, there was no public market for our common stock. An active, liquid, and orderly market for our common stock may not develop or be sustained, or we may in the future fail to satisfy the continued listing requirements of Nasdaq.

Prior to our IPO, there was no public market for our common stock. Our common stock only recently began trading on the Nasdaq Global Select Market (Nasdaq), and we can provide no assurance that we will be able to develop an active trading market for our common stock. Even if an active market is developed, it may not be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business. If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with the listing requirements of Nasdaq.

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they paid. The market price for our common stock may be influenced by those factors discussed in this “Risk Factors” section and many others, including:

- results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to enroll patients in our future clinical trials;
- our ability to obtain and maintain regulatory approval of our ecDTx or additional indications thereof, or limitations to specific label indications or patient populations for their use, or changes or delays in the regulatory review process;
- regulatory or legal developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;
- the success or failure of our efforts to develop, acquire, or license additional ecDTx;
- innovations, clinical trial results, product approvals and other developments regarding our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- manufacturing, supply, or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators, or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or development timelines or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors;
- market conditions in the biopharmaceutical sector and issuance of securities analysts’ reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by us, our insiders, or our stockholders, as well as the anticipation of lock-up releases or expiration of market stand-off or lock-up agreements;
- general economic, industry, geopolitical, and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control;
- additions or departures of senior management, directors, or key personnel;
- intellectual property, product liability, or other litigation against us or our inability to enforce our intellectual property;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations, or principles.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies’ stock. Such litigation, if instituted against us, could cause us to incur substantial costs, divert our management’s attention and resources and damage our reputation, which could have a material adverse effect on our business, financial condition and results of operations and prospects.

Our executive officers, directors, and principal stockholders, if they choose to act together, will continue to have the ability to significantly influence all matters submitted to stockholders for approval.

As of May 6, 2024, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 55.4% of our outstanding common stock. As a result, such persons, acting together, will have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership

may have the effect of delaying, deferring, or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

We do not currently intend to pay dividends on our common stock, so any returns on your investment will be limited to the value of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity or equity-linked securities.

In connection with our IPO, our directors and executive officers and the holders of substantially all of our outstanding securities prior to our IPO have entered into lock-up agreements with the representatives of the underwriters for the IPO pursuant to which they may not, with limited exceptions and among other things, for a period of 180 days from the date of the Prospectus for the IPO, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of Goldman Sachs & Co. LLC, Leerink Partners LLC, Piper Sandler & Co., and Guggenheim Securities, LLC. The underwriters may permit our officers, directors, and other securityholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements at any time in their sole discretion. After the lock-up agreements expire, these shares of common stock will be eligible for sale in the public market, except that shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, as of March 31, 2024, 4,169,881 shares of common stock that are subject to outstanding options under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, and Rule 144 and Rule 701 under the Securities Act. If there are any sales of these shares of common stock, or if it is perceived that they will be sold, in the public market, this could cause the trading price of our common stock to decline.

Holders of 14,740,840 shares of our outstanding common stock, or approximately 66.2% of our total outstanding common stock based on shares outstanding as of May 6, 2024, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We are an emerging growth company and a smaller reporting company, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer”, as defined under the Exchange Act, our annual gross revenue exceeds \$1.235 billion, or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley);
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, unless the SEC determines the new rules are necessary for protecting the public;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions from reporting. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. 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 these accounting standards until they would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this exemption 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. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year, and our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents will include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death, or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of 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 acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend, or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees, or the underwriters for any offering giving rise to such claim.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our amended and restated certificate of incorporation provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees and result in increased costs for investors to bring a claim. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General Risk Factors

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and certain corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory “say on pay” voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. The increased costs will decrease our net income or increase our net loss, and may require us to reduce expenditures in other areas of our business. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to comply with these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. We could face criminal liability and other serious consequences for violations, which could harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department’s Office of Foreign Assets Controls and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad if and when we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors, and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities, and any training or compliance programs or other initiatives we undertake to prevent such activities may not be effective.

Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain.

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage, or disposal of these materials could be time-consuming or costly.

We and any of our third-party manufacturers or suppliers and current or potential future collaborators may use biological materials, potent chemical agents, and hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state, and local laws and regulations govern the use, generation, manufacture, storage, handling, and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, neither we or our third-party manufacturers and suppliers can eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury at our or our manufacturers' or suppliers' sites, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with the storage or disposal of biologic, hazardous, or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development, or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations, and prospects.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations and the operations of our suppliers, CROs, CMOs, and clinical sites could be subject to earthquakes, power shortages, telecommunications or infrastructure failures, cybersecurity incidents, physical security breaches, water shortages, floods, hurricanes, typhoons, blizzards and other extreme weather conditions, fires, public health pandemics or epidemics (including, for example, the COVID-19 pandemic), and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers or suppliers to produce our ecDTx and its components and on CROs and clinical sites to conduct our clinical trials, and do not have a redundant source of supply for all components of our ecDTx. Our ability to obtain clinical or, if approved, commercial, supplies of our ecDTx could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption, and our ability to commence, conduct or complete our clinical trials in a timely manner could be similarly adversely affected by any of the foregoing. In addition, our corporate headquarters is located in San Diego, California near major earthquake faults and fire zones, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may have serious adverse consequences on our business, financial condition, and stock price.

From time to time, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, Israel and Hamas and other parties in the Middle East, terrorism, or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. In addition, in 2023 the closures of financial institutions and their placement into receivership with the FDIC created bank-specific and broader financial institution liquidity risk and concerns. Future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. 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 or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers, and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

Changes in tax law may materially adversely affect our financial condition, results of operations and cash flows, or adversely impact the value of an investment in our common stock.

New income, sales, use or other tax laws, statutes, rules, regulations, or ordinances could be enacted at any time, or interpreted, changed, modified, or applied adversely to us, any of which could adversely affect our business operations and financial performance.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market, or our competitors. If one or more of the analysts who covers us downgrades our stock, or if we fail to meet the expectations of one or more of these analysts, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting, and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2025. When we lose our status as an “emerging growth company” and do not otherwise qualify as a “smaller reporting company” with less than \$100.0 million in annual revenue, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, even if ultimately decided in our favor, it could result in substantial costs and a diversion of our management’s attention and resources, which could harm our business.

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

(a) Recent Sales of Unregistered Securities.

During the quarter ended March 31, 2024, we granted to certain of our employees, and directors options to purchase an aggregate of 1,375,088 shares of common stock at a weighted average exercise price of \$11.23 per share. The stock options were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act and Rule 506 promulgated thereunder as a transaction not involving any public offering.

(b) Use of Proceeds.

On March 27, 2024, our registration statement on Form S-1 (File No. 333-277696) was declared effective by the SEC for our IPO. At the closing of the IPO on April 2, 2024, we sold 6,250,000 shares of common stock at a public offering price of \$16.00 per share and received gross proceeds of \$100.0 million, which resulted in net proceeds to us of approximately \$87.7 million, after deducting underwriting discounts and commissions of \$7.0 million and other offering expenses of approximately \$5.3 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to

their associates, or to our affiliates. Goldman Sachs & Co. LLC, Leerink Partners LLC, Piper Sandler & Co., and Guggenheim Securities LLC acted as joint book-running managers for the offering.

There has been no material change in the planned use of proceeds from the IPO from that described in the Prospectus.

(c) Issuer Purchases of Equity Securities.

Not applicable.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Arrangements

From time to time, our officers (as defined in Rule 16a-1(f) of the Exchange Act) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the three months ended March 31, 2024, none of our officers or directors adopted, modified, or terminated any such trading arrangements.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	8-K	4/2/24	3.1	
3.2	Amended and Restated Bylaws	8-K	4/2/24	3.2	
4.1	Specimen stock certificate evidencing the shares of common stock	S-1/A	3/21/24	4.1	
4.2	Amended and Restated Investor Rights Agreement, dated April 5, 2023, by and among the Registrant and certain of its stockholders	S-1	3/6/24	4.2	
10.1#	Boundless Bio, Inc. 2018 Equity Incentive Plan, as amended, and form of stock option agreement and form of restricted stock agreement thereunder	S-1	3/6/24	10.1	
10.2#	Boundless Bio, Inc. 2024 Incentive Award Plan and form of stock option agreement and form of restricted stock unit agreement thereunder	S-1/A	3/21/24	10.2	
10.3#	Boundless Bio, Inc. 2024 Employee Stock Purchase Plan	S-1/A	3/21/24	10.3	
10.4#	Non-Employee Director Compensation Program	S-1/A	3/21/24	10.4	
10.5#	Amended and Restated Employment Offer Letter Agreement, dated March 5, 2024, between Zachary D. Hornby and the Registrant	S-1	3/6/24	10.6	
10.6#	Amended and Restated Employment Offer Letter Agreement, dated March 5, 2024, between Jami Rubin and the Registrant	S-1	3/6/24	10.8	
10.7#	Amended and Restated Employment Offer Letter Agreement, dated March 5, 2024, between Klaus Wagner, M.D., Ph.D. and the Registrant	S-1	3/6/24	10.10	
10.8#	Amended and Restated Employment Offer Letter Agreement, dated March 5, 2024, between Christian Hassig, Ph.D. and the Registrant	S-1	3/6/24	10.12	
10.9#	Amended and Restated Employment Offer Letter Agreement, dated March 5, 2024, between Neil Abdollahian and the Registrant	S-1	3/6/24	10.14	
10.10#	Amended and Restated Employment Offer Letter Agreement, dated March 5, 2024, between Jessica Oien and the Registrant	S-1	3/6/24	10.16	
10.11#	Severance and Change in Control Severance Plan	S-1	3/6/24	10.17	
10.12#	Corporate Bonus Plan	S-1	3/6/24	10.18	
10.13#	Form of Indemnification Agreement for Directors and Officers	S-1/A	3/21/24	10.19	
10.14#	Policy for the Recovery of Erroneously Awarded Compensation	S-1	3/6/24	10.20	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
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.				X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

Indicates management contract or compensatory plan.

* These certifications are deemed not filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

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.

Boundless Bio, Inc.

Date: May 13, 2024

By: /s/ Zachary D. Hornby
Zachary D. Hornby
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 13, 2024

By: /s/ Jami Rubin
Jami Rubin
Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certifications are being furnished solely pursuant to 18 U.S.C. Section 1350 and are not being filed as part of the Report or as a separate disclosure document.

**Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Zachary D. Hornby, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Boundless Bio, Inc.;
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 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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2024

/s/ Zachary D. Hornby

Zachary D. Hornby

President and Chief Executive Officer

(Principal Executive Officer)

**Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Jami Rubin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Boundless Bio, Inc.;
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 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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2024

/s/ Jami Rubin

Jami Rubin

Chief Financial Officer

(Principal Financial and Accounting Officer)

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

In connection with the Quarterly Report on Form 10-Q of Boundless Bio, Inc. (the Company) for the quarter ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the Report), Zachary D. Hornby, President and Chief Executive Officer of the Company, and Jami Rubin, Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to his or her knowledge, that:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 13, 2024

By: /s/ Zachary D. Hornby
Zachary D. Hornby
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 13, 2024

By: /s/ Jami Rubin
Jami Rubin
Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certifications are being furnished solely pursuant to 18 U.S.C. Section 1350 and are not being filed as part of the Report or as a separate disclosure document.
